

agencies to have a more customer-centric focus. Because of this, GSA anticipates an increase in requests to use this generic clearance, as the plan states that: A customer-centric principle charges us to do several things: conduct research to understand the customer's business, needs and desires; "make content more broadly available and accessible and present it through multiple channels in a program- and device-agnostic way; make content more accurate and understandable by maintaining plain language and content freshness standards; and offer easy paths for feedback to ensure we continually improve service delivery.

The customer-centric principle holds true whether our customers are internal (e.g., the civilian and military federal workforce in both classified and unclassified environments) or external (e.g., individual citizens, businesses, research organizations, and state, local, and tribal governments)."

B. Annual Reporting Burden

Respondents: 500,000.

Responses per Respondent: 1.

Total Annual Responses: 500,000.

Hours per Response: 60.446 minutes.

Total Burden Hours: 32,970.72.

C. Public Comments

A 60-day notice published in the **Federal Register** at 87 FR 14532 on March 15, 2022. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, in all correspondence.

Beth Anne Killoran,

Deputy Chief Information Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; State Access and Visitation Grant Application (OMB #0970-0482)

AGENCY: Office of Child Support Enforcement (OCSE), Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The federal Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting a 3-year extension of the State Access and Visitation Grant Application (OMB #0970-0482, expiration 5/31/2022). There are changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 created the "Grants to States for Access and Visitation" program (AV grant program). Funding for the program began in fiscal year 1997 with a capped, annual entitlement of \$10 million. The statutory goal of the program is to provide funds to states that will enable them to provide services for the purpose of increasing noncustodial parent access to and visitation with their children. State governors decide which state entity will be responsible for implementing the AV grant program in addition to determining who will be served, what services will be provided, and whether the services will be statewide or in local jurisdictions. The statute specifies certain activities which may be funded, including voluntary and mandatory mediation, counseling, education, the development of parenting plans, supervised visitation, and the development of guidelines for visitation and alternative custody arrangements. Even though OCSE manages this program, funding for the AV grant is

separate from funding for federal and state administration of the Child Support program.

Section 469B(e)(3) of the Social Security Act (Pub. L. 104-193) requires that each state receiving an AV grant award shall monitor, evaluate, and report on such programs in accordance with regulations. Additionally, the Catalog of Federal Domestic Assistance states that there is an application requirement for Grants to States for Access and Visitation Programs (93.597). The application process assists OCSE in complying with this requirement and emphasizes program efficiency, coordination of services, building support for parenting time services, and ensuring the safety of parents and children.

Specifically, the application requires states to submit a detailed program plan indicating how they anticipate spending their funds within the program statute and regulations. The applications cover 3 fiscal years and any changes made to the plan during the 3-year period will require a notification of change to OCSE.

OCSE will review the applications to ensure that planned services meet the requirements laid out in section 469B(e)(3) of the Social Security Act (Pub. L. 104-193). This review will include monitoring of program compliance and the safe delivery of services. In addition to monitoring, the report will also assist in OCSE's ability to provide technical assistance to states that request assistance.

The State Access and Visitation Grant Application is proposing changes to the application itself, including requirements for states and territories to:

- Address disparities in access;
- ensure the proactive identification of systemic barriers to AV grant services for people of color and other underserved populations;
- describe how grant activities will redress such barriers; and
- describe how outreach and recruitment efforts will promote equity in access for underserved or marginalized populations.

The grant application also expands requirements for partnerships with domestic violence service providers to

address the access issues experienced by marginalized victims of domestic violence.

Respondents: Recipients of the State Access and Visitation Grant (54 states and territories).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
State Access and Visitation Grant Application	54	1	10	540	180

Estimated Total Annual Burden Hours: 180.

Authority: Sec. 469B(e)(3), Pub. L. 104–193.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0517]

Medical Devices; 510(k) Sterility Change Master File Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA, Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its 510(k) Sterility Change Master File Pilot Program (“510(k) Sterility Pilot Program”). The 510(k) Sterility Pilot Program is voluntary and intends to give interested companies that terminally sterilize single-use devices (“sterilization providers”) using certain sterilization methods a pathway to submit a Master File for FDA’s review. FDA will accept a Master File into the 510(k) Sterility Pilot Program when it determines, among other things, that there is not a likelihood that switching from a fixed chamber ethylene oxide (EtO) sterilization method to the sterilization method described in the Master File could significantly affect the safety or effectiveness of a 510(k)-cleared device that meets the product definition in the Master File and that satisfies other conditions outlined in this document. If a Master File is accepted into the 510(k) Sterility Pilot Program, manufacturers of 510(k)-cleared devices (“510(k) holders”) may choose to reference the Master File in internal documentation in support of a justification for not submitting a new premarket notification (510(k)) under

certain conditions as outlined in this document. This voluntary pilot program seeks to encourage industry to consider new, innovative ways to sterilize devices that reduce the potential impact of EtO on the environment and on public health, while ensuring consistent patient access to safe devices and providing a framework for future regulatory approaches that would help address potential device shortages related to EtO sterilization.

DATES: FDA is seeking participation in the voluntary 510(k) Sterility Pilot Program beginning May 20, 2022. See the “Participation” section for selection criteria for sterilization providers to participate in the 510(k) Sterility Pilot Program and the “Procedures” section for instructions on how to submit a Master File for consideration for inclusion into the 510(k) Sterility Pilot Program. Up to nine eligible sterilization providers may be selected for participation in the 510(k) Sterility Pilot Program.

FOR FURTHER INFORMATION CONTACT: Clarence W. Murray, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4536, Silver Spring MD 20993, 301–796–0270, clarence.murray@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

EtO sterilization is an important sterilization method that is widely used to keep devices safe. It is estimated that approximately 50 percent of all sterile devices in the United States are sterilized using EtO (Ref. 1). For many devices, sterilization with EtO may be the only method¹ currently evaluated that effectively sterilizes and does not damage the device during the sterilization process. However, there have been concerns about the effects of EtO exposure and environmental emissions.

In 2019, FDA was made aware of closures of device sterilization facilities

¹ In this notice, “method” generally refers to the type of sterilization and “processes” generally refers to steps within that method to achieve a sterile device.

due to concerns about the level of EtO emissions (Ref. 2). The Agency closely monitored the situation and worked with device manufacturers affected by the closures to minimize impact to patients who needed device access. Future losses of sterilization capacity due to facility closure have the potential to result in shortages of sterile devices if an alternative for sterilization is not readily available for the devices sterilized at a closed facility. FDA continues to work with manufacturers on site changes, engage with manufacturers about potential solutions to shortage concerns, and collaborate with external stakeholders to help reduce barriers to the utilization of innovative device sterilization technologies. FDA has also taken several actions to advance device sterilization, including sponsoring two innovation challenges to identify alternatives to EtO sterilization methods (Ref. 3) and approaches to reduce EtO emissions (Ref. 4); convening the General Hospital and Personal Use Devices Panel on November 6 and 7, 2019 (“November 2019 Panel Meeting”), to discuss the role of EtO sterilization in maintaining public health (84 FR 46546, September 9, 2019; see also Ref. 5); and announcing an Ethylene Oxide Sterilization Master File Pilot Program (“EtO Pilot Program”) for devices subject to Premarket Application (“PMA”) approval (84 FR 65162, November 26, 2019; see also Ref. 1).

For devices subject to 510(k) requirements, before most sterile devices are cleared for marketing, FDA reviews the submitted 510(k) information to determine, among other considerations, if the provided sterility information is adequate (e.g., in accordance with internationally agreed upon voluntary consensus standards that FDA recognizes). In some cases, if a device manufacturer changes the sterilization method or process for sterilizing the device identified in its original 510(k) submission, the manufacturer may need to submit a new 510(k) for FDA review of these changes and clearance prior to marketing (Ref. 6). However, in addition to public