**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 11, 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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation; *Use:* Sections 1857(e) and 1860D–12 of the Social Security Act (''the Act'') authorize CMS to establish information collection requirements with respect to MAOs and Part D sponsors. Section 1857(e)(1) of the Act requires MAOs to provide the Secretary of the Department of Health and Human Services (DHHS) with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to Prescription Drug Plans (PDPs) as indicated in section 1860D–12. Pursuant to statutory authority, CMS codified these information collection requirements in regulation at §§ 422.516(g) Validation of Part C Reporting Requirements, and 423.514(j) Validation of Part D Reporting Requirements, respectively.

Data collected via Medicare Part C and Part D reporting requirements are an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of Medicare benefits to beneficiaries. CMS uses the findings collected through the data validation process to substantiate the data reported via Medicare Part C and Part D reporting requirements. Data validation provides CMS with assurance that plan-reported data are credible and consistently collected and reported by Part C and D SOs. CMS uses validated data to respond to inquiries from Congress, oversight agencies, and the public about Part C and D SOs. The validated data also allows CMS to effectively monitor and compare the performance of SOs over time. Validated plan-reported data may be used for Star Ratings, Display measures and other performance measures. Additionally, SOs can take advantage of the DV process to effectively assess their own performance and make improvements to their internal operations and reporting processes. *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 809; *Total Annual Responses:* 809; *Total Annual Hours:* 10,500. For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.

Dated: August 2, 2023.

**William N. Parham, III,**

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

[FR Doc. 2023–16804 Filed 8–10–23; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Formative Data Collections for ACF Research and Evaluation (Office of Management and Budget #0970–0356)

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) proposes to extend data collection under the existing overarching generic clearance for Formative Data Collections for ACF Research and Evaluation (Office of Management and Budget (OMB) #0970–0356). There are no changes proposed.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* ACF programs promote the economic and social well-being of families, children, individuals, and communities. The Office of Planning, Research, and Evaluation (OPRE) studies ACF programs, and the populations they serve, through rigorous research and evaluation projects. These include evaluations of existing programs, evaluations of innovative approaches to helping low-income children and families, research syntheses, and descriptive and exploratory studies. OPRE's research

offers further understanding of current programs and service populations, explores options for program improvement, and assesses alternative policy and program designs. OPRE anticipates undertaking a variety of new research projects related to welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, family and youth services, home visiting, child welfare, trafficking, community services, and other areas of interest to ACF. Some ACF program offices conduct their own research and evaluation projects and may utilize this generic.

Under this generic clearance, ACF engages in a variety of formative data collections with researchers, practitioners, technical assistance providers, service providers, and potential participants throughout the field to fulfill the following goals: (1) inform the development of ACF research, (2) maintain a research agenda that is rigorous and relevant, (3) ensure that research products are as current as possible, and (4) inform the provision of technical assistance and supports around research and evaluation. ACF envisions using a variety of techniques including semi-structured discussions, focus groups, surveys, and telephone or in-person interviews, in order to reach these goals. Information collected under this overarching generic is meant to inform ACF research activities and may be incorporated into documents or presentations that are made public.

The following are some examples of ways in which we may share information resulting from these data collections: research design documents or reports; research or technical assistance plans; background materials for technical workgroups; concept maps, process maps, or conceptual frameworks; contextualization of research findings from a follow-up data collection that has full PRA approval; informational reports to TA providers; or project specific reports, or other documents relevant to the field, such as federal leadership and staff, grantees, local implementing agencies.

Following standard OMB requirements, ACF has and will continue to submit to OMB information about individual information collection activities proposed under the generic clearance. ACF will provide OMB with a copy of the individual instruments or questionnaires, as well as other materials describing the project. ACF requests OMB's review within 10 days of submission of individual requests under this generic.

*Respondents:* Respondents could include key groups involved in ACF projects and programs, state or local government officials, service providers, participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF research and programs, or others involved in conducting ACF research or evaluation projects.

*Annual Burden Estimates*

Find currently approved information collections here: *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0970-0356.* The request to OMB will include an extension request for approved information collections that are planned to continue beyond November 2023.

ANNUAL BURDEN ESTIMATES—NEW REQUESTS

| Instrument | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|
| Semi-Structured Discussions and Focus Groups | 3,000 | 1 | 2 | 6,000 |
| Interviews | 1,500 | 1 | 1 | 1,500 |
| Questionnaires/Surveys | 1,125 | 1 | .5 | 563 |
| Total | ..... | ..... | ..... | 8,063 |

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2023–17205 Filed 8–10–23; 8:45 am]

**BILLING CODE 4184–79–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–E–1865]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; Vercise Genus Deep Brain Stimulation System

**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 VERCISE GENUS DEEP BRAIN STIMULATION SYSTEM (VERCISE GENUS DBS SYSTEM) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 10, 2023. 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 February 7, 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