criteria outlined in statute. Sections 226A of the Act authorizes entitlement for Medicare Hospital Insurance (Part A) if the individual with ESRD files an application for benefits and meets the requisite contributions through one's own employment or the employment of a related individual to meet the statutory definition of a ''currently insured'' individual outlined in section 214 of the Act. Further, for individuals who meet the requirements for premium-free Part A entitlement, Medicare coverage starts based on the dates in which the individual started dialysis treatment or had a kidney transplant. These statutory provisions are codified at 42 CFR 406.7(c)(3) and 407.13. *Form Number:* CMS–43 (OMB control number: 0938–0080); *Frequency:* Once; *Affected Public:* Individuals and Households *Number of Respondents:* 45,200; *Total Annual Responses:* 45,200; *Total Annual Hours:* 18,984. (For policy questions regarding this collection contact Candace Carter at 410–786–8466 or *Candace.Carter@cms.hhs.gov*).

William N. Parham, III,

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

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; The Understanding and Expanding the Reach of Home Visiting (HV-REACH) Project (New Collection)

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: As part of the Understanding and Expanding the Reach of Home Visiting (HV-REACH) project, the Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services is proposing to collect qualitative data to understand the features of centralized, coordinated, or collaborative intake systems used by seven purposively selected sites that refer families to early childhood home visiting (ECHV) programs.

DATES: *Comments due September 9, 2024.* 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: The HV-REACH project is proposing to conduct seven qualitative case studies to provide an in-depth understanding of centralized intake systems, including how centralized intake systems reach potentially eligible families, and how staff and families think centralized intake systems support and expand the recruitment and enrollment of families in ECHV programs.

The goals of the study are to understand (1) the features, strengths, and challenges of centralized intake systems that refer to ECHV programs; (2) how centralized intake systems support outreach to and enrollment of families in ECHV programs; (3) enrolled families' experiences with centralized intake systems.

We will conduct virtual or in person site visits in seven sites, where a site is defined as including a centralized intake organization(s) and one or two associated home visiting programs. We will collect documentation related to:

- outreach, enrollment, screening, and referrals processes and pathways, and data about the defining characteristics of centralized intake systems;
- local contexts and community needs;
- communication processes and feedback loops with families and programs;
- successes and challenges of the system and opportunities for improvement or technical assistance;
- home visiting program staff and family perceptions of centralized intake;
- implementation of centralized intake;
- staff and family experiences with outreach and enrollment processes using centralized intake; and
- staff and family background characteristics.

Findings will highlight opportunities for program improvement efforts, technical assistance, or changes to centralized intake system processes. We will disseminate findings in a report, research briefs, and presentations or briefings.

Respondents: Centralized intake administrators and other staff responsible for overseeing outreach and enrollment; home visiting program directors and other staff responsible for overseeing outreach and enrollment; home visitors and other staff responsible for conducting outreach and enrollment; and families enrolled in home-visiting programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Centralized Intake Administrator Screening	[1] 9	1	0.33	3
On site coordination [1]	14	1	4.0	56
Centralized Intake Administrator and Other Staff Interview Protocol	42	1	1.5	63
Document Review Request	21	1	0.25	5
Home visiting program director and Other Staff Interview Protocol	28	1	1.0	28
Home visitor and Other Staff Interview Protocol	42	1	1.0	42
Family interview protocol	42	1	1.0	42
Participant characteristics form	114	1	0.08	9

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Total Annual Burden	.....	.....	.....	248

[1] There is no instrument associated with this activity, which refers to the time spent by the on-site coordinator (nominated by the home visiting program director) to help the research team coordinate data collection activities.

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.

Authority: Social Security Act, title V, section 511 (42 U.S.C. 711), as extended by the Consolidated Appropriations Act of 2023 (Pub. L. 117–328) (fiscal years 2023–2027).

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1464]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 8, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0117. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Investigational Use

OMB Control Number 0910–0117—Extension

This information collection helps support implementation of Agency statutory and regulatory requirements regarding the approval of new animal drugs. FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support a NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping to qualify for the exemption from section 512(a) of the FD&C Act. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

Our regulations require that certain information be submitted to us in a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. We also require reporting by importers of investigational new animal drugs (INDs) for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to help ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bioresearch Monitoring Program. This program permits us to monitor the validity of the studies and to help ensure the proper use of the drugs is maintained by the investigators.

Sponsors use eSubmitter, a secure online, question-based submission tool, to submit the NCIE electronically (*https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs*).

Description of Respondents: Respondents to this collection of information are persons who use new animal drugs for investigational purposes. INDs are used primarily by drug industry firms, academic institutions, and the government (*i.e.,*