

You Handbook published each fall and on the Medicare Plan Finder website. Beneficiaries can compare CAHPS scores for each health and drug plan as well as compare MA and FFS scores when making enrollment decisions. The Medicare CAHPS also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. CAHPS data are included in the Medicare Part C & D Star Ratings and used to calculate MA Quality Bonus Payments. *Form Number:* CMS–R–246 (OMB control number: 0938–0732); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 794,500; *Total Annual Responses:* 794,500; *Total Annual Hours:* 192,265. (For policy questions regarding this collection contact Lauren Fuentes at 410–786–2290).

3. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* End-stage Renal Disease (ESRD) Quality Incentive Program (QIP): Study of Quality and Patient Experience; *Use:* The Centers for Medicare & Medicaid Services (CMS) oversees the quality of care provided by dialysis facilities by administering the Quality Incentive Program (QIP). As part of the evaluation of this program, CMS seeks to gain a deeper understanding of emerging trends observed across the dialysis landscape by conducting qualitative data collection and analysis. These primary qualitative data collection activities seek to answer the following research questions related to dialysis quality, access to care, health equity, and quality of life:

1. What aspects of patient dialysis care do patients report as a priority?
2. How, if at all, do dialysis facilities evaluate the quality of care they provide?
3. What strategies do providers and dialysis facilities use to improve access to care for underserved populations?
4. What do patients, providers, and stakeholder organizations believe contributes to high quality of life for patients with ESRD? Do perceptions vary by respondent type or respondent characteristics?
5. How do dialysis facilities measure patient satisfaction and quality of life?
6. How do dialysis providers and stakeholder organizations think quality of life for dialysis patients has changed over time? What was the impetus for that change?

We are requesting to collect information through in depth interviews with stakeholders of the CMS end-stage

renal disease (ESRD) Quality Incentive Program (QIP). The interviews will collect data from individuals with ESRD, dialysis facility administrators, dialysis social workers, transplant center administrators, corporate representatives from dialysis organizations, and patient advocacy organizations.

This data collection seeks to answer several research questions specific to health outcomes for dialysis patients, as measured by the QIP, that are not available through current literature or secondary data collection. In preparation for this study, the evaluation team conducted a scan of peer-reviewed literature and document review of previous ESRD QIP monitoring and evaluation reports and policy documents describing CMS priorities. Based on the results from this scan, the study team identified persistent knowledge gaps and opportunities for primary data collection. Drawing on high-quality data, empirical rigor, and knowledge of nonprogrammatic factors, the evaluation will benefit CMS by providing data-driven findings and recommendations to improve patient care, reduce health disparities, and promote health equity.

This primary data collection will allow CMS to more comprehensively understand the data being compiled and analyzed quantitatively and will provide more context related to dialysis quality, quality of life of individuals with ESRD, access to dialysis care, and the patient experience, which are current CMS priorities. *Form Number:* CMS–10823 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions), Individuals and Households; *Number of Respondents:* 1,945; *Total Annual Responses:* 1,945; *Total Annual Hours:* 604. (For policy questions regarding this collection contact Christopher King at (410) 786–6972).

Dated: April 28, 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

### Administration for Children and Families

#### Submission for OMB Review; 2024 National Survey of Early Care and Education (OMB #: 0970–0391)

**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), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the 2024 National Survey of Early Care and Education (NSECE) to be conducted October 2023 through July 2024. The objective of the 2024 NSECE is to document the nation's use and availability of early care and education (ECE) services, building on the information collected in 2012 and 2019 to describe the ECE landscape in the U.S. The 2024 NSECE will collect information on families with children under age 13 years, on ECE providers that serve families with children from birth to 13 years in the U.S., and on the workforce providing these services.

**DATES:** *Comments due within 30 days of publication.* The *Office of Management and Budget (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](http://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 [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

*Description:* The 2024 NSECE will consist of four coordinated nationally-representative surveys:

1. a survey of households with at least one resident child under the age of 13 (Household Interview),

2. a survey of individuals providing care for children under the age of 13 in a residential setting (Home-based Provider Interview) including individuals appearing on state and national lists of ECE providers (listed) and individuals not appearing on such lists (unlisted),

3. a survey of center-based ECE providers offering care for children age 5 years and under, not yet in kindergarten, in a non-residential setting (Center-based Provider Interview), and

4. a survey conducted with individuals employed in center-based ECE programs working directly with children in classrooms serving children age 5 years and under, not yet in kindergarten (Workforce Interview).

The household, home-based provider, and center-based provider surveys will require a screener to determine eligibility for the specific survey.

The 2024 NSECE data collection efforts will provide urgently needed information about the use and supply of ECE available to families across all income levels, including providers serving low-income families of various racial, ethnic, language, and cultural backgrounds, in diverse geographic areas. The household data will include characteristics of households with children under age 13, such as parental employment status and schedules, preferences and choices of non-parental care, and other key factors that affect their need for and access to ECE. The provider data will include home-based or center-based ECE providers (e.g., private, non-profit, Head Start-funded, state or local Pre-K, or based in public schools) that do or do not participate in the child care subsidy program, and are or are not regulated, registered, or otherwise appear in state or national lists. Accurate data on families with young children and the availability and

characteristics of ECE providers are essential to assess the current and changing landscape of ECE since the 2019 NSECE data collection, and to provide insights to advance policy and initiatives in the ECE field. The two previous rounds of NSECE, collected in 2012 and 2019, produced critical data about providers of ECE services, the ECE workforce, and families' needs and use of child care throughout the U.S. that remain unmatched by other data sources available.

*Respondents:* Households with resident children under age 13, home-based ECE providers serving children under age 13 (listed and unlisted), center-based ECE providers serving children age 5 and under (not yet in kindergarten), and classroom-assigned instructional staff (workforce) members working with children age 5 and under (not yet in kindergarten) in center-based ECE programs.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Household Screener (screening only) .....	62,758	1	.1	6,276
Household Questionnaire (no screener) .....	10,000	1	1	10,000
Home-based Provider Screener (screening only, listed home-based providers) .....	2,064	1	.03	62
Home-based Provider Questionnaire including screener (listed home-based providers) .....	4,360	1	.67	2,921
Home-based Provider Questionnaire, including screener (unlisted home-based providers) .....	1,158	1	.33	382
Center-based Provider Screener (screening only) .....	10,050	1	.1	1,005
Center-based Provider Questionnaire, including screener .....	8,392	1	.75	6,294
Workforce (Classroom Staff) Questionnaire .....	7,418	1	.33	2,448

*Estimated Total Annual Burden Hours:* 29,388.

*Authority:* Child Care and Development Block Grant Act of 1990 as amended by the CCDBG Act of 2014 (Pub. L. 113–186). Social Security Act 418 as extended by the Continuing Appropriations Act of 2017 and the TANF Extension Act of 2019. Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2023–N–1585]

#### Identification, Assessment, and Control of Nitrosamine Drug Substance-Related Impurities in Human Drug Products; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the establishment of a docket to solicit public comments on the identification, assessment, and

control of N-nitrosamine (nitrosamine) drug substance-related impurities (NDSRIs) that may be considered by the Agency in its regulation of these types of impurities in drug products. This notice identifies scientific and regulatory considerations regarding the identification, assessment, and control of NDSRIs, including areas that may benefit from collaborative efforts, and requests comments on these topics. This notice is not intended to communicate FDA's regulatory expectations on these issues but is instead intended to seek input from the public to inform scientific and/or regulatory approaches as appropriate.

**DATES:** Either electronic or written comments must be submitted by July 3, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late,