Supporting Statement Part A

OMB No. 0938-[NEW]

End-stage Renal Disease (ESRD) Quality Incentive Program (QIP): Study of Quality and Patient Experience

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Part A. Justification

A.1. Background, need and legal basis

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?

This is a new information collection request. The Centers for Medicare & Medicaid Services (CMS) is requesting an Office of Management and Budget (OMB) approval to collect information through indepth 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.

There are no legal or administrative requirements directly related to this data collection. 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.

A.2. Information Users

Participant audiences will include individuals with ESRD, dialysis facility administrators, dialysis facility social workers, nephrologists, corporate representatives from dialysis organizations, representatives from patient advocacy organizations, and transplant center administrators. Figure A.2.1 displays which research topic will be covered with each participant type.

Figure A.2.1. Research Topic by Participant Type

Participant Type	Dialysis Quality	Access and Equity	Quality of Life
Patients	●	●	●
Dialysis facility administrators	●	●	●
Dialysis facility social workers	●	●	●
Nephrologists	●	●	●
Dialysis facility corporate representatives	●	●	No
ESRD patient advocacy organizations	No	●	●
Transplant center administrators	No	●	No

Data from the interviews will be analyzed and compiled into a summary report to be used by CMS to make ESRD QIP-related policy decisions. The information collected will support the mixed methods analyses conducted for the ESRD QIP Monitoring and Evaluation contract and will provide additional context and depth to the quantitative analyses. 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. At the discretion of CMS, the contractor will draft manuscripts for each research domain for submission into peer-reviewed journals. The primary data collection activities for this study will be conducted from fall 2023 to spring 2024.

A.3. Use of Information Technology

Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

This collection of information is 100 percent electronic. This section describes data collection approaches for each data collection activity. Potential interview participants, across all participant interview types (e.g., patients, facility administrators, social workers) will be emailed or contacted via telephone based on the study team's ability to obtain email addresses. Correspondence will be conducted via telephone or email, depending on how participants respond to initial correspondence. The data collection will be conducted via telephone interview to eliminate burden of in-person data collection and travel. The use of telephone interviews provides the opportunity to include geographically diverse participants and those who are busy professionals because they can call from any location convenient for them. The dialysis patient population may also have difficulty fitting an in-person interview into their schedule because most dialysis patients have their dialysis sessions three times a week for at least 4 hours per session. Conducting interviews over the telephone minimizes respondent burden and provides a more geographically diverse sample.

At the end of each interview, participants will be invited to provide additional voluntary feedback via email or telephone if they wish to contact the study team after the interview. This opportunity will be voluntary and enable participants to share feedback they find important but

did not have the opportunity to share because of the interview's time constraints. The collection of all interview data will not require a signature from the participants. The explanation of confidentiality and informed consent will be conducted verbally at the beginning of the interview or focus group over the phone.

A.4. Duplication of Efforts

There is no similar prior or ongoing information collection that duplicates the efforts of the proposed data collection. CMS has determined that no comprehensive efforts have been made to interview these stakeholder types to assess their experiences with dialysis quality, access to care, health equity, and quality of life. Literature reviews have also identified knowledge gaps this data collection will aim to fill.

A.5. Impacts on Small Businesses or Other Small Entities

If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Some small entities may be involved in this data collection. Although small businesses or entities are not specifically targeted in this data collection, some of the interviewees could be employees of small businesses or not-for-profit organizations involved in ESRD care and/or advocating for individuals with ESRD. As such, the study must include these organizations. The interview protocols have been designed to impose minimal burden on participating businesses and organizations (appendices A, B, C, D, E, F, and G). The interviews will request the minimum amount of information required for the intended use. CMS estimates that of the businesses to be interviewed for this study, approximately 10 percent are considered small businesses.

A.6. Consequences of Collecting the Information Less Frequently

Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

This is a one-time data collection request. If this information collection is not conducted, CMS will have a limited understanding of the quantitative data it receives for the ESRD QIP quality metrics.

This data collection will provide more context to the quantitative data, helping CMS decisionmakers make policy decisions that ultimately aim to maintain and improve the quality of care dialysis patients receive.

A.7. Special Circumstances Relating to the Guideline of 5 C.F.R. § 1320.5

There are no special circumstances.

A.8. Federal Register Outside Consultation

Federal Register *Notice and Comments*

The 60-day Federal Register notice published on December 22, 2022 (87 FR 27864).

Public comments were received requesting that CMS ensure patients on home dialysis and their providers are included in the information collection. There were concerns about addressing any inequities in access to home dialysis, education from providers, and transplantation access. These areas of focus are already included in the data collection materials and analysis plans for the information collection, therefore no changes to the data collection plan or instruments were made.

The 30-day Federal Register notice published on May 4, 2023 (88 FR 28554).

CMS obtained a subject matter review of data collection instruments with Insight Policy Research's diversity, equity, and inclusion expert and two representatives from two renal network organizations. As a result of these reviews, more inclusive and clarifying language was incorporated into a small number of questions to ensure participants had a clear understanding of the questions and the questions did not elicit a biased response.

A.9. Payment/Gifts to Respondents

It is common practice to provide participants with a monetary token of appreciation in recognition of their time and travel costs. We will provide a $100 VISA or MasterCard gift card token to patients, facility administrators, social workers, and nephrologists, and a $50 VISA or MasterCard gift card token to transplant center administrators. The respondents will receive the gift cards following their interviews. The gift cards will be delivered via traceable U.S. mail or

email, depending on participant preference. By helping reduce interview respondents' burden of participation, these tokens of appreciation will help ensure these necessary individuals, who have critical information to share, are able to participate in the study. Because the perspectives of these patients and staff are critical to the success of the study, ensuring their participation will improve data quality and decrease the rate of nonresponse. The payment amount is consistent with that provided in other similar studies.

Low response rates are problematic because they can lead to increased nonresponse bias (Groves et al., 2006). Nonresponse from key stakeholders could contribute to missing information that could bias the findings that inform policymakers' decision-making surrounding the quality of dialysis care and access to ESRD treatment options that improve patient quality of life and health outcomes. Tokens of appreciation can help reduce efforts to recruit study participants and thereby lower the amount of time needed to recruit the necessary respondents without affecting data quality (Dillman, 2000; Singer, 2006). Mercer and colleagues' (2015) meta-analysis estimated surveys that promised a $10 token of appreciation generated response rates 5 percentage points higher than surveys that offered no such incentive. Tokens of appreciation can also improve sample representativeness and reduce nonresponse bias (Groves et al., 2000; Messer & Dillman, 2011) by encouraging those less interested in research to participate (Groves et al., 2006; Singer & Kulka, 2002).

Tokens of appreciation reduce respondent burden because they help offset costs associated with participating in the interview (Lavrakas, 2008). For example, a token of appreciation can offset costs such as childcare that may be needed while respondents complete the interview, cell phone and data usage costs associated with recruitment and scheduling, and/or cell phone and data usage costs to participate in the interview itself when it is conducted via telephone. The token of appreciation is also offered because of the "opportunity cost" associated with participation; respondents may need to forgo other sources of income as a consequence of participating in the interview (U.S. Department of Health and Human Services, Office for Human Research Protections, Secretary's Advisory Committee on Human Research Protections, 2019).

No payment or gift will be provided to corporate representatives and patient advocacy groups that participate in the interviews. The study team believes that providing feedback on these topics is within the purview of the occupations of these participant types and, therefore, does not warrant additional monetary compensation.

A.10. Confidentiality

Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

In accordance with the Privacy Act of 1974 (Pub. L. 93–579, 5 U.S.C. § 552a), the study team will protect the privacy of all information collected for the study and use it for research purposes only. No information that identifies any study participant will be released. Because of a limited number of dialysis organizations and patient advocacy organizations, it may be possible to attribute certain remarks to a specific organization. Study participants will be informed of this fact, allowing them to disclose the information they are comfortable sharing in this regard. Study respondents will be notified the information they provide will not be released in a form that identifies them except as otherwise required by law. No identifying information will be attached to any reports or data supplied to CMS or other researchers. The identities of all will not be disclosed. As part of the data collection process, all interview participants will be asked for their verbal consent to participate in the study and informed that participation will in no way affect their insurance coverage or employment, nor will any information provided be released except as otherwise required by law (see appendix L).

A statement to this effect will be included with all requests for data. All members of the study team with access to the data will be trained on the importance of privacy and data security. All data will be kept in secured locations. Identifiers will be destroyed as soon as they are no longer required.

CMS staff will never handle or see any personal data collected, and Insight Policy Research's systems do not operate in any of CMS's data management and analysis systems. Insight Policy

Research's data creation and processing systems were not created for this contract agreement. CMS does not have any control over the contractor's systems.

As CMS's contractor, Insight Policy Research will employ the following safeguards to protect privacy during the study:

- Computer datafiles will be protected with passwords, and access will be limited to specific users on the research team.
- Employees must notify their supervisor, the project director, and the contractor's security officer if secured and private information has been disclosed to an unauthorized person, used in an improper manner, or altered in an improper manner.

A.11. Sensitive Questions

This information collection request includes no questions of a sensitive nature.

A.12. Burden Estimates

This new information collection will contact approximately 1,945 respondents (480 patients, 750 facility administrators, 300 nephrologists, 200 dialysis facility social workers, 200 transplant center administrators, 10 corporate representatives from dialysis organizations, and 5 representatives from ESRD patient advocacy organizations). Of the 1,945 contacted, 129 are anticipated to be responsive and 1,816 nonresponsive. The burden estimates for respondents are shown in table A.12.1. The estimated annual burden is 1,098 hours (752 hours for responsive participants and 346 hours for nonresponsive participants). The estimated time of response varies from 0.5 hours to 1.9 hours, depending on respondent group and activity. No respondents will be asked to keep records of data as part of this data collection; therefore, no burden hours have been estimated for recordkeeping. Table A.12.1 and Excel workbook titled "ESRD OY2 Data Collection Burden Table_05092022" provide more detailed information about the burden and annualized costs to respondents for this collection.

Table A.12.1. Total Public Burden Hours and Respondent Costs

Interview Type	Data Collection Activity and Type of Participant	Estimated Number of Participants (1)	Number of Responses per Participant (2)	Hours per Response (3)	Estimated Annual Burden Hours (4= 1*2*3)	Hourly Wage Rate* (5)	Estimated Total Annual Participant Cost** (6=4*5)
Interviews with Providers	Dialysis Facility Administrators: Recruitment	750	1	0.25	187.5	$89.48	$16,777.50
	Dialysis Facility Administrators: Interview	36	1	1	36	$89.48	$3,221.28
	Nephrologists: Recruitment	300	1	0.25	75	$249.52	$18,714.00
	Nephrologists: Interview	10	1	1	10	$249.52	$2,495.20
	Transplant Center Administrators: Recruitment	200	1	0.25	50	$61.80	$3,090.00
	Transplant Center Administrators: Interview	10	1	0.5	5	$61.80	$309.00
	Social Workers: Recruitment	200	1	0.25	50	$59.92	$2,996.00
	Social Workers: Interview	10	1	1	10	$59.92	$599.20
	Corporate Representatives Dialysis Companies: Recruitment	10	1	0.25	2.5	$153.10	$382.75
	Corporate Representatives Dialysis Companies: Interview	10	1	0.5	5	$153.10	$765.50
Interviews with Advocacy Organizations	Patient and Provider Organizations: Recruitment	5	1	0.25	1.25	$48.56	$60.70
	Patient and Provider Organizations: Interview	5	1	0.75	3.75	$48.56	$182.10
Interviews with Patients	Individuals with ESRD: Recruitment	480	1	0.25	120	$7.25	$870.00
	Individuals with ESRD: Interview	48	1	1	48	$7.25	$348.00
Total for all respondents		**1945**	**N/A**	**N/A**	**604**	**N/A**	**$50,811.23**

*Wage rates are based on the Bureau of Labor Statistics, May 2021 National Occupational Employment and Wage Estimates United States and doubled to account for fringe benefits for the professional stakeholders, https://www.bls.gov/oes/currentoes_nat.htm. Federal minimum wage information is from the Department of Labor, Wage and Hour Division, https://www.dol.gov/WHD/minimumwage.htm.

Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

The annualized cost of respondent burden is the product of each type of respondent's annual burden and average hourly wage rate. The total estimated annualized cost to respondents for the hour burdens for collection of information is $26,014.62 ($9,999.39 for dialysis facility administrators, $1574.13 for dialysis organization corporate representatives, $10,604.60 for nephrologists, $1,699.50 for transplant center administrators, $1,797.60 for social workers, $121.40 for patient and provider advocacy organizations, and $1,218.00 for individuals with ESRD). This total annualized cost is calculated as the sum of the annualized costs by respondent category. For each respondent category, the annualized cost is the product of burden hours (including nonresponse burden) and an assumed wage rate for a corresponding occupation.

The wage rates were estimated based on the most recently available national occupational employment and wage data from the U.S. Department of Labor's Bureau of Labor Statistics (DOL BLS).[1] The wage rate of dialysis facility administrators ($44.74) is the average hourly wage of registered nurses. The wage rate of corporate representatives ($76.55) is the average hourly wage of management of companies and enterprises. The wage rate of nephrologists ($124.76) is the average hourly wage of physician specialists. The wage rate of transplant center administrators ($30.90) is the average hourly wage for other specialties within healthcare practitioners and technical occupations. The wage rate of dialysis facility social workers ($29.96) is the average hourly wage of healthcare social workers. The wage rate of patient advocacy organizations representatives ($24.28) is the average hourly wage for community and social service specialists. The wage rate of individuals is the Federal minimum wage, $7.25 an hour.[2]

A.13. Capital Costs

There are no capital costs.

[1] For wage rates, see DOL BLS. (n.d.). *May 2021 national occupational employment and wage estimates United States* [Dataset]. https://www.bls.gov/oes/current/oes_nat.htm

[2] For Federal minimum wage information, see DOL, Wage and Hour Division. (n.d.). Minimum wage [Web page]. https://www.dol.gov/WHD/minimumwage.htm

A.14. Cost to Federal Government

Provide estimates of annualized cost to the Federal Government. Also, provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The total cost to the Federal Government is $202,401 over a 36-month period, or an average of $67,467 per year. The largest cost to the Federal Government is to pay a contractor $202,401 to conduct the study and deliver datafiles. The information collection also assumes a total of 76.75 hours of Federal employee time per year: for the average Federal Employee in the Washington, DC, locality, at $43.51 per hour for a total of $3,339. Federal employee pay rates are based on the rates provided at FedSmith.com as of July 25, 2022.

A.15. Changes to Burden

This is a new information collection.

A.16. Tabulation dates

The schedule for data collection, tabulation, and publication is provided in table A.16.1.

Table A.16.1. Project Time Schedule

Activity	Activity Period
Data collection and analysis	September 2023–May 2024
Delivery of draft reports to CMS	June 2024–August 2024
Approval of final reports to CMS	September 2024

A.17. Expiration Date

All data collection instruments will display the OMB Control number and expiration date.

A.18. Certification Statement

No exceptions are necessary for this information collection.

References

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