

Supporting Statement Part A

National Implementation of the In-Center Hemodialysis CAHPS Survey

(CMS-10105, OMB 0938-0926)

A. JUSTIFICATION

The Centers for Medicare & Medicaid Services (CMS) is requesting clearance from the Office of Management and Budget (OMB) to continue the In-center Hemodialysis CAHPS (ICH CAHPS) Survey to measure patients' experience of care with in-center hemodialysis (ICH) facilities under Contract Number HHSM-500-2017-00068G.

A.1 Circumstances Making the Collection of Information Necessary

The U.S. Department of Health and Human Services (DHHS) developed the National Health Care Quality Strategy (NQS) to create national aims and priorities to guide local, state, and national efforts to improve the delivery of health care services, patient health outcomes, and population health. Since the NQS was developed, CMS has launched quality initiatives that require public reporting of quality measures for a variety of health care delivery settings, including nursing homes, hospitals, home health care, and kidney dialysis centers. Collection and public reporting of health care quality measures:

- provides information that consumers can use to assist them in making health care choices or decisions;
- aids health care systems and providers with internal quality improvement efforts and external benchmarking; and
- provides CMS with information for monitoring health care providers' performance.

Surveys focusing on patients' experience of care with their health care providers are an important part of the NQS. In addition to publicly reporting *clinical* quality measures, CMS is currently reporting measures from patient experience of care surveys in a variety of settings, including in-center hemodialysis (ICH) centers, hospitals, home health agencies, hospices, health and drug plans on the [Medicare web site](#) Web site. Publicly reporting comparative survey results related to patients' perspectives of the care they receive from providers and plans collected through the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Surveys support CMS's efforts to put patients first and improve the beneficiary experience. CAHPS is a

standardized family of surveys developed by the Agency for Healthcare Research and Quality (AHRQ) for patients to assess and report the quality of care they receive from their health care providers and health care delivery systems.

In its October 2003 Report to Congress, the Medicare Advisory Payment Commission (MedPAC) recommended that CMS collect information on End-Stage Renal Disease (ESRD) patients' satisfaction with access to and quality of care.¹ In 2004, CMS partnered with AHRQ to develop and test a standardized survey to measure the experiences of patients who receive ICH care from Medicare-certified ICH facilities. As a result of that effort, the ICH CAHPS Survey was developed for patients treated in ICH facilities to assess their dialysis providers, including nephrologists, medical and nonmedical staff, and the quality of dialysis care they receive.

CAHPS Surveys are a crucial component of patient-centered care and a valuable feedback tool to help CMS continually improve the products and services it purchases for Medicare beneficiaries. A national implementation of the ICH CAHPS Survey and publicly reporting comparative results from that survey is especially important for Medicare beneficiaries with ESRD because:

1. ESRD patients are a **vulnerable, minority population** that is totally reliant on the ESRD facility and its staff for life-sustaining care. Additionally, this population is characterized by declining cognitive function², high incidence of mental health disorders, and an average of 3.5 comorbidities (Dora et al., 2008)³.
2. Some patients might be reluctant to provide feedback on the dialysis care they receive for **fear of retribution**; others might be reluctant to report facilities to ESRD networks or state survey agencies because they might perceive that these bodies are not responsive to patient concerns. In addition, many patients might not be able to switch to another facility if they are unhappy with their care, making them a **captive population**, because there is not another facility close enough, or no other has any openings in its schedule. Moreover, some patients might not understand what mechanisms are available for them to provide feedback on facility practices.
3. According to the National Kidney Foundation, Medicare provides coverage for over 90% of all dialysis patients.⁴

¹ Medicare Payment Advisory Commission (MedPac). (2003, October). Report to the Congress: Modernizing the outpatient dialysis payment system. Retrieved from http://www.medpac.gov/documents/oct2003_Dialysis.pdf

² M. Kurella Tamura, K.E. Covinsky, G.M. Chertow, K. Yaffe, C.S. Landefeld, C.E. McCulloch. Functional status of elderly adults before and after initiation of dialysis. *N. Engl. J. Med.*, 361 (16) (2009), pp. 1539-1547

³ Dora, M., Zalai, M. D., & Novak, M. (2008). Depressive disorders in patients with chronic kidney disease. *Primary Psychiatry*, 15(1), 66–72.

⁴ Medicare (2019, March 27). Retrieved from the [National Kidney Foundation](#)

Prior to the ICH CAHPS Survey, no standardized, validated survey existed for collecting ESRD patients' assessment of the quality of dialysis care they receive, and the ones that are currently being used lack methodological rigor, peer review, and validation in survey development or its administration.

Since Fall 2014, CMS and its contractor conducted the ICH CAHPS Survey twice a year. The Fall survey covers the sampling window of April-June of the same year and the Spring survey covers the sampling window of October-December of the previous year.

CMS began publicly reporting clinical quality measures for kidney dialysis centers on Dialysis Facility Compare (DFC) on the [Medicare web site](#) in 2001. Patients with end-stage renal disease (ESRD) can compare the services and quality of care that dialysis facilities provide, and the DFC contains other resources for patients and family members who want to learn more about chronic kidney disease and dialysis. Prior to the national implementation of the ICH CAHPS Survey, a major gap in the information that was being publicly reported was the lack of quality information about the experience of in-center dialysis patients. However, starting in October 2016, CMS began publicly reporting ICH CAHPS data that included survey results from the Spring 2015 and Fall 2015 collections. Public reporting has continued with updates occurring April and October, with each refresh including a rolling average of the two most recent survey periods available.

Survey results from ICH CAHPS complement the clinical quality measures that CMS has been publicly reporting on DFC. Both clinical and patient experience quality measures enable consumers to make more informed decisions when choosing a dialysis facility. Furthermore, survey results can aid facilities in their quality improvement efforts, and help CMS monitor the performance of ICH facilities.

This OMB submission is in support of ESRD Quality Improvement Program (QIP) requirement for the national implementation of the ICH CAHPS survey. Starting in calendar year (CY) 2014, Medicare-certified ESRD facilities were required to collect and submit to CMS the ICH CAHPS Survey data as part of the value-based purchasing program for payments under the Medicare program. ICH facilities are required to contract with a CMS-approved, independent

third-party survey vendor to implement the ICH CAHPS survey on their behalf and to submit ICH CAHPS Survey data to CMS.

A.1.1 ICH CAHPS: Major Features

AHRQ conducted a field test of the ICH CAHPS Survey in 2005 to test the reliability and validity of the survey items and to shorten the number of items in the survey. The field test was conducted in both English and Spanish. After reviewing field test results with a technical expert panel (TEP) consisting of ESRD experts, patient advocates, and researchers, the ICH CAHPS Survey was finalized with supplemental items that are optional.

ICH CAHPS survey measures were endorsed by the National Quality Forum (NQF) in 2007. It contains questions about the patient’s interactions with the facility providers, the staff’s competence and professionalism, staff communication, care and emotional support, nephrologist’s communication and care, coordination of care, handling complaints, patient involvement in decision making, safety and environment, patient rights, and privacy. Patients are also asked to provide overall ratings of nephrologists, the medical and nonmedical staff, and the dialysis facility. Since the ICH CAHPS Survey was finalized and placed in the public domain, the “About You” Section has changed to comply with the U.S. Office of Minority Health’s requirements on data collection standards for race, sex, ethnicity, primary language, and disability status. The survey is available in English, Spanish, Samoan, Simplified Chinese, and Traditional Chinese. A copy of the ICH CAHPS survey questionnaire is included in **Attachment A** (a crosswalk of changes from the previously cleared version to the current questionnaire is included in **Attachment B**).

ICH facilities are able to choose a vendor from a list of CMS-approved vendors to administer the survey using one of three data collection modes: mail only, telephone only, and mixed mode (mail survey with telephone follow-up of non-respondents). Because data from the ICH CAHPS Survey are used to produce comparative results, and because the survey is conducted by multiple independent survey vendors, it is important that all vendors administer the survey using the same survey administration protocols and specifications. Therefore, vendors conducting the ICH CAHPS Survey on behalf of ICH facilities are required to use survey administration specifications developed by CMS.

A.2 Purpose and Use of Information

Data collected in the national implementation of the ICH CAHPS Survey are used for the following purposes:

- To provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection.
- To aid facilities with their internal quality improvement efforts and external benchmarking with other facilities.
- To provide CMS with information for monitoring and public reporting purposes.
- To support the ESRD Quality Improvement Program.

A.3 Use of Improved Information Technology

The national implementation of the ICH CAHPS Survey is designed to allow third-party, CMS-approved survey vendors to administer the ICH CAHPS Survey using mail only, telephone only, or mixed (mail with telephone follow-up) modes of survey administration. Experience from previous CAHPS surveys shows that mail, telephone, and mail with telephone follow-up data collection modes work well for respondents, vendors, and health care providers. Any additional forms of information technology, such as web surveys, is under investigation as a potential survey option in this population.

The CMS-approved survey vendors who administer the survey during the national implementation use an electronic data collection or computer-assisted telephone interview (CATI) system if they administer a telephone-only or mixed-mode survey. CATI was also used for telephone follow-up with mail survey nonrespondents during the mode experiment. There are numerous advantages to administering a telephone interview using a CATI system, including the following:

- costs less than in-person data collection;
- allows for a shorter data collection period;
- allows for less item nonresponse because the system controls the flow of the interview and complex routing;
- increases data quality by allowing consistency and data range checks on respondent answers;
- creates a centralization of process/quality control; and
- reduces post-interview processing time and costs.

A.4 Efforts to Identify Duplication

Many dialysis facilities, most notably large dialysis organizations (LDOs), had been carrying out their own patient experience of care surveys prior to ICH CAHPS. These diverse surveys did not allow for comparisons across facilities. Making comparative performance information available to the public helps consumers make more informed choices when selecting a dialysis facility and creates incentives for facilities to improve care they provide. With a standardized tool for collecting such information, comparisons across all facilities enables consumers to make the kind of “apple to apple” comparisons needed to support consumer choice. National implementation of the ICH CAHPS survey produces a core data collection protocol that can be integrated into current efforts by dialysis facilities.

The current ICH CAHPS survey consists of a core set of questions followed by optional supplemental questions. In addition, dialysis facilities may add their own questions to the existing ICH CAHPS survey as long as the dialysis-specific questions follow the core survey questions and are approved by CMS. The additional dialysis-specific questions are not submitted to CMS. We expect that there will be little duplication of effort on the part of the facilities in completing this survey.

A.5 Involvement of Small Entities

Not applicable. This information collection request does not involve any small businesses.

A.6 Consequences If Information is Collected Less Frequently

The national implementation of the ICH CAHPS Survey on a semiannual basis allows for the collection of data about patients’ experience with dialysis care at different points in time during a calendar year. The Spring Survey captures information on the quality of dialysis care (from the patients’ perspective) provided by ICH CAHPS facilities to patients during the first four months of each calendar year. Similarly, the Fall Survey collects data about patients’ experiences with dialysis care received during the summer months (June through September). In determining the periodicity of the survey administration, we weighed respondent burden with the need for accurate and timely information. We implemented semiannual survey administration to not overburden patients at small facilities and as a means to capture timely information. Less

frequent data collection might result in outdated information for public reporting and quality monitoring purposes as well as an increase in respondent recall errors. We also observed seasonal affects where average Spring survey scores tended to be or lower than Fall scores, warranting the need to measure at multiple points in a year.

Furthermore, less frequent collection of ICH CAHPS will lead to a lower number of facilities meeting the minimum requirement of 30 completed surveys in order to be reported on DFC. Currently, about half of the facilities meet the minimum number to be reported on DFC. It is estimated that reducing to an annual survey would drop the percentage of reportable facilities on the DFC to less than 15.

A.7 Special Circumstances

There are no special circumstances with this information collection request.

A.8 Federal Register Notice and Outside Consultations

A.8.1 Federal Register Notice

The 60-day *Federal Register* notice was published on 5/13/2019 (84 FR 20890) One comment was received. An attachment to this package provides details about the comment and our response.

The 30-day *Federal Register* notice was published on 08/15/2019, 84 FR 41721.No comments were received.

A.8.2 Outside Consultations

CMS's ICH CAHPS contractor convened a 10-member TEP and obtained guidance and input from the TEP on the sample design and survey administration specifications for both the national implementation of the ICH CAHPS Survey and the ICH CAHPS mode experiment. The TEP members consulted represented the following organizations:

- American Association of Kidney Patients
- American Nephrology Nurses Association
- CMS' Office of Minority Health
- Council of Nephrology Social Workers, National Kidney Foundation
- Dialysis Patient Citizens (ESRD patient advocacy organization)

- ESRD Network 8
- ESRD Network 15
- Harvard University Medical School
- National Renal Administrators Association
- RAND Corporation

A.9 Payments/Gifts to Respondents

No payments or gifts will be provided to respondents.

A.10 Assurance of Confidentiality

Individuals contacted as part of this data collection are assured of the confidentiality of their replies under 42 U.S.C. 1306, 20 CFR 401 and 422, 5 U.S.C. 552 (Freedom of Information Act), 5 U.S.C. 552a (Privacy Act of 1974), and OMB Circular A-130.

Concern for the confidentiality and protection of respondents' rights is critically important on any patient experience of care survey. Because ESRD patients are dependent on dialysis treatments for their survival, they are an especially vulnerable patient population. Some dialysis patients might not be willing to participate in the survey for fear of retribution from the facility staff. There is also a concern that some patients might respond to the survey but might respond in a way that does not reflect their actual experiences with dialysis care. Therefore, assurances of confidentiality are even more critically important with this patient population.

In-center hemodialysis facilities are required to contract with an independent, CMS-approved survey vendor to administer the ICH CAHPS survey. The use of staff at the dialysis facility to assist in questionnaire completion is prohibited because it might introduce bias, especially because among other things, patients are being asked to evaluate both the facility and the staff employed there. However, we recognize that because of fatigue and existing comorbidities, completing the survey without assistance might prove difficult for this patient population. As a result, it is permissible for respondents to ask family members or friends to help with completing the survey such as by reading the questions aloud to the respondent, translating questions into the language they speak, or writing the answers on the mail survey for the respondent.

Dialysis patients are more willing to participate if an outside organization administers the survey. In addition, ICH facilities are asked that they not discuss the survey with their patients, and especially in any way that might influence the patients' decision to participate in the survey or their responses to the survey. The cover letter included with the mail survey questionnaire sent to sample patients encourages patients to call the survey vendor's toll-free telephone number if they have any questions about the survey (sample cover letters are included in **Attachment D**).

ICH CAHPS Survey vendors are required to include the following assurances of confidentiality in communications with ICH CAHPS sample patients:

- the purposes of the survey and how survey results will be used;
- participation in the ICH CAHPS Survey is voluntary;
- the information they provide is protected by the Federal Privacy Act of 1974 (and that all ICH CAHPS project staff have signed affidavits of confidentiality and are prohibited by law from using survey information for anything other than this research study);
- their survey responses will never be linked to their name or other identifying information;
- all respondents' survey responses will be reported in aggregate, no ICH facility will see their individual answers;
- they can skip or refuse to answer any question they do not feel comfortable with; and
- their participation in the study will not affect the dialysis care or Medicare benefits they currently receive or expect to receive in the future.

A.10.1 Data Security

Survey vendors approved to conduct the ICH CAHPS survey for ICH facilities are required to have systems and methods in place to protect the identity of sampled patients and the confidential nature of the data that they provide. The survey vendor receives PII for sampled patients to administer the survey. After collecting and processing the survey data collected from the patients in the survey sample, the survey vendors submit only de-identified ICH CAHPS Survey data to CMS' contractor. CMS reviews each approved ICH CAHPS Survey vendor's data security systems during periodic site visits during the national implementation.

A.11 Questions of a Sensitive Nature

There are no questions of a sensitive nature included in this survey; that is, there are no questions that ask about what is typically considered as "sensitive," such as questions about

illegal or criminal activities, sexual behavior or orientation, or income. However, although the questions in the ICH CAHPS survey might not be deemed sensitive themselves, it must be acknowledged that responding to a survey about life-sustaining dialysis care might be a sensitive issue to a vulnerable ESRD patient population. Administration of the ICH CAHPS Survey by an independent survey organization and the steps described in **Section A.10** should help minimize or assuage any concerns that patients have about responding to this survey.

A.12 Estimates of Annualized Burden Hours and Costs

There is no cost to respondents other than spending approximately 16 minutes of their time to complete the survey. Estimated annualized burden hours and costs to the respondent for the ICH CAHPS Survey are shown in **Exhibits A.1** and **A.2**. We have estimated the maximum burden possible by assuming that 30.0% of approximately 350,000 ICH patients will complete the survey. Patients will be eligible to be sampled for both the Spring and Fall Surveys; therefore, the number of responses per sampled patient is two. Over the course of OMB’s 3-year approval period, we estimate a burden of 326,400 respondents, 652,800 responses, and 176,256 hours.

Exhibit A.1 Estimated Annualized Burden Hours: National Implementation of ICH CAHPS Survey

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
ICH CAHPS Survey (mail only, telephone only, and mail with telephone follow-up data collection modes)	108,800	2	.27	58,753

Exhibit A.2 Estimated Annualized Cost Burden: ICH CAHPS Survey

Form name	Number of respondents	Total burden hours	Average hourly wage rate+fringe*	Total cost burden
ICH CAHPS Survey (mail only, telephone only, and mail with telephone follow-up data collection modes)	108,800	58,753	\$54.60	\$3,207,859

The estimated annualized annual costs are outlined in Exhibit A.2. The estimated annualized costs to respondents is based on the Bureau of Labor Statistics (BLS) data from October 2018 (“Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted,” U.S. Department of Labor, Bureau of Labor Statistics, <https://www.bls.gov/news.release/empsit.t19.htm>, accessed November 21, 2018). The mean hourly wage for all occupations is \$27.30. The employee hourly wage estimates are then adjusted by a factor of 100 percent to account for fringe benefit costs (totaling \$54.60 for wage plus fringe benefits). This is a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The costs to ICH facilities will be determined by the selected data collection mode (mail, telephone, or mixed mode) and by the number of sample patients included in the facility sample. The cost to the government for CMS’ ICH CAHPS contractor to coordinate the national implementation of the ICH CAHPS Survey for Option Year 2 (9/2019-9/2020) is \$1,287,944.

A.13 Estimates of Annualized Respondent Capital and Maintenance Costs

There are no capital or maintenance costs associated with this collection.

A.14 Estimates of Annualized Cost to the Government

The total cost for the upcoming Option Year 2 is \$1,287,944 for labor hours, materials and supplies, overhead, and general and administrative costs and fees. The costs include the cost of development and maintenance of systems, protocols, and materials for training and technical

assistance that will be provided to survey vendors participating in the base year, and for conducting mode experiment data collection and analysis activities.

A.15 Changes in Hour Burden

The hour burden has decreased from 59,037 in the previous projection to 58,752 due to improved estimates of survey size and response rates. See section **B.3. Methods to Maximize Response Rate** for more information on the ICH CAHPS Survey response rate.

A.16 Time Schedule, Publication, and Analysis Plans

Data collection for the national implementation of ICH CAHPS survey began in CY2014. Sampling and data collection is conducted on a semiannual basis by survey vendors under contract with sponsoring ICH facilities. The key survey periods are shown in **Exhibit A.3**. ICH dialysis patients 18 years old and older who receive dialysis care in January through April and have received dialysis care from their current ICH facility for three months or longer will be eligible to be included in the sample for the Spring Survey. Patients who meet survey eligibility criteria (are 18 years or older, received dialysis care at their current facility for three months or longer) and receive dialysis care in June through September will be eligible for inclusion in the Fall Survey. Data collection for the Spring Survey will take place from June through August of each year. Data collection for the Fall Survey will take place from November through January.

Exhibit A.3 National Implementation Key Survey Periods

Key survey periods	Spring survey	Fall survey
Sampling window (when patient treated)	January–April	June–September
Data collection period	June–August	November–January

Survey vendors will submit data to CMS’ ICH CAHPS Data Center (maintained and operated by CMS’ ICH CAHPS contractor) by an established data submission deadline for each semiannual survey. The ICH CAHPS Survey results that will be publicly reported will be based on data from two semiannual surveys and will reflect one year’s worth of data. In each semiannual submission, we will adjust the survey results for mode of survey administration,

patient mix, and nonresponse, if necessary. The results posted on the DFC on the [Medicare website](#) will reflect data collected in the two most recent surveys.

A.17 Exemption for Display of Expiration Date

CMS does not seek this exemption. The Expiration Date and OMB control number will be displayed at the bottom of every survey.

A.18 Exceptions to Certification Statement 19

There are no exceptions taken to item 19 of OMB Form 83-1.