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-500-2012-00151G.

A.1 Circumstances Making the Collection of Information Necessary

The U.S. Department of Health and Human Services (DHHS) developed the National Quality Strategy (NQS) that was called for under the Affordable Care Act to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care to Medicare beneficiaries. 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 of hospital and home health care patients on the Hospital Compare and Home Health Compare links, respectively, on the www.Medicare.gov Web site. Comparative survey results from patients' perspective of the care they receive from hospitals and home health care agencies are based on data collected in surveys that use the applicable Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey. 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.

The survey is conducted twice a year, in the Fall covering the sampling window of April-June of the same year and in the Spring covering the sampling window of October-December of the previous year. Thus far, we have conducted the survey four times: Fall 2014, Spring 2015, Fall 2015 and Spring 2016.

Since 2001, CMS has been publicly reporting quality measures for kidney dialysis centers on Dialysis Facility Compare (DFC) on www.Medicare.gov. 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. However, 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. Starting in October 2016, CMS plans to remedy that situation by publicly reporting ICH CAHPS data. We anticipate our first public report will include results of the Spring 2015 and Fall 2015 surveys. Public reporting will be ongoing and will include a rolling average of the two most recent survey periods.

Survey results from ICH CAHPS will complement the clinical quality measures that CMS has been publicly reporting since 2001. Both clinical and patient experience quality measures will enable consumers to make more informed decisions when choosing a dialysis facility, will aid facilities in their quality improvement efforts, and will help CMS monitor the performance of ICH facilities.

In its October 2003 Report to Congress, the Medicare Advisory Payment Commission (MedPAC) recommended that CMS collect information on ESRD patients' satisfaction with access to and quality of care (MedPAC, 2003). 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 lower than average cognitive function (Kurella et al., 2008), high incidence of mental health disorders, and an average of 3.5 comorbidities (Dora et al., 2008).

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. Medicare provides coverage for about 85%–87% of all dialysis patients.

4. Payment systems have significantly changed recently for both practitioners and facilities that manage the care of ESRD beneficiaries. The impact of these changes on patient care is unclear.

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.

This OMB submission is in support of the payment year (PY) 2018 and subsequent years' requirement for national implementation of the ICH CAHPS survey with reporting to CMS. 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.

The ICH CAHPS Survey instrument 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 will also be asked to provide overall ratings of nephrologists, the medical and nonmedical staff, and the dialysis facility. ICH CAHPS survey measures were endorsed by the National Quality Forum (NQF) in 2007. 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 original to the current questionnaire is included in ***Attachment B***).

ICH facilities will be 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 will be 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 value-based purchasing 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, would be less feasible with ICH patients, many of whom are very ill, elderly, and lack access to the Internet.

The CMS-approved survey vendors who administer the survey during the national implementation will use an electronic data collection or computer-assisted telephone interview (CATI) system if they administer a telephone-only or mixed-mode survey. CATI will also be 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), are already carrying out their own patient experience of care surveys. These diverse surveys do not allow for comparisons across facilities. Making comparative performance information available to the public can help consumers make more informed choices when selecting a dialysis facility and can create incentives for facilities to improve care they provide. With a standardized tool for collecting such information, comparisons across all facilities will enable consumers to make the kind of "apple to apple" comparisons needed to support consumer choice. National implementation of the ICH CAHPS survey will produce 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. 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.

A.7 Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;

- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

- Use a statistical data classification that has not been reviewed and approved by OMB;

- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

A.8 Federal Register Notice and Outside Consultations

A.8.1 Federal Register Notice

The 60-day notice published in the Federal Register on June 13, 2016 (81 FR 38187). Refer to Attachment F to review responses to the three comments received.

Also, subsequent to the publication of the FRN, the Group Director of Medicare Drug Benefit and C&D Data Group (signatory on prenotification letters) changed her name, which is reflected in the pre-notification letters in Attachment C.

A.8.2 Outside Consultations

CMS' 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 will be 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 submits 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 27.3% of approximately 400,000 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.

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)	109,328	2	.27	59,037

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

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
ICH CAHPS Survey (mail only, telephone only, and mail with telephone follow-up data collection modes)	109,328	59,037	$25.35	$1,496,591

* Based on average hourly wages, "National Compensation Survey: Occupational Earnings in the United States, February 2016" U.S. Department of Labor, Bureau of Labor Statistics (http://www.bls.gov/news.release/empsit.t19.htm), March 29, 2016

The costs to ICH facilities will be determined by the contract agreed to between the facility and CMS-approved vendor the facility chooses. Vendors offer different data collection modes (mail, telephone, or mixed mode) which have different costs. Vendors also offer different service and report packages, which also impact costs. The number of sample patients included in the facility sample will also affect the charges by the vendor. ICH facilities are able to choose from a list of 16 CMS-approved vendors which offer a wide variety of services and costs. A list of CMS-approved vendors can be found on the survey web site, https://ichcahps.org.

The cost to the government includes survey sampling, maintenance of the survey data warehouse and the survey web site, plus vendor training and technical assistance to facilities and vendors (see section 15 of this Supporting Statement).

A.13 Estimates of Annualized Respondent Capital and Maintenance Costs

The only cost is that for the time of the respondent.

A.14 Estimates of Annualized Cost to the Government

The cost to the government for CMS' ICH CAHPS contractor to coordinate the national implementation of the ICH CAHPS Survey for Option Year 4 (9/19/2016 --9/18/2017) is $1,764,387. The cost to the government includes survey sampling, maintenance of the survey

data warehouse and the survey web site, plus vendor training and technical assistance to facilities and vendors.

A.15 Changes in Hour Burden

The implementation hour burden has been reduced from 86,400 as approved in the currently approved projection to 59,037 (-27,363) due to a lower response rate than originally planned. See section **B.3. Methods to Maximize Response Rate** for more information on the ICH CAHPS Survey response rate.

The mode experiment is complete, reducing the time estimate by an additional -1,350 hours.

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 www.Medicare.gov will reflect data collected in the two most recent surveys.

A.17 Exemption for Display of Expiration Date

CMS does not seek this exemption.

A.18 Exceptions to Certification Statement 19

There are no exceptions.