

Supporting Statement part A
National Implementation of the In-Center Hemodialysis CAHPS Survey
CMS-10105, OCN 0938-0926

Terms of Clearance (12/20/2004): Prior to resubmission of this information collection or prior to use of the survey beyond the pilot test, the agency will provide OMB with the results of the pilot test.

Response: See Attachment A - ICH CAHPS Pilot Test Summary Report.

A. JUSTIFICATION

The Centers for Medicare & Medicaid Services (CMS) is requesting clearance from the Office of Management and Budget (OMB) to implement nationally 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. Under this information collection request, CMS is also seeking review and approval for a mode experiment that will be conducted to determine the impact of using different data collection modes in the national implementation of the ICH CAHPS Survey.

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.

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. ***A major gap in the information that is being publicly reported, however, is the quality of in-center dialysis care from ESRD patients' perspective.*** 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. Prior to the pilot testing phase, significant background research was conducted by AHRQ and its CAHPS Consortium (RAND and the American Institute for Research) in preparation for development of the ICH CAHPS survey. A rigorous process involved:

- *Literature review.* An exhaustive literature review was performed, gathering results from ESRD surveys in use, as well as identification and cataloging of existing surveys in the public domain and selected proprietary surveys made available to the team.
- *Original Research.* Original research was conducted with patient and nephrologist focus groups and interviews with facility administrators and Network executives designed to ascertain patient and provider use of the results of a dialysis patient survey.

- *TEP Input.* This important background information was then provided to a Technical Expert Panel (TEP) of ESRD clinicians, researchers, providers, patients, facility administrators, network executive directors, and Large Dialysis Organization (LDO) representatives at a meeting convened by the CAHPS team in June 2003. The purpose of the meeting was to discuss the content, focus, and method of implementation of an ESRD CAHPS survey, to understand the extent to which facilities currently administer and how they use the results of patient surveys, and to understand how a standardized survey could be developed and implemented in a way that would provide maximal benefit to patients, providers, facilities and CMS, and minimal disruption and burden to facilities and LDOs. The TEP was also given the opportunity to provide feedback on the feasibility report prepared by AHRQ for delivery to CMS concerning the precise focus and content of the survey.
- *Federal Register Notice.* A Federal Register call for measures was issued on August 25, 2003, and closed on October 24, 2003. A total of 16 instruments were submitted under this solicitation. They were used by the ICH CAHPS instrument team as the basis for developing the initial ICH CAHPS Survey.
- *Renal Community Involvement.* An open meeting with a broader set of ESRD stakeholders meeting was held in March of 2004 to solicit feedback on both the draft survey instrument and the proposed method of implementation.
- *Review of submitted instruments.* Submitted instruments were then thoroughly reviewed by AHRQ and the CAHPS grantee team. Second, items from all submitted instruments were entered into a comprehensive database, allowing the comparison of items from different questionnaires that covered the same topics. Individual items were examined by the team for possible inclusion in an ESRD CAHPS draft questionnaire. AHRQ and the CAHPS instrument team, along with CMS and renal clinicians, met weekly, from November 2003-March 2004, to craft a survey that included items relevant to the main topic areas identified in the literature review and existing patient surveys, and that would be useful for quality improvement as well as public reporting. The survey went through six full iterations before the team approved it as a “first draft”.
- *Cognitive Testing.* Once a testable draft was produced, the instrument team conducted cognitive testing in several locations across the country. Cognitive interviews are structured discussions conducted with patients as they complete the questionnaire. During the interviews, researchers explore the respondent’s understanding of the questions and terms, their ability to navigate and complete the survey, and the relevance of the questions to the patient. The team prepared a summary of the findings from these cognitive interviews and revised the instrument based on the patients’ feedback.
- *Public Comment.* In early March 2004, the initial ICH CAHPS Survey instrument was submitted to CMS and the TEP for further comment and revision. Another federal register notice was published on January 30, 2004, seeking public comment on the draft instrument and protocol. The additional feedback received through this process was also used to refine the survey instrument.

AHRQ conducted a field test of the ICH CAHPS Survey from January through April 2005 to test the reliability and validity of the survey items. The field test included 3,143 sampled patients from a total of 32 ICH facilities located across the United States. Sampled patients were randomly assigned by facility to either a telephone-only or mixed-mode (mail with telephone follow-up) data collection effort. Of the 3,143 sample patients, 1,454 responded to the survey resulting in an overall response rate of 46%. Of those respondents, 56% responded by telephone and 44% responded by mail. Analytic methods included both confirmatory and exploratory methods to describe the structure underlying responses to the quality report items, as well as evaluation of the measurement properties of the composites using classical psychometric methods. More information regarding the results of the field test can be found in **Attachment A**.

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 one that 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) 2016 requirement for national implementation of the ICH CAHPS survey with reporting to CMS. Starting in calendar year (CY) 2014, Medicare-certified ESRD facilities will be 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 will be 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 National Implementation: Major Features

CMS-approved survey vendors will be required to use the ICH CAHPS Survey. As discussed above, 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 as a 58-item survey instrument with supplemental items that are optional. The field test version of the ICH CAHPS Survey with changes noted can be found in ***Appendix A***. A crosswalk of changes from the field test version of the ICH CAHPS Survey to the national implementation version can be found in ***Attachment B***.

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 been 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 final ICH CAHPS survey questionnaire in both English and Spanish is included in ***Attachment C***.

Because data from the national implementation of the ICH CAHPS Survey will be used to produce comparative results, and because the national implementation of the survey will be conducted by multiple independent survey vendors, it is important that all vendors administer the survey using the same survey administration protocols and specifications. Therefore, CMS-approved survey vendors conducting the ICH CAHPS Survey on behalf of ICH facilities will be required to use survey administration specifications developed by CMS. ICH facilities will be able to choose a vendor 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 nonrespondents).

CMS will begin publicly reporting comparative results from the ICH CAHPS Survey after each facility has conducted data collection over a year. Survey results from the national implementation will complement the quality clinical measures that CMS has been publicly reporting since 2001. Both clinical and survey 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.

A.1.2 ICH CAHPS Mode Experiment

In order for patients to make objective and meaningful comparisons between dialysis facilities, methods and adjustments must be put into place to account for significant sources of bias outside the control of the dialysis facilities. Known sources of bias include data collection mode and variability in patient-mix and response propensity across patients within dialysis facilities. As part of this information collection request, CMS is requesting approval to conduct a randomized mode experiment with a sample of patients receiving in-center hemodialysis to determine whether they respond differently to the survey based on data collection mode. In addition, data from the mode experiment will be used to determine which, if any, patient characteristics affect the ratings of the care they receive. If needed, during the national implementation of the ICH CAHPS Survey, CMS will develop models to statistically adjust survey results before comparative results are publicly reported. Comparative results from the ICH CAHPS mode experiment will not be publicly reported.

A.2 Purpose and Use of Information

Data collected in the national implementation of the ICH CAHPS Survey will be 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 supplemental questions that may be included. 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. 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

CMS will conduct the ICH CAHPS mode experiment as a one-time (cross-sectional) survey of patients currently receiving care from ICH facilities. A random sample of ICH patients who received dialysis care during the preceding five months will be selected and contacted to gather data about their experiences with dialysis care. CMS will construct the sample frame for the mode experiment using patient information that is available on CMS’s Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) database. Data collection for the mode experiment will take place in the fall of 2013 or immediately after OMB approval for this information collection request is received. Conducting this one-time survey prior to the national implementation of the ICH CAHPS survey is crucial for determining differences in survey

responses based on the three modes of data collection and to determine patient characteristics that might affect experiences and the ratings of the care they receive.

The national implementation of the ICH CAHPS Survey on a semiannual basis will allow for the collection of data about patients' experience with dialysis care at different points in time during a calendar year. The Spring Survey will capture 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 will collect 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 propose 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 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 published on April 19, 2013 (78 FR 23566). 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's 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 will be 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 will be 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 will be 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 will be more willing to participate if an outside organization administers the survey. In addition, ICH facilities will be 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 will encourage patients to call the survey vendor's toll-free telephone number if they have any questions about the survey.

ICH CAHPS Survey vendors will be 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.

For sample patients who will be surveyed via mail and mixed mode data collection methods, assurances of confidentiality will be included in the mail survey cover letters (see **Attachment D**). For sample patients who are included in the phone only data collection mode, assurances of confidentiality are included in the telephone script (see **Attachment E**) and will be read to the respondent by the telephone interviewer.

A.10.1 Mode Experiment

During the mode experiment, CMS will provide to its ICH CAHPS contractor an electronic file containing information about dialysis patients, including personally identifiable information (PII; name, address, date of birth and telephone number). The file will also include protected health information (PHI) used for patient-mix analysis, including the age at which the patient first began dialysis treatments, primary diagnosis, and other diagnoses. Social Security numbers will not be provided.

A.10.2 National Implementation

Survey vendors approved to conduct the ICH CAHPS survey for ICH facilities participating in the national implementation will be 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 will receive 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 will submit only de-identified ICH CAHPS Survey data to CMS's contractor. CMS will review 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

A.12.1 Mode Experiment

There is no cost to respondents other than approximately 16 minutes of their time to complete the survey. The Bureau of Labor Statistics reported that the average hourly wage for civilian workers in the United States in 2010 (U.S. Department of Labor, 2012) was \$21.29. An estimate of \$22 per hour allows for inflation and represents a conservative estimate of the wages of respondents. Estimated annualized burden hours and costs to the respondent for the mode experiment are shown in **Exhibits A.1** and **A.2**. The cost to the government for conducting the mode experiment is \$669,618.

Exhibit A.1 Estimated Annualized Burden Hours: Mode Experiment

| 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) | 5,000 | 1 | .27 | 1,350 |

Exhibit A.2 Estimated Annualized Cost Burden: Mode Experiment

| 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) | 5,000 | 1,350 | \$22.00 | \$29,600 |

* Based on average wages, “National Compensation Survey: Occupational Earnings in the United States, 2010,” U.S. Department of Labor, Bureau of Labor Statistics (<http://www.bls.gov/ncs/home.htm>).

A.12.2 National Implementation

As with the mode experiment, 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 national implementation are shown in **Exhibits A.3** and **A.4**. We have estimated the maximum burden possible by assuming that 40% 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.3 Estimated Annualized Burden Hours: National Implementation

| 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) | 160,000 | 2 | .27 | 86,400 |

Exhibit A.4 Estimated Annualized Cost Burden: National Implementation

| 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) | 160,000 | 86,400 | \$22.00 | \$1,900,800 |

* Based on average wages, “National Compensation Survey: Occupational Earnings in the United States, 2010,” U.S. Department of Labor, Bureau of Labor Statistics (<http://www.bls.gov/ncs/home.htm>).

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’s ICH CAHPS contractor to coordinate the national implementation of the ICH CAHPS Survey implementation is \$1,339,243.

A.13 Estimates of Annualized Respondent Capital and Maintenance Costs

The only cost is that for the time of the respondent. There is no anticipated recordkeeping burden because respondents are not required to keep a copy of the survey.

A.14 Estimates of Annualized Cost to the Government

The total cost for the contracted base-year service will be \$1,339,243 for the upcoming survey for labor hours, materials and supplies, overhead, and general and administrative costs and fees. The total contract base-year service costs include the cost of development 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 field test burden was discontinued in 2007. This is a Reinstatement that adds burden associated with the mode experiment and the national implementation.

While the overall burden has increased from adding the mode experiment and the national implementation, the annual (per response) burden for the mode experiment and national implementation have decreased. The hours per response for the field test were approximately .50 hr, compared to the estimated .27 hr for both the ICH CAHPS Survey mode experiment and national implementation.

The estimated annualized burden hours and costs to the respondent from the field test are shown in **Exhibits A.5** and **A.6**. Due to changes made to the ICH CAHPS Survey following the field test, there is an expected decrease in annual burden hours for the mode experiment and national implementation. The hours per response for the field test were approximately .50, compared to the estimated .27 for the ICH CAHPS Survey mode experiment (*Exhibits A.1* and *A.2*) and national implementation (*Exhibits A.3* and *A.4*).

Exhibit A.5 Estimated Annualized Burden Hours: 2005 Field Test

| Form name | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|--|-----------------------|------------------------------------|--------------------|--------------------|
| ICH CAHPS Survey Field Test (telephone only and mail with telephone follow-up data collection modes) | 3,143 | 1 | .50 | 1,572 |

Exhibit A.6 Estimated Annualized Cost Burden: 2005 Field Test

| Form name | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|--|-----------------------|--------------------|---------------------------|-------------------|
| ICH CAHPS Survey Field Test (telephone only and mail with telephone follow-up data collection modes) | 3,143 | 1,572 | \$19.00 | \$29,868 |

* Based on average wages, “National Compensation Survey: Occupational Earnings in the United States, 2005,” U.S. Department of Labor, Bureau of Labor Statistics (<http://www.bls.gov/ncs/home.htm>).

A.16 Time Schedule, Publication, and Analysis Plans

A.16.1 National Implementation of ICH CAHPS

Data collection for the national implementation of ICH CAHPS survey is scheduled to begin in CY2014. Sampling and data collection will be conducted on a semiannual basis by survey vendors working under contract with the sponsoring ICH facilities. The key survey periods are shown in **Exhibit A.7**. ICH dialysis patients 18 years old and older who receive dialysis care in January through April and who 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 who 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.7 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 |

CMS will begin publishing results from the national implementation of ICH CAHPS after each participating ICH facility has submitted data from the two semiannual surveys. Survey vendors will submit data to CMS’s ICH CAHPS Data Center (maintained and operated by

CMS's 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.16.1a ICH CAHPS Mode Experiment

As previously mentioned, the ICH CAHPS mode experiment will be a one-time (cross-sectional) survey of a sample of patients 18 years old and older who receive in-center hemodialysis care for three months or longer from their ICH facility. The mode experiment sample will consist of 11,115 ICH patients, of whom 4,486 will be randomly assigned to the mail-only mode, 3,489 to the telephone-only mode, and 3,140 to the mixed-mode survey. Data collection for the mode experiment will take place in the fall of 2013 or as soon as possible after OMB clearance is received.

We will send a pre-notification (advance) letter (see ***Attachment F***) to all sample patients in each mode the first week of the data collection period. After the pre-notification letter is mailed, data collection for each mode will consist of the following:

- *Mail-only Mode:* All ICH patients included in the mail-only sample will be sent a first package consisting of a cover letter, the ICH CAHPS questionnaire, and a pre-addressed, postage-paid return envelope. A second mailing containing a questionnaire and cover letter will be mailed to all sample patients who do not respond to the first mailing.
- *Telephone-only Mode:* In this mode, all sample patients will be contacted via telephone by professional telephone interviewers who will be trained on ICH CAHPS survey administration procedures, including procedures for working with dialysis patients. Telephone interviewers will be trained on the appropriate response to common questions and concerns that dialysis patients may have about survey participation. A maximum of 10 telephone contact attempts per patient will be implemented to complete the survey.
- *Mixed Mode:* All sampled patients included in the mixed-mode data collection sample will receive an initial mailing of a questionnaire, cover letter, and postage-paid return envelope that patients included in the mail-only sample will receive. Sample patients assigned to this mode who do not respond to the mail survey will be assigned to the telephone follow-up. Telephone interviewers will make up to 10 attempts to complete

the interview by phone with all mail survey nonrespondents included in the mixed-mode sample.

The data collection schedule for the mode experiment is described in **Exhibit A.8**.

Exhibit A.8 Mode Experiment Data Collection Schedule

| Action | Timing |
|---|---------------|
| Mail-Only Survey | |
| Mail pre-notification letter | Week 1 |
| Prepare and mail the first questionnaire package to all sample members | Week 2 |
| Mail second questionnaire package to all sample members who do not respond to first questionnaire mailing | Week 5 |
| End data collection | Week 8 |
| Phone-Only Survey | |
| Mail pre-notification letter | Week 1 |
| Begin telephone contact with sample members | Week 2 |
| End telephone data collection | Week 8 |
| Mixed-Mode Survey | |
| Mail pre-notification letter | Week 1 |
| Mail questionnaire with cover letter to sample members | Week 2 |
| Initiate telephone follow-up contact for all mail survey nonrespondents | Week 5 |
| Complete data collection | Week 8 |

Data from the mode experiment will be analyzed to assess the impact of nonresponse and to determine whether patients rate their dialysis care differently based on data collection mode. Mode experiment data will also be analyzed to determine which, if any, patient characteristics affect patients' ratings of their dialysis care. CMS will use data from the mode experiment to develop models that will be used to statistically adjust survey results from the national implementation to account for factors that are beyond the control of ICH facilities. Results from the mode experiment will not be publicly reported on the DFC. CMS's ICH CAHPS contractor will prepare a technical report describing the mode experiment results and recommendations for adjusting survey results for nonresponse, mode, and patient-mix.

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 taken to item 19 of OMB Form 83-1.