

## **SUPPORTING STATEMENT**

### **Part A**

Evaluation of Patient Satisfaction and Experience of Care for Medicare Beneficiaries with End-Stage Renal Disease (ERSD): Impact of the ESRD Prospective Payment System (PPS) and ESRD Quality Incentive Program (QIP)

Version: July 19, 2013

Centers for Medicare & Medicaid Services

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## **A. Justification**

### **1. Circumstances That Make The Collection of Information Necessary**

Section 2991 of the Social Security Amendments of 1972, Public Law 92-603, established the ESRD program under Medicare. That law extended Medicare coverage to individuals regardless of age who have permanent kidney failure, requiring either dialysis or kidney transplantation to maintain life, and meeting certain other eligibility criteria.

As a result of statutory requirements, final regulations implementing the composite payment system were published on May 11, 1983 (48 FR 21254), effective August 1, 1983. This composite payment was limited to payments for the costs incurred by dialysis facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies. Although relatively comprehensive with respect to the renal dialysis services included as part of the composite payment bundle, over time a substantial portion of expenditures for renal dialysis services became excluded from the composite payment system and reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payments for erythropoiesis stimulating agents (ESAs) such as epoetin alfa (EPO, for example, Epogen) and darbepoetin alfa (ARANESP) used to treat anemia, and vitamin D analogues (paracalcitol, doxercalciferol, calcitriol), were made outside of the composite payment. Prior to the ESRD PPS, these separately billable services comprised about 40 percent of total spending for outpatient maintenance dialysis.

Between 1983 and 2001, the composite payment rates were increased only three times. During the last few years, policymakers and other interested parties, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO), have examined the Medicare outpatient maintenance dialysis payment system and suggested a bundled prospective payment approach. The ESRD PPS would combine composite rate dialysis services with separately billable services under a single payment adjusted to reflect patient differences in resource needs or case-mix. As in any PPS, dialysis facilities would keep the difference if Medicare payments exceeded costs for the bundled services, and would be liable for the difference if costs exceeded Medicare payments.

*The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA)* (see Attachment A), required the Secretary of HHS to submit to Congress a report detailing the elements and features for the design and implementation of a bundled ESRD PPS, specifying that such a system should include the bundling of separately billed drugs, clinical laboratory tests, and other items “to the maximum extent feasible”. A copy of this report may be found at:  
<http://www.cms.gov/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf>.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed the Secretary of HHS to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment.

The Final Rule for the ESRD PPS was published in the Federal Register on August 12, 2010 and may be found at: <http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi>. MIPPA also stipulated the development of quality incentives for the ESRD program. In the case when a provider of services or a renal dialysis facility does not meet (or exceed) the total performance score, a payment reduction of up to two percent, depending upon the degree of failure to meet (or exceed) the total performance score, is assessed. CMS has developed the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to address this provision of the legislation. The Final Rule for the ESRD QIP was published in the Federal Register on January 5, 2011 and may be found at: <http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi>.

In order to assess how the Final Rule on ESRD has resulted in changes in the delivery of care to ESRD beneficiaries, and to get a measure of beneficiary experiences, satisfaction, and health outcomes, CMS is requesting OMB approval to conduct data collection to obtain input on the effect of the Final Rule on our ESRD beneficiaries.

In evaluating changes resulting from the implementation of the ESRD PPS/QIP and beneficiary experience and satisfaction, CMS is specifically interested in answering the following research questions:

1. What is beneficiary satisfaction under the ESRD PPS/QIP?
2. What is the beneficiary experience of care under the ESRD PPS/QIP?
3. What is beneficiaries' perception of their quality of life under the ESRD PPS/QIP?
4. What is the quality of dialysis services (e.g., dialysis length, frequency of dialysis, comfort, etc.) under the ESRD PPS/QIP ?
5. Do vulnerable populations (e.g., minorities, the elderly, beneficiaries living in rural areas, etc.) or for smaller segments of the dialysis population (e.g., home hemodialysis patients, peritoneal dialysis patients, etc.) have unintended consequences under the ESRD PPS/QIP? What are the unintended consequences?
6. What is the experience of ESRD beneficiaries in obtaining ESRD-related oral drugs under the ESRD PPS/QIP? Are there any issues with obtaining ESRD-related medications? Are there any issues with accessing pharmacies? Is there confusion among the beneficiaries on oral medications covered by Part D and ESRD-related medications not covered by Part D?
7. What are the beneficiary out-of-pocket (OOP) costs compared to out-of-pocket (OOP) costs under the ESRD PPS/QIP the ESRD PPS/QIP?

8. What is the beneficiary education, including discussion of modality choice, referral for renal transplant for appropriate patients, and home dialysis training under the ESRD PPS/QIP?
9. What is the beneficiary perception of their outcomes (e.g. experience of infections, hospitalizations, and/or emergency department visits, etc.) under the ESRD PPS/QIP?

Attachment D includes a mapping of research questions to Beneficiary Survey items. Attachment E includes a mapping of research questions and Stakeholder interview domains.

## ***2. Purpose and Use of Information***

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed the Secretary of HHS to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The end-stage renal disease (ESRD) prospective payment system (PPS or “bundled payment”) combines composite rate dialysis services with separately billable services under a single payment adjusted to reflect patient differences in resource needs or case-mix. MIPPA also stipulated the development of quality incentives for the ESRD program, known as the ESRD Quality Incentive Program (QIP). In the case when a provider of services or a renal dialysis facility does not meet (or exceed) the total performance score, a payment reduction of up to two percent, depending upon the degree of failure to meet (or exceed) the total performance score, is assessed.

An important part of the evaluation of the ESRD Services Monitoring and Evaluation of the ESRD PPS/QIP will be to assess the Medicare beneficiary’s perception of their satisfaction and experience of care under this new system. The purposes of this data collection effort are to assess beneficiary satisfaction and experience of care in terms of access to services, quality of care, outcomes, and cost. This will be measured through telephone surveys with ESRD beneficiaries and through interviews with key stakeholders in the renal health care community. The information obtained from the beneficiary respondents and key stakeholders will be used to provide an initial reporting and inform the Centers for Medicare & Medicaid Services (CMS) of beneficiary satisfaction, experience of care, and unintended consequences under the ESRD PPS/QIP, and will be used by CMS for consideration of future modification of the programs.

### **Research Design**

The research design includes dual data collection streams. The first piece of the research design uses a telephone survey to collect quantitative data about healthcare experience of and satisfaction among ESRD beneficiaries. The second piece of the research design targets professionals working in renal care and other relevant stakeholders in the renal community using in-depth interviews to gather information on care delivery and management and changes seen as a result of the PPS/QIP. The dual approach allows CMS to collect qualitative and quantitative data from a range of sources to answer the broad and layered research questions about the impact of the PPS/QIP. Beneficiaries are the best source of information about their own experiences as ESRD patients. Based on

initial exploratory interviews and survey testing, CMS found that beneficiaries are unlikely to accurately remember what their care was like before the implementation of the ESRD PPS/QIP (January 2011) but can describe their kidney care over the past 3 months. Most beneficiaries do not have clinical knowledge or understanding of policy of payment changes put in place under the PPS/QIP. Professionals working in renal care and other stakeholders in the renal community provide key information to complete the understanding of the impacts of the PPS/QIP by describing changes in the structure and clinical approach to care provision since the introduction of the PPS/QIP.

### **Beneficiary Survey**

The purpose of Beneficiary survey is to collect information in a systematic and scientifically rigorous manner from Medicare beneficiaries with ESRD. The survey encompasses the following important domains:

- access to care and services,
- communication
- care coordination,
- comprehensiveness of care
- healthcare outcomes,
- cost of care.

The survey instrument underwent cognitive testing and was subsequently revised as described in Attachment F. Upon receipt of OMB approval, 2,500 beneficiary completed surveys will be completed. The proposed data collection instrument is included as Attachment B.

It is noted that because the beneficiary survey is being administered after the PPS and QIP have been implemented, data will reflect patient experience and satisfaction under the PPS/QIP model. Direct comparisons cannot be made to patient experience and satisfaction prior to the PPS/QIP.

A crosswalk of the research questions, domains, and Beneficiary survey items are included as Attachment D. Attachment D also crosswalks items originating from the ICH-CAHPS survey to the current ESRD Beneficiary survey and describes if and why modifications were made to existing ICH-CAHPS items.

### **Stakeholder Interviews**

The purpose of the Stakeholder interviews is to gather information in a semi-structured manor from program administrators, providers in dialysis facilities, other relevant providers, and patient advocates about the changes seen in the organization, management, and delivery of care to ESRD patients after the introduction of PPS/QIP. Additionally, stakeholders will be asked for input about possible missing domains or topics in the current ICH-CAHPS survey. The information obtained from key stakeholders in the renal community regarding any possible missing domains or topics in the current ICH-CAHPS could be used as an initial step to guide CMS in any process to update the ICH-CAHPS survey in the future. Upon receipt of OMB approval, 40 in-depth interviews will be conducted with:

- CMS staff,

- ESRD Network staff,
- beneficiary groups/patient advocates,
- dialysis center staff,
- pharmacists,
- other stakeholders.

A draft interview protocol was tested on a limited number of stakeholders in the renal community to inform the design of the beneficiary survey and to prepare an interview protocol for OMB review (Attachment C).

While the Stakeholder interviews will use a qualitative approach, collecting data from 40 stakeholders is expected to yield sufficient information capture a detailed perspective of the impact of the PPS/QIP.

### ***3. Use of Improved Information Technology***

CMS will utilize computer-assisted telephone interviewing to conduct the surveys with ESRD beneficiaries (see Attachment B). ESRD beneficiaries tend to be older and more frail and CMS finds that telephone interviews are more successful with this population.

CMS plans to collect information from stakeholders through an established qualitative evaluation methodology, which includes telephone interviews with study respondents (see Attachment C for a draft interview discussion guide). Because most interview questions are open-ended to allow for in-depth exploration of issues, electronic submission of responses is not a viable option.

### ***4. Efforts to Identify Duplication***

To date, neither CMS nor any other known organization has conducted an evaluation of the ESRD PPS/QIP legislation on patient satisfaction and experience of care.

CMS is familiar with the CAHPS In-Center Hemodialysis (ICH) survey instrument that measures patient experience with receiving hemodialysis care in a dialysis center. ICH-CAHPS is a publically available instrument though CMS does not currently have access to any large-scale data resulting from an ICH-CAHPS data collection. The CAHPS consortium funded through AHRQ currently maintains the ICH-CAHPS instruments but does not maintain a database of resulting data. The ICH-CAHPS survey was designed specifically for in-center hemodialysis patients and does not apply to patients receiving home dialysis or peritoneal dialysis. The ICH survey was used as the basis for many of the patient experience questions in the proposed Beneficiary survey though was expanded to cover a wider range of patients and a broader set of topics beyond patient experience.

### ***5. Involvement of Small Entities***

As noted above, the audiences to be included in the assessment include ESRD beneficiaries and also key stakeholders in the renal community. It is expected that some of the stakeholders may be members of small businesses, but at this time it is unclear what portion of stakeholder respondents would be part of a small entity. Study participation is voluntary and CMS will be respectful of study participants' time. Interviews will be scheduled at times convenient for respondents.

## **6. Consequences if Information Collected Less Frequently**

This is a one-time collection.

## **7. Special Circumstances**

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

## **8. Federal Register Notice and Outside Consultations**

### **8.a. Federal Register Notice**

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on May 11, 2012 for 60 days (see Attachment XX). XX comments were received (see Attachment XX).

### **8.b. Outside Consultations**

CMS consulted with its evaluation contractors, Acumen and Westat, as well as ESRD clinical expert, Dr. Jay Wish in developing the data collection plan. No other outside consultants contributed to the formation of the study design.

## **9. Payments/Gifts to Respondents**

No incentives (either payment or gift) are planned for either the beneficiary or stakeholder data collection.

## **10. Assurance of Confidentiality**

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent.

The study will collect information from beneficiary respondents about their experiences and satisfaction with care. CMS will also collect demographic information about the respondent, along with tracking information such as name and phone number. The study will ask stakeholders about the relevant domains and topics, as well as questions about patient outcomes, including unintended consequences.

All respondent involvement will be voluntary. Only oral consent for participation will be obtained from respondents. Respondents will be informed that: (1) the project team will not share their name, their personal information or copies of their individual survey responses or interview notes with anyone outside of the team; (2) respondent open-ended comments may be included in reports and publications but will not be attributed to specific individuals or organizations; and (3) staff members who interview the stakeholders will have a system to mark specific comments in interview notes as off-limits for reports and publications when notified to do so by the respondent.



All electronic files will be password protected and accessible only from a secured network. When not in use by project staff, all printed information or materials that could potentially identify participants in the study will be stored in locked cabinets that are accessible only to project team members.

**11. Questions of a Sensitive Nature**

No questions of a sensitive nature will be asked. Further, during the introduction to the interview, respondents will be informed that their participation is voluntary and that they can refuse to answer any question.

**12. Estimates of Annualized Burden Hours and Costs**

The annual burden costs were estimated to be \$28,581.22 in the 60 day Federal Register notice. In the 30 day Federal Register notice, the annual burden cost changed to \$15,237.47 because the contractor shortened the survey to accommodate potential Medicare beneficiaries with end stage renal disease (ESRD) who are very sick. During cognitive testing, ESRD beneficiaries complained that the survey was too long and some participants had to hang up early because they were feeling sick during the cognitive interview.

Exhibit 1 shows the estimated annual burden hours for each respondent’s time to participate in this evaluation. The total number of burden requested for the effort is 661.7 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondent time to participate in this evaluation. The total annual burden is estimated to be \$15,237.47.

**Exhibit 1. Estimated Annualized Burden Hours**

Interview Type	Number of respondents	Number of responses per respondent	Avg. Time for Response (in minutes)	Total burden hours
ESRD Beneficiary Survey	2,500	1	15	625
Key Stakeholder Interviews	40	1	55	36.7
<b>Total</b>	2,540			661.7

**Exhibit 2. Estimated Annualized Cost Burden**

Interview Type	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
ESRD Beneficiary Survey	2,500	625	\$21.35	\$13343.75
Key Stakeholder Interviews	40	36.7	\$51.6	\$1,893.72
<b>Total</b>	2,540	661.7	NA	\$15,237.47

\*For the purposes of estimating cost burden, we have assumed the hourly wage for the ESRD beneficiaries is the same as the national average (\$21.35).

May 2010 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics Division of Occupational Employment Statistics  
[http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000)

For purposes of estimating cost burden for the stakeholders, we have used a weighted average based on the hourly wage of Physicians (\$86.96) and RNs (\$32.56). For purposes of calculating the cost burden, we assumed approximately 14 stakeholders will be physicians and the remainder will be RNs or similar.

May 2010 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics Division of Occupational Employment Statistics  
[http://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](http://www.bls.gov/oes/current/oes_nat.htm#29-0000)

### **13. Estimates of Annualized Respondent Capital and Maintenance Costs**

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

### **14. Estimates of Total and Annualized Cost to the Government**

The estimated total cost to the Federal Government for the data collection portion of this project is \$265,856 over a 4-month period. Data collection is currently planned to begin October 1, 2012 and end January 31, 2013 (pursuant to OMB approval).

### **15. Changes in Hour Burden**

Between the 60-day Federal Register notice and the 30-day Federal Register notice, the annual burden hours have decreased from 1,250 to 661.7 due to the fact that Medicare beneficiaries with end stage renal disease (ESRD) are very sick and unable to remain cognitively aware for 30 minutes. Early cognitive interview findings of the ESRD Beneficiary Survey submitted during the 60 day notice exhibited respondent complaints that the survey was too long and some participants had to hang up early because they were feeling sick. The ESRD Beneficiary Survey was significantly shortened so that the time necessary to interview a single participant was reduced from 30 to 15 minutes.

### **16. Time Schedule, Publication and Analysis Plans**

**Time schedule and publication plans.** The anticipated schedule for this project is shown in Exhibit 3. Once clearance from the Office of Management and Budget is obtained, CMS will begin preparation for data collection.

#### **Exhibit 3. Anticipated Schedule**

<b>Activity</b>	<b>Estimated timeline following OMB clearance</b>
Data collection preparation	Month 1
ESRD Beneficiary Survey data collection	Months 2 – 5
Stakeholder Interview data collection	Months 2 – 5
Analyze Results	Months 5 – 8
Reporting	Months 9 – 13

At the present time there are no plans for publication of the evaluation results. Rather, CMS will use results from the evaluation to (1) Assess the impact of the ESRD PPS/QIP legislation on ESRD beneficiary satisfaction and health outcomes and (2) Consider modifications to the ICH-CAHPS instrument.

## **Analysis plans.**

The objectives of this research study are 1) to obtain information from Medicare beneficiaries and key stakeholders in the renal community on patient satisfaction and experience of care under the ESRD PPS/QIP; and 2) to obtain information from key stakeholders in the renal community regarding any possible missing domains or topics in the ESRD Beneficiary Survey. The information obtained from the beneficiary respondents and other stakeholders will be used both to provide an initial reporting of beneficiary satisfaction and experience of care (including unintended consequences) under the ESRD PPS/QIP and to inform CMS and its stakeholders of areas of strengths and weaknesses of these programs for future modification of the programs. Below we present the analysis plans for the stakeholder interviews and the beneficiary survey.

**Stakeholder Interviews.** After receipt of the OMB PRA approval, we will conduct all of the activities necessary for completing the stakeholder interviews, including making logistical arrangements, recruiting participants, and conducting the interviews. The in-depth interviews with stakeholders will explore and document their perceptions about the effects of the ESRD PPS/QIP delivery of care to beneficiaries. The interviews will also obtain information from key members of the renal community regarding any possible missing domains or topics in the ICH CAHPS Survey.

Findings will be presented by topic area supported by direct quotations from the in-depth interview participants. Also included in the report will be a task overview stating the goals of the in-depth interviews; a methodology section with citations to the literature that support Westat's approach; and a recruiting section that discusses the methods used to recruit participants and ensure that the participants represent all important and relevant types of stakeholders.

During the course of the in-depth interviews with stakeholders, Westat will prepare a short abstract of each interview at the conclusion of the interview. The abstract will include the important points that emerged during the interview, and more detailed summaries will be developed concurrently with the conduct of the interviews. The detailed summaries will include direct quotations as examples of the language the participants used and in support of the main points in the analysis. Study staff members will listen to the recordings of the interviews when developing the detailed summaries.

The analysis will consist of synthesizing themes and perceptions of stakeholders about their views on the current ICH CAHPS Survey's level of comprehensiveness and appropriate domains and topics in the survey, including nephrologists' communication and caring; quality of dialysis center care and operations; and provision of information to patients. In addition, we will explore their perception of missing content, such as transitions of care, care coordination, and patient safety issues, to supplement the current topics/domains (e.g. for the quality of dialysis care center and operations category, does the facility open on time?). All themes will be supported by direct quotations from the participants. Importantly, we will capture the natural language that the stakeholders use for potential modifications to the survey that we will derive from the analysis. We will

leverage relevant literature to corroborate themes that surface from the interviews, as well as expert critique and input from an ESRD clinical expert.

The major topic areas around which we will organize the analysis are intended to link directly to CMS' research questions and flow from the topics explored through the interview. Analytic topics will include:

- Effects of PPS/QIP
  - ESRD beneficiary access to care
  - Cost of care (to beneficiary and providers)
  - Use of and changes in drugs and biologicals
  - Use of and changes in laboratory tests
  - Quality of care measure and health outcomes
  - Beneficiary choice and education
  - Consumer satisfaction/experience of care
  - Supplies, devices, and durable medical equipment
  - Care delivery and implementation issues
- The domains and topics covered by the ICH-Survey

Because of the nature of qualitative work, CMS expects most of our Stakeholder findings to be descriptive in nature. We will attempt to the greatest degree possible to report findings that are “analytic” and suggest themes across subgroups to the degree that the material allows. With 40 in-depth interviews we expect to be able to collect data from a wide range of sources representing the stakeholders from across the nation. Our recruitment will focus on including stakeholders representing the following:

- Employees at for-profit and not-for-profit dialysis facilities,
- Employees at high and low-volume dialysis facility,
- Stakeholders in urban/suburban/rural settings.

Using the Stakeholder interviews we hope to be able to suggest possible analytic themes related to dialysis facility type and urbanicity.

**Beneficiary Survey.** Analysis of the Beneficiary Survey data will focus on identifying and reporting on the measures of beneficiary satisfaction and beneficiary experience receiving care. Data analysis will rely on summary statistics for relevant comparison populations, specifically beneficiaries who are receiving:

- In-center vs. home or peritoneal dialysis;
- Race/ethnicity;
- Gender;
- Age; and
- Urban/rural.

The analysis of the Beneficiary Survey will rely on univariate and multivariate analysis techniques. Each of the five primary domains will be explored in a section of the report (satisfaction, experience of care, quality of care, education and awareness, and cost). Within each domain section of the report, we will present survey findings using

frequencies and cross tabulations to highlight the experience of ESRD beneficiaries nationally. Additionally, experiences of the ESRD beneficiary sub-populations will be described where those experiences vary from the broader population in significant or meaningful ways. As described in Supporting Statement B, the sample has been specifically designed to permit subgroup analysis. To illustrate the survey findings, tables and figures will be incorporated into the body of the report. Univariate techniques, including proportions, frequencies, and cross-tabulations, will be used to respond to study research questions and detail survey findings related to the following topic areas:

1. **Satisfaction** – satisfaction with ESRD care.
2. **Experience of care** – current experience of care delivery under the PPS/QIP.
  - a. Perceived quality of care/treatment
  - b. Care outcomes (e.g. experience of infections, hospitalizations, readmissions, and/or emergency department visits, etc.)
  - c. Types, length, frequency of care, and treatment
  - d. Impact on obtaining oral drugs and/or medications or accessing pharmacies
3. **Quality of life** – current perceived quality of life and changes under the PPS/QIP.
4. **Education and Awareness**
  - a. Discussion of modality choice, referral for renal transplant for appropriate patients, and home dialysis training.
  - b. Understanding of oral medications covered by Medicare Part D and ESRD-related medications not covered by Medicare Part D
5. **Costs** – current OOP costs under the PPS/QIP.

Special attention will be paid to describing the satisfaction and experience of care for vulnerable populations (e.g. minorities, the elderly, beneficiaries living in rural areas, etc.). As appropriate and where statistically valid differences are noted, the experience and perception of specific segments of the ESRD populations will be contrasted with the overall ESRD population. Analytic findings will be conveyed using tables and charts to best illustrate the key findings.

The Beneficiary Survey will be made up primarily of close-ended responses which lend themselves to quantitative analysis as described above. To supplement the quantitative data, four open-ended questions will be incorporated into the survey. These questions will be asked of 30 respondents and will elicit open-ended commentary on the beneficiary's experience with access to care, quality of care, health outcomes, and cost of care and treatment. The qualitative questions asked of 30 respondents are expected to help provide a more detailed picture of the experiences of beneficiaries. This information will be used in conjunction with quantitative data from beneficiaries as well as qualitative information from stakeholders. Thirty sets of qualitative responses from beneficiaries about their experiences is expected to achieve content saturation – the point at which few new ideas or concepts are being reported.

The open-ended questions (OP1-OP4) have been incorporated at the end of the survey. Based on cognitive testing, we found that placement of the open-ended questions at the end of the survey facilitates the smoothest transition for respondents as they shift from

responding to closed-ended questions and begin providing open ended, discussion-type responses.

Prior to beginning data collection, 60 beneficiary cases will be flagged for administration of the open-ended questions. Selection of these 60 cases will mirror the stratification of the broader beneficiary sample in the hopes of obtaining open-ended responses from all sub-populations of interest. A daily report will be run to track the number and type of cases completed with open-ended questions. After 30 sets of open-ended responses have been collected across the sub-population groups, any remaining flagged cases will be un-flagged and will receive treatment as standard cases without the open-ended questions.

Responses from the four open-ended questions will be used to provide a rich back-story to the quantitative data findings. Quotes and themes from the open-ended responses will be incorporated into the domain sections of the report to help shed light on the underlying factors driving beneficiary satisfaction and ratings related to experience of care.

In addition to the text narrative and the supporting tables and figures, the analytic report will include an appendix containing data frequencies. The appendix of frequencies will be organized by domain to supplement to order and flow of the report. Each substantive question asked in the survey will be presented as a frequency output.

### ***17. Exemption for Display of Expiration Date***

CMS does not seek this exemption.

### ***List of Attachments***

Attachment A – The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA)

Attachment B – ESRD Beneficiary Survey

Attachment C – Stakeholder Interview Guide

Attachment D – Beneficiary Survey Crosswalk

Attachment E – Stakeholder Interview Crosswalk

Attachment F – Beneficiary Survey Pilot Test Report

Attachment XX – Federal Register Notice

Attachment XX – Public Comment and CMS Response