Attachment C

ESRD Stakeholder Interview Protocol

Introduction and Informed Consent Script: ESRD Stakeholder Interviews

The Centers for Medicare and Medicaid Services (CMS) has implemented revisions to its reimbursement system for ESRD beneficiaries. These changes are being rolled out in stages with the ESRD Prospective Payment System (PPS) started in January 2011 and the Quality Incentive Program (QIP) starting in 2013 and 2014. The new system entails bundled reimbursements that are linked to performance measures and beneficiary outcomes.

This interview will focus on how the ESRD Prospective Payment System (PPS)/Quality Incentive Program (QIP) has affected beneficiary care, for example, beneficiary experience of and satisfaction with care; beneficiary quality of life; quality of dialysis; intended versus un-intended consequences for beneficiary care, changes in beneficiary access to care; and beneficiary safety issues.

Now I will read you some important information from the Paperwork Reduction Act:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is XXXX-XXXX. The time required to complete this information collection is estimated to average 55 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Purpose: The information gathered in this interview will help CMS in understanding the effects of the ESRD PPS QIP.

Sponsorship: Westat is a subcontractor to Acumen who is conducting this project on behalf of CMS.

What is involved: We will be asking you to discuss various topics related to the ESRD PPS QIP. Sometimes we will ask you to say more about certain topics or for clarification or examples.

Voluntary: Your participation in this research project is voluntary, and you have the right to stop at any time or to refuse to answer any question. The session will take approximately 60 minutes.

Recording: We would like to record the interview. Sometimes it is helpful to review the recording as we develop our notes. If the recording is reviewed later, it will only be by a few Westat staff. The recordings will be destroyed within 6 weeks of the end of the study.

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Confidentiality: You will never be identified by name. The things you say may be put in a written summary of this discussion, but there will be no way to identify who said what, and your name will not be used anywhere.

Risks: The only cost to you is the time and effort to participate in this interview.
Benefits: There are no direct benefits to you for participating in this study. However, you will be helping with an important research project.

Questions: If you have questions about the project, you may call the Project Director, Stephanie Fry at 301-294-2872. For questions about your rights and welfare as human subjects in this study, you may call the Institutional Review Board at Westat at 301-610-8828.

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1. Provider/Expert Understanding of and Experience with ESRD PPS/QIP

a. Could you tell us about your organization?
   Probe:
   a. Non-profit/for profit; urban/rural, suburban, geographic area, high/low volume organization, etc. What does the organization do?
   b. How does your job bring you into contact with ESRD beneficiaries?

b. Could you tell us in your own words what the ESRD PPS/QIP is all about?
   Probe:
   a. Could you provide some examples?

2. Effects and Implications of the ESRD PPS/QIP Changes

1. Access to Care

a. Can you say something about the factors that determine access to care for beneficiaries?
b. Have any disparities in access to care emerged or has access to care remained the same?
c. How about vulnerable populations: minorities, elderly, rural, noninsured, undocumented, mental health comorbidities, home hemodialysis beneficiaries?
d. Have any beneficiaries not been accepted under the new system who would have been accepted under the previous system?

Can you say more about that?

Access to Care Checklist

e. Any cherry picking among beneficiaries
f. Increase or decrease in voluntary discharges due to lack of adherence?
g. Any facility closure without alternatives for beneficiaries?

Can you say more about that?

2. Cost of Care

h. Can you talk about the cost of care to beneficiaries under the ESRD Bundling PPS, and QIP?
i. Can you talk about the cost of care to providers under the ESRD Bundling PPS, and QIP?

Can you say more about that?

Cost of Care check list

j. Shift of costs through copays/self-pay for therapies, supplies, drugs, etc.
k. Shift of costs to other care setting: hospital ER; dual eligible state Medicaid, other agencies?

3. Drugs and Biologicals

l. Have beneficiaries at your facility/organization experienced any of the following as a consequence of the implementation of ESRD bundling, PPS, or QIP?

- Formulary and protocol changes;
- Use of oral drugs vs. injectable equivalents (iron, vitamin D)
- Changes in the use of erythropoiesis stimulating agents (ESA) – costs, therapeutic options, administration mode, dosing intervals, etc.;
- Use of antibiotic therapies (e.g. daptomycin, vancomycin) for ESRD related infections;
- Treatment of bone and mineral disorders;
- Implications of other drug coverage (e.g. Part D) and confusion of what drugs are included;
- Availability of mail order options for beneficiaries;
- Availability of pharmacy services in small organizations; and
- Any adverse events related to medication incentive changes.

Can you say more about that?

4. Laboratory Tests

m. Since the implementation of ESRD PPS/QIP, have you seen a reduction or increases in the frequency laboratory tests have been prescribed for beneficiaries?
n. Since the implementation of ESRD PPS/QIP, have you seen that the responsibility for ESRD laboratory tests have shifted to other providers (e.g. primary care physicians)?
o. Since the implementation of ESRD PPS/QIP, have ESRD related tests, for example, transplant evaluation, not been included in the serviced provided to beneficiaries?
p. Has the coordination of lab results for beneficiaries been achieved among providers and labs since the implementation of ESRD PPS/QIP?
q. Has the implementation of ESRD PPS/QIP affected the tracking or billing of lab tests?

Can you say more about that?

5. Quality of Care measure and Health Outcomes

p. Can you say something about how ESRD bundling, PPS, and QIP have affected health outcomes for beneficiaries?

- Hospitalization rates;
- Anemia management, blood transfusion rates;
- Dialysis adequacy;
- Levels of phosphorous, calcium; parathyroid hormone;
- Beneficiary safety issues, including under treatment;
- Use of evidence based protocols, plans of care;
- Infection rates, including vascular access; and
- Complication rates of dialysis.

6. Beneficiary Choice and Education

r. How easy or difficult has it been for beneficiaries to understanding the changes?
s. Has the information/education provided to beneficiaries regarding treatment options other than in-center dialysis changed since ESRD PPS started? [IF YES] Can you say more about that?
t. Are there mechanisms in your organization that allow beneficiaries to share in the decision- making for different treatment options?
u. How much choice do beneficiaries have regarding treatments and medicines under the new ESRD PPS/QIP?
v. What type of impact you think that ESRD PPS/QIP has had on patient education (e.g., self management activities, fluid, nutrition, medications, vascular, access, drugs, and so forth)?

[POSITIVE IMPACT TO IMPROVE COMPLIANCE AND QIP SCORE OR NEGATIVE IMPACT BECAUSE OF COMPETING PRIORITIES FOR FACILITY PERSONNEL]

Can you say more about that?

7. Consumer Satisfaction/Experience of Care

v. Has the ESRD PPS/QIP changed any of the following for the beneficiaries:

- perceptions that the facility is adequately staffed;
- increase in cost to the beneficiary:
- inconvenience, e.g. lab tests at multiple places, less beneficiary centered
- increased or decreased quality of life;
- health outcomes (increase in hospitalizations, ER visits, infections)

Can you say more about that?

8. Supplies, Devices and Durable Medical Equipment

w. Since implementation, have you seen that lower cost supplies or less expensive devices have been substituted?

x. Since implementation, have you seen that fewer supplies have been available for beneficiaries?

y. Since implementation, have you seen that fewer beneficiary choices are available to beneficiaries and that supply costs have been shifted to the beneficiaries?

z. Since the implementation, have you seen any difference in beneficiaries' ability to obtain necessary item cost effectively outside a group purchasing organization?

Can you say more about that?

9. Implementation Issues

aa. Has implementation changed the way organization/facilities:

i. Bill or process claims?
ii. Staff the dialysis facilities?

bb. Have the changes been implemented in a uniform way or have different beneficiaries had different experiences of implementation?

10. ICH-CAHPS Survey

How familiar are you with the current ICH-CAHPS survey? [The CAHPS In-Center Hemodialysis Survey asks adults with end-stage renal disease about their experiences with the facility that provides their hemodialysis.]

cc. Do you use the findings from this survey or use the survey questions to improve the experience of care by patients?

dd. The ICH-CAHPS survey covers patient experience measures related to:
a. Nephrologist's Communication and Caring
b. Quality of Dialysis Center Care and Operations
c. Dialysis Center Staff Providing Information to Patients

ee. As a measure of patient experience with in-center hemodialysis, what other topics should be covered?

ff. Thinking about the implementation of ESRD PPS/QIP, what other domains or topics could be included in the ICH-CAHPS survey, for example to measure beneficiary experience of care? Ttransitions of care, care coordination among providers, beneficiary knowledge of local resources, benefits, eligibility for assistance, beneficiary rights, beneficiary safety issues, beneficiary self-management? Or perhaps facility issues, e.g. open on time, waiting room for family, staff professionalism; need for additional surveys relevant to home dialysis or peritoneal; survey translated into other languages.

gg. Other topics?

hh. Do you see the ICH-CAHPS data used in presentations or articles?

ii. How useful would you say the current ICH-CAHPS survey is?

jj. Has your organization seen or used other survey instruments that were useful? Can you say more about that?

11. Closing

kk. Do you have any other comments about the effects on beneficiaries that the ESRD PPS/QIP has had?