Appendix J: Informed Consent

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 0938-XXXX (Expires XX/XX/XXXX). This is a voluntary information collection. The time required to complete this information collection is estimated to average 30 to 60 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. Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Christopher King at Christopher.King@cms.hhs.gov or (410) 786-6972.

[*These participant consent forms will be sent to participants prior to the scheduled interview and read aloud to them at the start of each interview. The interviewer will obtain recorded, verbal consent before continuing the interview beyond this point.*]

J.1. Patient Consent Form

Project Overview

The Centers for Medicare & Medicaid Services (CMS), the agency that runs Medicare, put in place the ESRD Quality Incentive Program (QIP) in 2012 to improve the quality of ESRD treatment. The broad goals of the ESRD QIP are to encourage patient and family-centered care and improve patient health. We are talking to dialysis patients about their experiences receiving ESRD treatment, learn about what is going well and what should be improved.

Informed Consent

Insight will conduct interviews with patients and dialysis providers to gain an in-depth perspective of the patient experience of care in ESRD. Information gathered during these interviews will provide a foundation for future directions of ESRD care related to operational challenges, addressing patient needs, and identifying best practices in ESRD treatment, patient engagement, and coordination of care.

- Your participation is voluntary. You don't have to answer any questions you don't want to answer.
- After the call, you will receive $50 as a thank-you for your time.
- What you say on this call will be considered private. Nothing you say will ever be linked to your name, and nothing you say will affect your Medicaid or Medicare benefits if you currently receive them.
- We will summarize what we talk about today and put it together with information we will gather from other calls just like this.

- We will use the information you share with us for research purposes only.
- All information identifying you is stored securely and will be destroyed at the end of the study.

For additional information about the study, you can contact Carla Bozzolo at Insight Policy Research at (571) 758-5036 or cbozzolo@insightpolicyresearch.com.

J.2. Non-Patient Consent Form

Project Overview

The Centers for Medicare & Medicaid Services (CMS) implemented the ESRD Quality Incentive Program (QIP) in 2012 to improve the quality and efficiency of ESRD treatment. The broad goals of the ESRD QIP are to encourage patient- and family-centered care, improve patient health and outcomes, and reduce costs. The QIP is intended to improve the efficiency and quality of ESRD services and was developed to mitigate potential change sin practices by dialysis facilities resulting from the institution of the ESRD Prospective Payment System (PPS).

Informed Consent

Insight will conduct interviews with patients and dialysis providers to gain an in-depth perspective of the patient experience of care in ESRD. Information gathered during these interviews will provide a foundation for future directions of ESRD care related to operational challenges, addressing patient needs, and identifying best practices in ESRD treatment, patient engagement and access, and coordination of care.

- We will use the information you share with us for research purposes only.
- All your responses will be kept confidential. No one except the Insight research team will have access to the information you provide.
- We will use your answers to produce summaries from our collective set of interviews.
- We will not report information in any way that identifies you or the organization you are affiliated with to anyone outside the research team, except with your permission or as required by law. CMS will not see your name or your organization's name connected to your individual responses.
- All information identifying you is stored securely and will be destroyed at the end of the study.
- We'd also like to emphasize that your participation is completely voluntary:
  - Your participation or nonparticipation will not be reported to anyone.
  - You can stop the interview at any time for any reason, and you can decline to discuss any topic we raise.

For additional information about the study, you can contact Carla Bozzolo at Insight Policy Research at (571) 758-5036 or cbozzolo@insightpolicyresearch.com.