

Questions and Responses Regarding Federal Oversight of Dialysis Facilities and Public Access to Quality of Care and Safety Information

Question:

1. Dr. Barry Straube, Director & Chief Medical Officer of CMS, said that “although Fields’ investigation points to important issues, it overstates the degree of problems with dialysis centers in the real world.” Please describe in detail how CMS measures the degree of problems at dialysis centers and provide copies of reports of any audits, evaluations, investigations or any other reviews conducted by CMS or a CMS contractor to determine the extent of problems at dialysis clinics. This request covers the period of January 2008 through the date of this letter.

a. Please describe the major types of problems reported or detected by CMS.

Response:

Federal Oversight of Dialysis Facilities via Survey and Certification

Federal oversight of dialysis facilities is accomplished primarily through contracts with State Survey Agencies (SAs), as provided under section 1864 of the Social Security Act. The SAs are generally responsible for onsite surveys of all Medicare providers and suppliers that have Medicare Conditions of Participation (CoPs) or Conditions for Coverage (CfCs) (e.g., dialysis facilities, nursing homes, home health agencies, hospitals, hospices, etc).¹ The onsite surveys evaluate whether or not a facility is meeting the minimum quality requirements outlined in statute and/or regulation.

The SAs accomplish the surveys (including complaint investigations) of all Medicare providers and suppliers with a fixed monetary allocation that is provided by CMS, and use this funding to accomplish the priorities and targets CMS outlines for each provider and supplier type each year. Those provider types that have a statutorily-mandated survey interval have the highest priority (e.g., on average every year for nursing homes, every 36 months for home health agencies).

CMS funds and directs SAs to accomplish a variety of surveys:

Standard Surveys: Standard surveys comprehensively assess all dialysis CfCs. CMS policy is to conduct standard surveys on average once every 3 years (33% per year). While CMS has substantially increased the number of standard surveys, growth in the number of ESRD facilities has meant that the average frequency has remained relatively constant, at about a 30% per year rather than 33% (see the response to question # 5 for more detail).

Targeted Surveys: Beginning in 2006, CMS directed States to conduct a standard survey of one half of the lowest-performing quintile (one half of 20%) of ESRD facilities, even if the facilities were not otherwise due for a cyclical survey. This means that those dialysis facilities with problems tend to be more frequently surveyed. The Dialysis

¹ This does not include providers that choose to receive Medicare approval through an approved accrediting organization where accreditation by that organization would also convey deemed status. By statute, dialysis facilities may not be deemed for Medicare approval.

Facility Reports have been used each year since 2006 to identify the lowest-performing 20%.

Complaint Investigations: SAs investigate allegations of serious problems. In FY 2010 there were approximately 736 onsite complaint investigations, a 74.8% increase from the 421 conducted in FY 2002. This change is a result of both the increase in the number of facilities and the increased efforts in complaint investigations by CMS and States.

In addition, CMS measures State performance in reducing the time interval between surveys of a specific ESRD facility. In FY 2011 the time interval measure stated that no more than 3.5 years would elapse in between surveys of any one specific ESRD facility. States have had various levels of success in meeting these targets. In FY 2009, a total of 19 States were unable to meet the survey interval of 3.5 years for 100% of their dialysis facilities. On the other hand, the preponderance of States and territories (34 of 53 jurisdictions) did meet the 3.5 year maximum time interval for 100% of their facilities, and, in some States, the survey interval is much shorter than every 3.5 years.

Several factors have contributed to the inability of some States to meet all of the priorities outlined by CMS. In FY 2005-2008, the primary barrier was a severe limitation on the Medicare Survey & Certification budget. In FY 2009-2010, the effects of the economic recession and State budget deficits played a much larger role, as there were State hiring freezes, travel restrictions, personnel furloughs, and quality issues in other provider types that needed immediate attention. CMS has followed up with those States that have not met the performance target by requiring plans of correction for the State Survey Agency, and if necessary by withholding Federal funding.

Patterns in Deficiencies and Enforcement Activities

Deficiencies identified in a survey are categorized as Standard-level, Condition-level, or Immediate Jeopardy. A condition-level deficiency or immediate jeopardy determination are grounds for termination from the Medicare program. When these deficiencies are found in existing providers and suppliers, CMS allows the opportunity for a facility to come into compliance and improve care. If the facility does not come into compliance, Medicare termination occurs generally within 90 days for a condition-level deficiency and 23 days for a determination of immediate jeopardy.

CMS' goal is for facilities to come into compliance and to improve care. These improvements are then verified by the State agency through another onsite visit. Most deficiencies are corrected through this process. In FY 2009 and FY 2010, 15% of surveys (498) had Condition-level deficiencies. Of these, all but seven facilities came into compliance. The seven facilities were terminated from Medicare (involuntarily, or voluntarily in lieu of involuntary termination).

The table below describes the most common deficiencies found during the onsite survey process. Of the 16 Medicare Conditions for Coverage, two Conditions are cited most frequently: infection control and physical environment. As described in more detail later, CMS is partnering with other components of the Department of Health and Human Services (particularly the Agency for Healthcare Research and Quality (AHRQ) and the Center for Disease Control and Prevention (CDC)) to improve knowledge and oversight of infection control practices in dialysis facilities.

Onsite surveyors also review the dialysis facility's own performance monitoring as it relates to infection control. Medicare Conditions for Coverage require that dialysis facilities track, monitor, and take action to improve their own performance. These activities must include the analysis and documentation of the incidence of infection and the development of recommendations to minimize infection transmission, promote immunization; and reduce further incidences.

Table 1: Most Common Deficiencies Cited FY2009 and FY2010

Type of Deficiency (CMS Identifier)	FY2009: % of Surveys (n=1540)	FY2010: % of Surveys (n=1745)
Infection control		
Staff are wearing gloves and performing appropriate hand hygiene (113)	23.6%	27.2%
Processes are in place for cleaning and disinfecting contaminated surfaces, medical devices, and equipment, and these procedures are followed. (122)	20.3%	21.7%
Staff members wear protective clothing during (e.g., gowns, face shields) when soiling via blood might occur. Staff members do not eat, drink, or smoke in the dialysis treatment area or laboratory. (115)	11.1%	10.5%
Clean areas are designated for the preparation, handling and storage of medications and unused supplies and equipment; they are separate from contaminated areas. Do not use common medication carts to deliver medications to patients or carry multiple dose vials from station to station. (117)	10.4%	10.9%
Items taken into the dialysis station are disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. (116)	10.4%	11.8%
Physical Environment		
The dialysis facility has an implemented program to ensure that all equipment is maintained and operated in accordance with the manufacturer's recommendations. (403)	18.3%	22.1%
The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. (401)	12.0%	12.6%
The building must be constructed and maintained to ensure the safety of the patients, the staff and the public in accordance with State and local building codes. (402)	11.0%	11.7%
Medical Director Responsibility		
All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility (715)	15.7%	17.3%
Patient's Plan of Care		
The interdisciplinary team develops and implements a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, and includes measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes are consistent with current evidence-based professionally-accepted clinical practice standards. (541)	14.0%	15.3%
The interdisciplinary team must provide the necessary care and services to manage the patient's volume status which means that the amount and rate of fluid removal from the patient through the dialysis process is appropriate. Each patient should be weighed before and	9.0%	11.8%

after each treatment. (543)		
Medical Records – The dialysis facility must maintain complete, accurate, and accessible records on all patients (726)	9.7%	12.9%

Additional CMS Quality Improvement Activities through the ESRD Networks

CMS contracts with ESRD Network Organizations to monitor the quality of ESRD care, to facilitate improvements in care, and to ensure dialysis facility corrective action when the care is below the standard. The ESRD Networks use multiple data sources to monitor dialysis care delivery and to identify problems with the quality of dialysis care. These sources include Dialysis Facility Reports, Fistula First data, Electronic Laboratory Data, United States Renal System Data, CMS data repositories (Standard Information Management System (SIMS) and Renal Management Information System (REMIS)), Scientific Registry of Transplant Recipients data, and ESRD Network Complaint and Grievance data.

The ESRD Networks are charged with resolving certain complaints and grievances. The ESRD Networks received 1,919 complaints and grievances in CY 2008. Networks make onsite visits when needed to resolve complaints and grievances and to provide technical assistance. An example of a major problem detected by CMS was a Network 3 facility with significant infection control issues. Network 3 performed onsite visits to this particular facility and followed up with this facility over the course of a year in 2008. Improvement goals were set related to water treatment cultures, water system preventative maintenance, use of documentation logs, medication administration, and anemia management. After Network intervention and technical assistance this facility met 100% of the established goals.

Recognizing that the ESRD Networks can be further leveraged to protect patient safety and improve dialysis care, CMS is currently redesigning the renal network program to achieve the following aims:

- Increase the renal network interventions with poor performing facilities;
- Increase the accountability of the renal networks’ performance in their contractual duties by frequently measuring the network performance and linking funding to achieved goals; and
- Increase the “voice of the patient” by creating a system that is easily accessible by patients and encourages them to report safety and quality concerns.

b. ProPublica reported unsanitary treatment settings at some dialysis facilities. Does CMS collect data on the infection rates at individual dialysis facilities? If so, is that information made available to the public? If that information is not public, please explain why not.

Response: The Dialysis Facility Reports contain information as to whether or not individuals at the facility have infections that are dialysis access-related or not. Specifically, the following measures are included in the Dialysis Facility Reports:

- Percentage of deaths due to infections
- New patients- percentage of deaths due to infections
- Percentage of patients hospitalized for septicemia
- Percentage of patients with infection related to dialysis access

- Percentage of patients with infection not related to dialysis access
- Percentage of patients vaccinated for influenza

This information is used by the State Survey Agencies and the ESRD Networks to monitor the quality of care in dialysis facilities.

As we describe in more detail below, the Dialysis Facility Reports have not been posted publicly on the CMS website. However, CMS has been reviewing this policy and intends to make additional information available in the future.

2. *In July 2010, CMS issued a proposed rule establishing a quality incentive program (QIP) for facilities that provide dialysis services to Medicare patients with end-stage renal disease. Under the QIP, CMS would evaluate a facility's performance year to year on specific performance measures, and those facilities that do not meet those measures may have their payments for dialysis services reduced by up to 2 % starting January 1, 2012. CMS stated that in order for the payment reductions to occur on January 1, 2012, the performance period of review would need to occur before 2012 and calendar year 2010 claims would be the most recent full set of data upon which CMS would assess performance.*

a. *What is the full status of the proposed rule?*

Response: The ESRD *Quality Incentive Program* proposed rule was published in the Federal Register on August 12, 2010 (75 FR 49215). The corresponding final rule responding to public comments was put on display on December 29, 2010 and published on January 5, 2011 (76 FR 628).

b. *Please explain whether and how conditions such as unsanitary treatment settings and infection rates will be considered in the facility performance reviews.*

Response: As provided in the final rule, the initial year of the QIP will include three measures that pertain to anemia management and dialysis adequacy (i.e., Hemoglobin <10g/dL, Hemoglobin >12g/dL, and URR ≥65). However, the QIP is designed to evolve in future years and include a greater number of measures. Among potential future measures being considered are measures which would be reflective of unsanitary treatment settings and facility infection rates. New measures will be detailed in future rulemaking years.

c. *Please keep me apprised of any new developments in the ESRD QIP and the status of the performance reviews.*

Response: We will keep you apprised of any new developments in the ESRD *Quality Incentive Program* and performance information as requested.

3. *ProPublica states that “the government has withheld critical data about clinics’ performance from patients, the very people who need it most.” The CMS Dialysis Facility Compare website provides information on three quality measures: (1) Anemia – how many patients at a facility whose anemia (low red blood cell count) wasn’t controlled (hemoglobin less than 10.0 g/dL or hemoglobin greater than 12.0 g/dL); (2) Hemodialysis Adequacy – how many patients at a facility had enough waste removed from their blood during dialysis treatments (Urea Reduction Ratio (URR) of 65 or greater); and (3) Patient Survival – if the patients treated at a facility generally live longer than, as long, or not as long as expected. However, the “patient survival” measure for each facility, for example, only indicates whether the survival rates are “better than expected,” “as expected,” or “worse than expected.” There are no other details on a facility’s performance related to this measure.*

a. *What other data, if any, does CMS collect about the performance of dialysis facilities across the country?*

Response: As described earlier, the performance of dialysis facilities is collected via Dialysis Facility Reports, Fistula First Reports, Electronic Laboratory data, complaint data systems, and information in data repositories (SIMS, REBUS).

b. *Will CMS be providing greater details to the public on the data collected about the performance of dialysis facilities? If not, why not?*

Response: In November 2010, CMS released Dialysis Facility Reports (DFRs) for all ESRD facilities to ProPublica as per a Freedom of Information Act (FOIA) request. Up until that time CMS had not shared these reports publicly. The DFRs are prepared annually for each Medicare certified dialysis facility. The original intent for the reports was to provide individual ESRD providers, ESRD Networks, and State Survey Agencies with available data that may be useful for the development of quality improvement plans. Up until the release of the reports to ProPublica, CMS had not considered releasing the information more widely. However, after reviewing the FOIA request and reexamining the DFRs, CMS reconsidered the public release of the reports. At this time, the reports are available upon request and we are working to allow for more direct public access to the reports.

The National Quality Forum is also evaluating an additional 17 measures for potential endorsement to further evaluate the quality of care delivered to ESRD beneficiaries. Categories of the candidate measures include the following: anemia and iron management; mineral metabolism; hemodialysis vascular access related infections; pediatric hemodialysis adequacy; pediatric anemia management; fluid weight management; and standardized hospitalization rates. Once data are available for these new measures, CMS will publicly report the information on the agency’s *Dialysis Facility Compare* (DFC) website and incorporate the information into the Dialysis Facility Reports and the *Quality Incentive Program* for dialysis facilities.

c. *Please describe in detail any steps CMS is taking to ensure that patients have access to meaningful information about the quality of care provided at dialysis facilities so they can make informed decisions about their care.*

Response: CMS is actively pursuing a means for the general public to more easily access and download the DFRs via the Internet for all of the 5,000+ Medicare certified dialysis facilities in the country. Currently, the reports are available to the public by individual request. CMS will also be publishing performance scores for dialysis facilities later this fall as required by the **Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) ESRD Quality Incentive Program**; and this information will be published on CMS' DFC website. CMS anticipates adding hospitalization rate information on DFC in the fall, dependent upon the endorsement of the measure that was recently submitted to the National Quality Forum.

4. *According to the ProPublica article, "CMS can demand that facilities submit correction plans, but it cannot fine violators as it can nursing homes." What is CMS' position on Congress providing the Agency with the authority to fine clinics that fail to meet quality standards? Please specify what other statutory authorities the Agency needs in order to conduct appropriate oversight of dialysis facilities.*

Response: Currently, CMS has the authority to terminate a dialysis facility from the Medicare program when such a facility fails to meet quality standards. Congress has provided for alternative enforcement authorities in the context of nursing homes, such as civil monetary penalties (CMP), directed plans of correction, temporary manager, and denial of payment for new admissions and such options could also be a means of better addressing the nature and extent of problems in dialysis facilities. Additionally, relating to nursing homes, Congress recently granted CMS the authority to reinvest CMP funds for the purpose of quality improvement projects, provided the projects are 100% devoted to the protection and benefit of beneficiaries. We believe that the opportunity to re-invest CMP funds offers great potential to address problems of safety and poor quality.

5. *ProPublica reported that facilities are supposed to be inspected once every three years but as of October 2010, "almost one in 10 hadn't had a top-to-bottom check in at least five years" and "about 250 facilities hadn't had a full recertification inspection in seven years or more," according to CMS data.*

Response: In recent years CMS significantly increased the scale and strength of its oversight of dialysis facilities in the United States. Such increased oversight has taken many forms:

- **25.7% Increase in Surveys:** The number of full, onsite surveys increased from 1377 in FY2002 to 1732 in FY 2010. The number of investigated complaints increased by 74.8%, (from 421 to 736).
- **New, Better Regulations:** In 2009 we implemented an improved and more comprehensive set of standards for all dialysis facilities. The new regulation expanded the number of conditions for coverage from 11 to 16, added a requirement that all facilities have an internal quality assurance and performance improvement program,

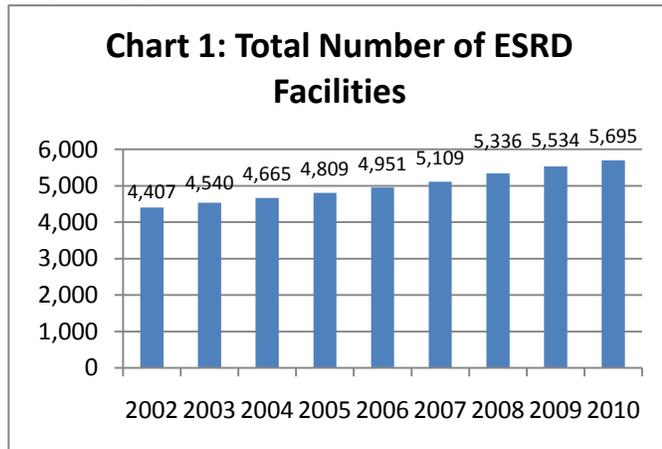
and strengthened the public's expectations for infection control, and dialysate and water quality.

- **54.7% Increase in Time Spent Onsite:** Primarily as a result of the new regulation, more thorough reviews are being conducted. As such, the amount of time that surveyors spend onsite during the course of a standard survey increased by 54.7% in 2010 from 2002 levels (from an average of 46.4 person-hours in FY2002 to 71.8 in FY2010).
- **Greater Financial Investment:** To accomplish the above, we increased the amount of survey & certification funding devoted to surveys of dialysis facilities. Such increased oversight was particularly made possible through Congress' full support of the President's budget request for Medicare survey & certification in FY2009 and FY2010.
- **Targeted Surveys:** In 2006, we implemented a program of additional surveys oriented to those facilities that have had the poorest outcomes (i.e., those facilities in the lowest quintile of performance, as measured by the Dialysis Facility Reports).

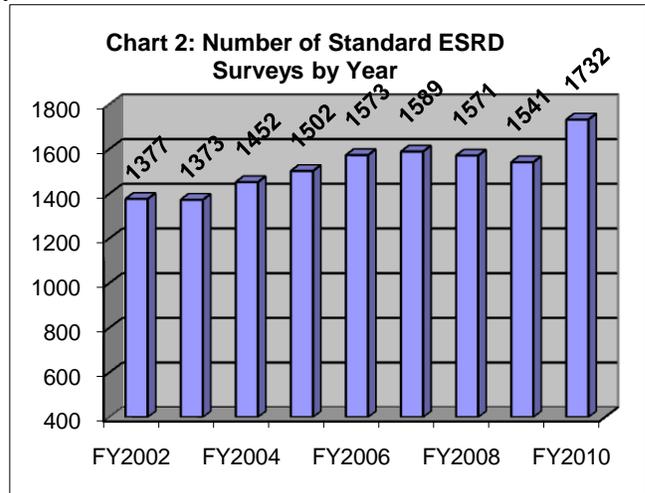
While the number of surveys increased, the average frequency of surveys has not changed. This is because the number of dialysis facilities has increased substantially. CMS policy is to survey dialysis facilities, on average, once every three years (or about 33% of all facilities each year). The actual frequency of completed, full surveys has consistently been closer to 30% due to the growth in the number of dialysis facilities. It is important to note that an average frequency of once every three years means that some individual facilities may go much longer in time between surveys.

In the remarks that follow, we provide the year by year information so that the entire trendline is fully apparent.

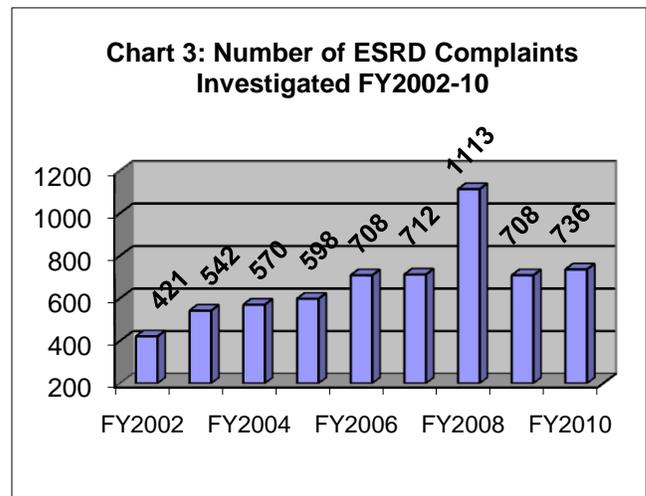
1) **Increase in the number of dialysis facilities:** Chart 1 shows the 29.2% increase in the number of dialysis facilities participating in Medicare between 2002 and 2010, from 4,407 facilities to 5,695, a 29.2% increase. This represents a significant increase in the survey workload for which State Survey Agencies are responsible to survey.



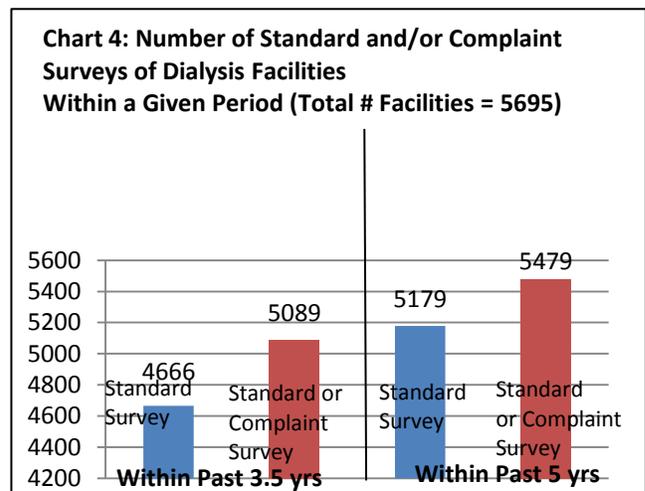
- 2) **Increase in the number of CMS' onsite surveys:** Between FY2002 and FY2010, the number of standard ESRD surveys rose from 1377 per year to 1732 per year, 25.8%. (Chart 2). As a result, the overall percentage of facilities surveyed each year has remained relatively constant.



Similarly the number of completed, onsite complaint investigations has increased from 421 in FY 2002 to 736 in FY 2010, a 74.8% increase (Chart 3).



- 3) **Combined Effect on Survey Frequency.** When both standard surveys and complaint investigations are taken into account, we find that only 4% of facilities had not had an onsite survey in the past 5 years (Chart 4).



- 4) **Improvements to the ESRD Conditions for Coverage and survey process have increased the average time spent surveying each dialysis facility by 41.8% in the last 2 years.**

The new ESRD Conditions for Coverage (CfC) replaced the first Medicare regulations for ESRD facilities, which were developed over 30 years earlier and were implemented in 1976. As would be expected, the 3 decades between regulation sets brought forth profound advances in both the technology associated with the delivery of dialysis treatments and in the care and management of the many medical and psychosocial difficulties which routinely afflict dialysis patients. Most of these advances were facilitated by recommendations developed and published by various ESRD professional workgroups, including the Association for the Advancement of Medical Instrumentation (AAMI) in the technical areas, the Centers for Disease Control and Prevention (CDC) in infection control, and the National Quality Forum (NQF) and the Kidney Disease Outcomes Quality Initiative (KDOQI) in the patient care and management areas. The new Conditions for Coverage published in 2008 and implemented in 2009 commendably acknowledged the effectiveness of the workgroup recommendations in optimizing the quality of care and outcomes for dialysis patients. The new regulations adopted by reference several published documents of the CDC and AAMI, and incorporated the expectation that dialysis facilities aim at achieving current community-identified clinical practice standards in 14 clearly identified "care areas".

The 11 CfCs in the 1976 regulations were generic, focused primarily on administrative processes. They also lacked specific requirements for the care and management of dialysis patients, and combined most of the many technical, physical environment, and infection control requirements under one CfC.

In contrast to the 1976 regulations, the 16 CfCs in CMS' new regulations focus primarily on quality outcomes. These include three CfCs dedicated to the care and management of dialysis patients and one CfC dedicated to the expectations of the facility internal program oversight through Quality Assessment and Performance Improvement (QAPI), all aimed at the achievement of clinical practice standards for individual patients and facility aggregate.

The new regulation also separates the previously combined technical areas into 4 individual CfCs for (a) water/dialysate, (b) infection control, (c) physical environment, and (d) dialyzer reprocessing. Those technical requirements are further divided into separate elements (e.g., from 2 infection control tags to 26, from four water treatment tags to 92). Whereas CMS' surveyor interpretive guidance for the 1976 CfCs was brief and, at times, vague, the interpretive guidance provided for each regulatory tag in the 2008 CfCs includes significant additional information related to the requirements and clarification of the intent of the regulation.

We believe that the vast regulatory improvement from the generic nature of the 1976 CfCs to the quality-based specificity of CMS' 2008 Conditions will positively impact the quality of the survey process as well as the quality of dialysis care delivery for several reasons:

Clarity of requirements: The 2008 CfCs effectively clarify what participating ESRD facilities must do to attain and maintain Medicare Certification. This creates transparency, putting surveyors and providers "on the same page", and limiting confusion and imposition of subjective requirements. Providers know what is expected, and surveyors know what to look for.

Comprehensive information: The inclusion of comprehensive, pertinent, current information in the regulatory requirements and the interpretive guidance of the 2008 CfCs provide surveyors and providers a valuable and educational tool regarding the care and services necessary to deliver safe, effective care to dialysis patients.

Division and separation of dissimilar requirements: Separating the technical, physical environment, and infection control requirements into individual CfCs, and dividing the requirements within those CfCs into separate elements brings more attention to the details of these vital safety areas of dialysis care. Previously deficient practices were not being identified as deficient in the various dissimilar areas when using the combined 1976 CfCs. The 2008 CfC now enable Condition level citations to be more reliably identified as serious systems problems.

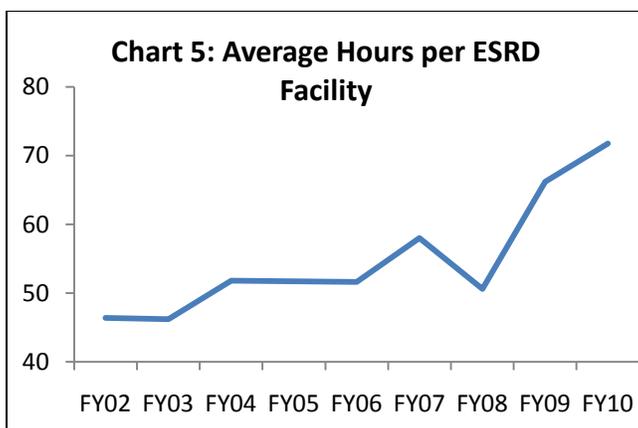
Emphasis on Evidence-Based Processes and Outcomes of Quality Care: The 2008 CfCs emphasis on elements that are related to the safety and quality of dialysis care, rather than administrative processes, focuses providers and surveyors on the aspects of dialysis care and management most relevant for improving the quality of care and optimizing the health and quality of life of the dialysis patients.

These improvements to the CfC’s resulted in revisions to the survey process which lengthened the time spent reviewing each facility (from an average of 50.6 hours per facility in FY 2008 to 66.2 hours in FY 2009 and 71.8 hours in FY2010, an increase of 41.9% (Table 2, Chart 5)).

Table 2:

Average Survey and Certification Hours Per ESRD Facility								
FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09	FY10
46.4	46.2	51.8	51.7	51.6	58.0	50.6	66.2	71.8

**Includes Survey and Certification Health & Life Safety Code Hours from Standard Survey and Revisits*



a. What data is collected and reviewed during the certification process for dialysis facilities?

Response: Prior to going onsite, surveyors review a facility’s data and history. They review the Dialysis Facility Report to familiarize themselves with the facility’s data and to identify any areas where there are outcomes that are worse than expected. They also review the facility’s certification history, including information about complaints, and past certifications. Additionally, they contact the ESRD Network to determine if there are any particular areas of concern.

The ESRD survey primarily focuses on observations of care, including infection control practices, water treatment procedures, reprocessing techniques, and monitoring the staff’s procedures for providing patient care. In addition to observations of care and procedures, surveyors conduct interviews of selected patients and staff and they review records.

The review of medical records includes a review of patient assessments and plans of patient care; laboratory values; physician orders; interdisciplinary team progress notes; dialysis treatment records; and patient education materials. The review of the facility’s Quality Assessment and Performance Improvement (QAPI) program includes a review of incident logs; trending data; and minutes/QAPI records which demonstrate analysis, interventions, as well as the impact and ongoing monitoring of the QAPI program.

Additional detail about the ESRD survey process can be found at: http://www.cms.gov/GuidanceForLawsAndRegulations/05_Dialysis.asp, including the four page *Outline of the Basic ESRD Survey Process*, which may be especially useful.

b. What data is collected and reviewed during the recertification process?

Response: The information specified above also applies to the recertification process.

c. What steps is CMS taking to improve its oversight of dialysis facilities? Please be specific.

Response: CMS is reviewing all areas of our dialysis facility oversight to outline suggestions and recommendations for improvement. We expect that this review will culminate in an ESRD Action Plan that would be made publicly available and would more clearly outline ESRD oversight activities already underway and provide specific improvements that we will be making.

In addition to the actions already outlined in the previous responses, further efforts include the following:

- (i) **Infection Control Issues in Dialysis Facilities:** CMS is working jointly with AHRQ and CDC to conduct a new ESRD Infection Control Initiative to reduce healthcare associated infections in ESRD facilities. AHRQ has contracted with the Health Research & Educational Trust to assist in implementing this project. The goal of the project is to improve adherence to infection control practices in ESRD facilities and to reduce preventable infections. The result will be two-fold:
 - First, the implementation of an infection control worksheet that can be used by ESRD facilities to assess their performance and by surveyors to

identify adherence to required infection control practice. The infection control worksheet would be accompanied by additional surveyor training in this area; and

- Second, the creation of technical assistance tools for dialysis facilities.

- (ii) **Emphasizing ESRD Facility’s Quality Assessment and Performance Improvement Program:** As described above regarding the new ESRD CfCs, the regulation requires facilities to have an ongoing, data-driven system to measure and track specific quality indicators. The facility must immediately correct any identified problems that threaten the health and safety of patients, and use the QAPI system to take actions that reduce future incidents. We will be providing additional guidance to surveyors on evaluating this area of performance. This guidance is expected to be released in 2011.
- (iii) **Ensuring Surveyors are Alert to the Impact of Bundling:** CMS will provide guidance to surveyors to pay special attention to any unintended negative consequences to patient choice and care as a potential effect of the new bundled payment system.
- (iv) **Engaging National Contractor to Assist States in Overdue Surveys:** CMS will explore the use of a national contractor to assist States in conducting overdue surveys of dialysis facilities, and provide additional quality assurance and evaluation of the survey process to establish the most efficient and effective review process.
- (v) **Continue Building Survey & Certification Infrastructure:** The improvements described above build on a strong infrastructure for the onsite surveyors that provide training, assistance, and support as they assess the quality of services for dialysis patients. Key areas of this infrastructure are outlined below:
- **Training:** CMS has an active surveyor training and support program specific to ESRD and requires all surveyors who conduct ESRD surveys to have completed this training. The training provides information and many tools to allow surveyors to competently survey this complex provider type.
 - **Ongoing Support:** The ongoing support for ESRD surveyors includes specialized support from experienced CMS staff at the Central and Regional Offices; online availability of technical support and rapid responses to questions; and an annual update training opportunity to keep surveyors current with clinical and technical advances in the field.
 - **STAR Technology:** CMS also created a software program for ESRD surveyors to use on a PC Tablet. This program, Surveyor Technical Assistant for Renal (STAR), is currently being updated. The STAR program adds consistency to the survey process.
- (vi) **Partnerships:** CMS actively educates and communicates with the renal community about the expectations of the ESRD survey process. CMS has established partnerships with many members of Department of Health and Human Services and the renal community to assist in establishing good guidance for the survey process, in training surveyors, and in improving oversight. These partners include Agency for Healthcare Research and Quality, Centers for Disease

Control, Food and Drug Administration, National Institutes of Health, patient organizations, professional organizations, voluntary organizations (e.g., National Kidney Foundation), and providers and manufacturers (e.g. Minntech).

(vii) **Redesign of Renal Network Program:** As described previously, CMS is currently redesigning the renal network program to achieve the following aims:

- Increase the renal network interventions with poor performing facilities;
- Increase the accountability of the renal networks performance in their contractual duties by frequently measuring the network performance and linking funding to achieved goals; and
- Increase the “voice of the patient” by creating a system that is easily accessible by patients and encourages them to report safety and quality concerns.

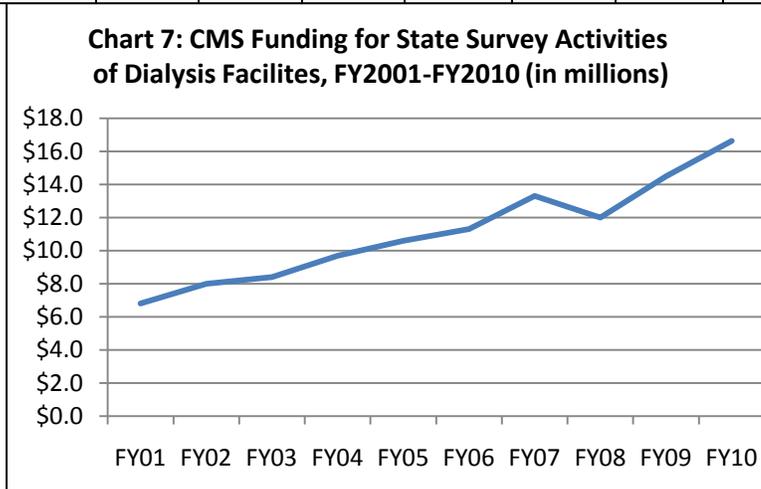
(viii) **Increased Availability of Dialysis Information for the Public:** As described in response to question 3b, CMS is in the process of developing additional quality measures for dialysis.

6. Please specify how much of appropriated dollars from Congress is spent each year on oversight of the quality of care in dialysis facilities, including facility inspections. Please also provide a breakdown of that spending.

Survey & Certification: In FY 2010, approximately \$16.6 million was spent for the onsite survey & certification process for dialysis facilities. The amount spent increased significantly in FY 2009-2010 over prior years, and enabled both more surveys and more time onsite during each survey (Table 3, Chart 7).

Table 3:

Funding for Survey and Certification Activities (in millions)									
FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09	FY10
\$6.8	\$8.0	\$8.4	\$9.7	\$10.6	\$11.3	\$13.3	\$12.0	\$14.5	\$16.6



Data and Measure Development: CMS estimates approximately \$1.65 million annually for 1) the development of quality measures for oversight and performance review; 2) the annual update to the Dialysis Facility Compare (which include the Quality Measures); and 3) the development of the annual Dialysis Facility Reports.

The *ESRD Network program* is funded under Section 1881 of the Social Security Act via a reduction in payment for each dialysis treatment by 50 cents. Funds are available on an annual basis. FY 2011 funding amount is \$28.9 million.