

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

December 21, 2010

Via Electronic Transmission

Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Berwick:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. As Ranking Member of the Committee, I have a responsibility to the more than 100 million Americans who receive health care coverage under these programs to oversee their proper administration and ensure that taxpayer dollars are appropriately spent on safe and effective medical treatments.

I was troubled by a recent investigative report by ProPublica regarding the state of some treatment facilities for kidney patients. Specifically, ProPublica reported that after reviewing thousands of inspection reports and interviewing hundreds of patients, advocates, doctors, policy makers, researchers, and industry experts, it found that “at clinics coast to coast, patients commonly receive treatment in settings that are unsanitary and prone to perilous lapses in care.”¹ According to ProPublica, inspection records for more than 1,500 clinics from 2002 to 2009 show that hundreds of clinics were cited for infection-control breaches, exposing patients to infectious agents such as HIV. Specifically, ProPublica reported that surveyors found “blood encrusted in the folds of patients’ treatment chairs or spattered on walls, floors or ceiling tiles” at some facilities.

ProPublica also stated that “the government has withheld critical data about clinics’ performance from patients,” such as mortality rates and the rate of hospitalization for infections. Furthermore, it notes that even if inspectors find noncompliant dialysis clinics, the Centers for Medicare and Medicaid Services’ (CMS/Agency) ability to hold the clinics accountable is limited because the Agency does not have the authority to impose fines on those who violate the quality standards.

Accordingly, I would appreciate your response to my questions regarding this matter. When responding, please repeat the question and follow with the appropriate response and documentation.

¹ Robin Fields, “In Dialysis, Life-Saving Care at Great Risk and Cost,” *ProPublica*, November 9, 2010, available at <http://www.propublica.org/article/in-dialysis-life-saving-care-at-great-risk-and-cost>.

1. Dr. Barry Straube, Director & Chief Medical Officer for 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 to or detected by CMS.
 - 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.
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 percent 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 status of the proposed rule?
 - b. Please explain whether and how conditions such as unsanitary treatment settings and infection rates will be considered in the facility performance reviews.
 - c. Please keep me apprised of any new developments in the ESRD QIP and the status of the performance reviews.
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?

- b. Will CMS be providing greater details to the public on the data collected about the performance of dialysis facilities? If not, why not?
 - 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.
- 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.
- 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.
 - a. What data is collected and reviewed during the certification process for dialysis facilities?
 - b. What data is collected and reviewed during the recertification process?
 - c. What steps is CMS taking to improve its oversight of dialysis facilities? Please be specific.
- 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.

Thank you for your attention to this important matter. I request that you provide a response by no later than January 4, 2011. If you have any questions or concerns, please feel free to contact Kathryn Ott at (202) 224-3744. All formal correspondence should be sent electronically in PDF format to Kathryn_Ott@grassley.senate.gov or via facsimile to (202) 224-6020.

Sincerely,



Charles E. Grassley
Ranking Member