



FEB 17 2011

Administrator

Washington, DC 20201

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510-6200

Dear Senator Grassley:

Thank you for your letter expressing concern regarding the quality and Federal oversight of dialysis facilities, as described in reports published by ProPublica and the Atlantic Monthly. You requested additional information about the level of Federal oversight, the Centers for Medicare & Medicaid Services' (CMS) activities to make End Stage Renal Disease (ESRD) data available to the public, and CMS' activities to improve oversight of dialysis facilities.

I wish to convey my deep appreciation for the concern that you have consistently expressed over the years for the quality of care received by dialysis patients, nursing home residents, and other Medicare beneficiaries. We welcome your questions and suggestions, and look forward to working with you to improve the health and health care of all Americans.

In the enclosure to this letter, we respond to your questions in detail. CMS has significantly increased its oversight of dialysis facilities. Examples include:

25.7 Percent Increase in Surveys: The number of full, onsite surveys increased from 1,377 in fiscal year (FY) 2002 to 1,732 in FY 2010. The number of investigated complaints increased by 74.8 percent (from 421 to 736) over the same period.

New, Better Regulations: In 2009, CMS 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 assessment and performance improvement program, and strengthened the public's expectations for infection control and dialysate and water quality.

54.7 Percent 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 the surveyors spend onsite during the course of a standard survey increased by 54.7 percent in 2010 from 2002 levels (from an average of 46.4 person-hours in FY 2002 to 71.8 in FY 2010).

Such increased oversight was in large part made possible through Congress' full support of the President's budget request for Medicare Survey & Certification in FY 2009 and FY 2010. This support is particularly important since the number of dialysis facilities has grown by 29.2 percent, from 4,407 in FY 2002 to 5,695 in FY 2010. So, while we have greatly increased the number of surveys, our increase has been somewhat exceeded by the growth in the number of ESRD facilities.

CMS has also made a substantial investment in providing the public with consumer-friendly information through the *Dialysis Facility Compare* Web site. We continue to make improvements to the Web site. Examples of further initiatives include the following:

Dialysis Facility Reports: We plan to make the full Dialysis Facility Reports (referenced in your letter) available to the public through CMS' *Dialysis Facility Compare* Web site in the future, if we can work out the technological challenges.

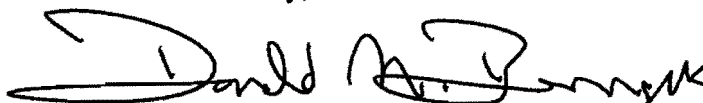
Quality Incentive Program: Our new ESRD *Quality Incentive Program (QIP)* has promise to align incentives more effectively with quality, and for the agency to obtain better data with regard to performance. We have adopted three performance measures for the first year of the *Quality Incentive Program*, and we anticipate expanding the program to include a larger, more robust set of measures to better incentivize ESRD providers and facilities to provide high quality dialysis care. We also anticipate adopting additional program measures that have been endorsed by the National Quality Forum. CMS currently has 29 endorsed clinical performance measures for which we have requested NQF renewed endorsement. Further, NQF is evaluating an additional 17 measures that may become available in the future. The measures will permit Web-based display of facility performance on individual measures and a total performance score. We believe that performance measure public reporting, combined with financial incentives, will motivate ESRD providers and facilities to make quality improvements.

Survey & Certification: The President's proposed Medicare budget for FY 2012 would further expand the number of surveys and certifications. With the support of Congress, in FY 2012, we hope to test a special survey tool to better identify infection control problems in dialysis facilities. Such a survey tool is currently being developed under leadership of the Agency for Healthcare Research and Quality.

To provide more information to Congress, dialysis facilities, and the public, we are planning to publish an *ESRD Action Plan* in the Fall of 2011 that will provide more information regarding efforts that are underway (or that ought to be undertaken in the long term) to advance the quality of care and safety in dialysis facilities.

Finally, as you indicate in your letter, alternative enforcement options, such as civil monetary penalties, may prove to better address the nature and extent of problems in a dialysis facility, compared to the current sole authority to terminate a facility from Medicare. I look forward to a continuing dialogue with you on this and other important topics.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald M. Berwick", with a stylized flourish at the end.

Donald M. Berwick, M.D.

Enclosure