

May 10, 2013

Tim Love  
Acting Deputy Director for Operations  
Center for Medicare and Medicaid Innovation  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: Comments on the Comprehensive End-Stage Renal Disease Care model**

Dear Mr. Love:

On January 31, 2013, CMS released a call for applications to participate in the Comprehensive End-Stage Renal Disease (ESRD) Care (CED) model that will test whether financial risk arrangements with guaranteed discounts will maintain or improve the outcomes of ESRD beneficiaries on dialysis, and reduce Medicare Parts A and B total per capita expenditures. Under this initiative, ESRD Seamless Care Organizations (ESCOs)—consisting of at least one Medicare-certified dialysis facility, one nephrologist or nephrology practice, and one other Medicare-enrolled provider<sup>1</sup>—will agree to take on the financial risk for a population of ESRD beneficiaries receiving dialysis treatment in a given area. An ESCO will be required to participate for at least three years and have a minimum of 350 beneficiaries matched to it. In urban areas, these beneficiaries must reside in an area that includes no more than two contiguous core-based statistical areas (CBSAs), and in rural areas (i.e., those areas not in CBSAs), all beneficiaries in the ESCO must reside in the same state.<sup>2</sup> CMS anticipates that between 10 and 15 ESCOs will participate, and that the initiative will begin in the last quarter of 2013. Letters of intent were due to the agency by March 15, 2013 and applications no later than May 1, 2013. Based on the high level of stakeholder interest and feedback on the need for additional time to prepare applications, CMS extended these deadlines to May 15, 2013 and July 1, 2013, respectively.

The Commission previously has said that if structured properly, a shared savings program (in this case for ESRD providers) could present an opportunity to correct some of the undesirable incentives inherent in fee-for-service payment and reward providers who are doing their part to control costs and improve quality. In this letter, we comment on: (1) establishing the historical spending baseline; and (2) selecting quality measures to assess the effect of the CED model.

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<sup>1</sup> DME and ambulance suppliers and drug and device manufacturers are not permitted to be participant owners.

<sup>2</sup> After reviewing numerous suggestions from organizations interested in the CED model, CMS announced (on May 3, 2013) that it was lowering the minimum beneficiary threshold required for eligibility from 500 to 350 beneficiaries.

### **Establishing the historical expenditure baseline**

Using an approach similar to the Medicare Shared Savings Program, CMS will calculate the historical spending baseline based on Parts A and B per capita expenditures in the three years prior to the first performance year.<sup>3</sup> Then, for each performance year, the historical baseline will be risk adjusted, trended, price-adjusted, and bundle-adjusted to form an updated benchmark reflecting the performance year to compare with the ESCO's actual performance year average per capita expenditure amount.

#### *Comment*

In setting the historical spending baseline, CMS should exclude some or all of the expenditures for nonemergency ambulance use by dialysis beneficiaries particularly in areas that have high per capita expenditures (e.g., greater than the 75<sup>th</sup> percentile). This comment is based on the Commission's finding that nonemergency dialysis-related transports appear to be excessive in some states and potentially fraudulent.

In its recent analysis of the ambulance payment system, the Commission raised concerns about the appropriateness of ambulance spending for dialysis beneficiaries.

- We found that in 2011, ambulance transports to and from dialysis facilities accounted for nearly \$700 million in Medicare spending; nearly all (97 percent) of these transports were nonemergency transports. Between 2005 and 2009, the US Renal Data System found that per dialysis beneficiary expenditures for ambulance services almost doubled.
- We found that in the five-year period between 2007 and 2011, the volume of dialysis facility transports increased 20 percent—more than twice the rate of all other transports combined.

The HHS Office of Inspector General (OIG) has been investigating fraud in the context of dialysis-related ambulance transports. Previous studies (in 1994 and 2006) by the OIG have found medically unnecessary dialysis-related transports. The OIG is currently analyzing trends in ambulance utilization from 2002 to 2011 and examining questionable billing for ambulance services, including potentially medically unnecessary transports to dialysis facilities.

### **Selecting quality measures to assess the effect of the CED model**

Similar to the Medicare Shared Savings Program, CMS will use five domains to assess quality: preventive health; chronic disease management; care coordination/patient safety; patient/caregiver experience; and patient quality of life. Each domain will be weighted equally when calculating the ESCO's overall quality score. CMS will use the quality score to assess each ESCO's overall performance and factor the performance into the calculation of shared savings and shared losses.

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<sup>3</sup> The weighted average per capita expenditures in the first two base years will be risk adjusted, trended, price-adjusted, and bundle-adjusted to be comparable to the third base year, then averaged.

ESCOs will need to meet a minimum attainment level for each quality measure domain and will be required to meet a minimum threshold score in order to be eligible for shared savings. CMS's request for applications did not include: (1) the quality measures and benchmarks that will be used to determine the ESCO's shared savings or shared losses, or (2) the methods that will be used to calculate ESCOs performance scores. According to the request for applications, CMS plans to provide an initial list of quality measures to interested parties during the application period.

*Comment*

CMS should use a focused set of quality indicators that reflect the outcomes ESCOs are designed to achieve: keeping the population healthy, better care coordination, and better patient experience. Key outcome measures specific to dialysis patients include: mortality, hospital admission, hospital re-admission, home dialysis use, and access to kidney transplantation. These measures focus on much needed system-level improvements, because achieving the best patient outcomes often requires carefully designed care processes, teamwork, and coordinated action on the part of many providers. Although patient experience measures are inherently subjective by nature, they capture an important patient-centered dimension of quality not available elsewhere (Medicare Payment Advisory Commission 2004).

CMS should give greater weight to the domains and measures associated with outcomes and patient experience over process measures. There is precedent for weighting outcomes more than process measures. The 2012 star rating methodology for Medicare Advantage program gives greater weight to outcomes and patient experience measures over process measures. Outcome measures provide an integrated assessment of quality because they reflect the result of multiple care processes provided by all health care providers involved in the patient's care. Consequently, it may not be necessary to include measures such as 'medication reconciliation after inpatient facility discharge' or 'outpatient medication reconciliation' (two sample measures that CMS included in the request for applications); the providers in each ESCO should have incentives to use such tools to improve care coordination.

When determining the set of measures for each domain, CMS should be mindful of the balance in the number of measures in each quality domain. Individual measures in effect will have more or less weight depending on the total number of measures in the domain. For example, individual measures in a domain with few total measures will have more weight in the quality score calculation, and vice versa.

To the extent possible, CMS should leverage its existing quality measurement data—the Quality Incentive Program (QIP)—when developing the ESCO's intermediate outcome measures (e.g., dialysis adequacy and anemia management outcomes) and process measures (e.g., monitoring mineral metabolism). If CMS decides to use measures for the ESCO that are not used in the QIP, CMS should, to minimize provider burden, try to rely on administrative claims data rather than chart review or survey data.

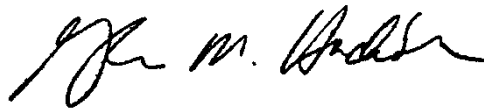
Tim Love  
Acting Deputy Director for Operations  
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## **Conclusion**

The Commission appreciates the opportunity to comment on this important policy initiative crafted by the Secretary and CMS. We also value the ongoing cooperation and collaboration between CMS and Commission staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth". The signature is fluid and cursive, with a large initial "G" and "H".

Glenn M. Hackbarth, J.D.  
Chairman

GMH/nr/cw