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February 8, 2007

Steve Phurrough, M.D.
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: National coverage determinations with data collection as a condition of coverage:
Coverage with evidence development (guidance document)

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' recent guidance that describes national coverage determinations (NCDs) that include, as a condition of payment, the collection of clinical data to supplement claims data. We appreciate your staff's ongoing efforts to administer and improve the coverage system, particularly considering the agency's competing demands.

CMS revised its guidance that describes when the agency will require additional information about a service's effectiveness in the national coverage process. Under coverage with evidence development (CED), CMS extends national coverage to a service that, in the past, the agency might not have covered due to insufficient data about its clinical appropriateness. The revised guidance lays out two pathways for covering services and collecting evidence about their clinical effectiveness:

- Under "coverage with appropriateness determination," CMS will require clinical data for a service determined to be reasonable and necessary so as to ensure that providers are furnishing the service to appropriate patients.
- Under "coverage with study participation," CMS will require clinical data for a service not otherwise considered reasonable and necessary.

Medicare policymakers and administrators need more information both to formulate better policies and to create tools to give useful information to beneficiaries and providers. Under CED, CMS is building the capacity to gather additional clinical data that will clarify the effect of a service on patients' outcomes. Ultimately, CED will help CMS make better coverage decisions.

Implementing this guidance is an important step to ensure that Medicare has the capacity to make evidence-based coverage decisions. However, it is also important to collect clinical evidence about the vast majority of services that do not go through the national coverage process. CMS has begun to require such data collection efforts. For example, the agency requires dialysis providers to report dialysis adequacy and anemia status information on claims for dialysis patients.

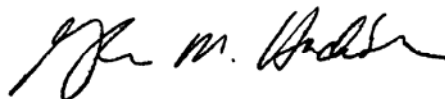
CMS has other opportunities to collect clinical information from providers that will give a more complete picture of patient care. For example, the Commission has recommended that:

- CMS require those who perform laboratory tests to submit laboratory values, using common vocabulary standards (March 2005 report to the Congress).
- CMS require providers to report patients' anemia status on all claims (not just dialysis claims) for erythroid growth factors to monitor patients' anemia status (January 2006 Effect of Medicare payment changes on oncology services).

In due course, considering evidence about the clinical and cost effectiveness of health services might increase the return on society's investment in health care.

MedPAC appreciates the opportunity to comment on guidance introduced by CMS. The Commission also values the willingness of CMS staff to provide relevant data and to consult with us concerning technical policy issues. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Glenn M. Hackbarth,
Chairman

GMH/nr/w