ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

November 8, 2005

The Honorable Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W., #314-G
Washington, D.C. 20201

Dear Dr. McClellan:

I am writing to express my views on the proposed rule to establish a process for prior determinations for certain items and services covered by Medicare (70 Fed. Reg. 51321 (August 30, 2005)). As you may know, I worked with former Representative Greg Ganske (R-IA) to include this provision in legislation passed by the Committee on Energy and Commerce, which was ultimately enacted as part of the Medicare Modernization Act of 2003. The prior determination process established by that Act would ensure that beneficiaries, particularly those with fewer resources, were not disadvantaged or discouraged from seeking needed care because Medicare's coverage of that service was in question.

I am concerned that as currently proposed, the rules to implement this provision are not sufficiently clear and access to necessary information will not be sufficient for either beneficiaries or providers to understand and use the process. I ask that you consider addressing the issues below in promulgating the final regulation, and that my comments be placed in the public record of the rulemaking.

In particular, the Centers for Medicaid and Medicare Services (CMS) has chosen to detail the procedures for requesting a prior determination in the contractor manual, which is not subject to public review and comment, rather than including the procedures in the proposed regulations, which would allow the opportunity for such review and comment. Moreover, contractor manual provisions do not have the same legal force as regulations. I strongly believe the process for requesting prior determinations should be detailed through the rulemaking process, not simply included as part of the contractor manual.

CMS also proposes that the list of those services eligible for prior determination be made public only through publication on a Medicare contractor's Web site. This will most certainly result in few knowing what services are eligible for review. I suspect that most beneficiaries do

not use the Internet, and would have no way of knowing whether an expensive service recommended by their doctor is subject to this new process. Medicare contractors should be required to annually send a mailing to both beneficiaries and providers that includes the list of services eligible for this prior determination process.

CMS proposes, as well, that updating the list of services eligible for prior determination be done through the contractor manual. This would again deny the public the opportunity to participate. The process for including additional services should be subject to public review and comment. It should be updated through regulation or other formal procedures. Physicians must be able to request a service that meets the requirements be added to the list.

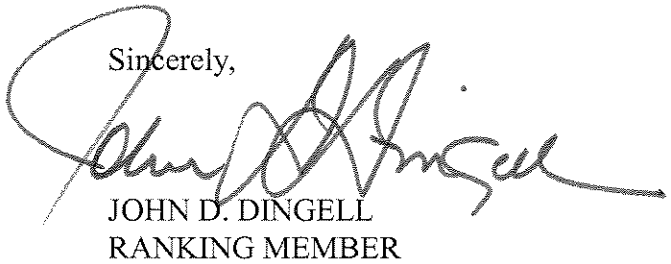
The regulation should also include information regarding how frequently CMS and its contractors will update the list. Updating the list randomly places a burden on physicians and beneficiaries, who would need to check the list of services eligible for review every time they wanted to recommend a service that they were uncertain would be covered by Medicare. The list should be updated only at standard periodic intervals so as to minimize confusion and burden on beneficiaries and providers.

In addition, excluding services from the prior determination process because there is a National Coverage Determination (NCD), Local Coverage Determination (LCD), or Local Medical Review Policy (LMRP) that CMS determines to provide sufficient specificity on coverage would potentially and unwisely exclude a number of services from this new process. For example, it is not uncommon that a policy that CMS believes states clearly whether an item is covered may not be interpreted the same way by a contractor.

The regulations should specify that beneficiaries and providers must receive proper notice to ensure they are fully aware of their rights. Any notice of denying should be in writing and must explain that anyone who receives such a notice may still obtain the service, submit a bill to Medicare, and appeal the decision if the service is denied coverage.

I believe the proper enactment of this provision will be of great assistance to both Medicare beneficiaries and their healthcare providers. I thank you for reviewing my views on this matter and hope you give them full consideration.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce