

Congress of the United States
Washington, DC 20515

September 17, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Dr. Berwick:

We write to express our concerns regarding the proposed Medicare outpatient prospective payment system (OPPS) regulation for Calendar Year (CY) 2011. In this rule, the Centers for Medicare & Medicaid Services (CMS) propose to require a modified level of physician supervision for a small number of specified hospital outpatient therapeutic services, beginning in 2011. We are concerned that this proposed change does not go nearly far enough to ensure continued access to the full range of outpatient therapeutic services in hospitals, particularly for small and rural facilities, such as critical access hospitals (CAHs).

Hospital outpatient therapeutic services have always been provided by licensed, skilled professionals under the overall direction of a physician. While hospitals recognize the need for direct supervision for certain outpatient services that pose high risk or are very complex, CMS' proposed policy still requires direct supervision for even the lowest risk services, such as simple injections of pain medication, minor wound debridement and drainage of wounds. There are many other procedures that can be, and are, safely furnished in hospital outpatient departments under the general supervision of a physician.

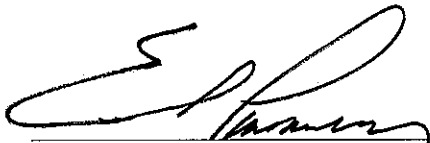
In the CY 2009 OPPS rules, CMS made a significant change in its policy, which the agency characterized as a "restatement and clarification" of existing policy. CMS "clarified" that its policy since 2000 required direct physician supervision in all hospital locations. CMS provided no clinical rationale for this change and, indeed, has publically acknowledged that the "restatement and clarification" in the 2009 final rule was issued without any allegations or evidence that quality of care or patient safety had been compromised in hospital outpatient departments.

In 2010, in response to public concern, CMS made a few limited – and in the case of CAHs, short-term – changes. CMS began to allow certain Non-Physician Providers (NPPs) to provide direct supervision of outpatient therapeutic services, and revised the policy around where the supervising professionals were required to be on the hospital campus. CMS also delayed enforcement of the direct supervision regulation for CAHs for CY 2010.

In the CY 2011 rule, CMS proposes that a set of 16 outpatient therapeutic services require direct supervision only for the initiation of the service, followed by general supervision for the remainder of the service. All other services would continue to require direct supervision. We do not believe this proposed change provides the relief that hospitals and CAHs need to staff appropriately and to continue to provide a full range of services to their communities. In fact, for CAHs and other small rural hospitals, located in communities where physician and NPP shortages are most severe, this modified supervision policy will not help at all, as they will still need to have a supervising physician or NPP on the premises and "immediately available" when these services are provided.

We also believe the same underlying concerns with the issue of direct supervision for outpatient therapeutic services are unaddressed: CMS' overall policy is unwarranted and unworkable, there is a shortage of physicians and NPPs and many hospitals and CAHs will find it difficult, if not impossible to meet the supervision requirements and these requirements severely restrict hospitals' ability to effectively use their existing staff. In addition, due to CMS' failure to rescind its retroactive reinterpretation of its previous supervision policy, hospitals and CAHs remain vulnerable to unwarranted, but significant, potential penalties and opportunistic whistleblowers.

We ask that you revisit this policy – going as far back as the 2009 "clarification" – and make a fundamental change in the supervision policy. Thank you for your consideration and we look forward to your response to this letter.



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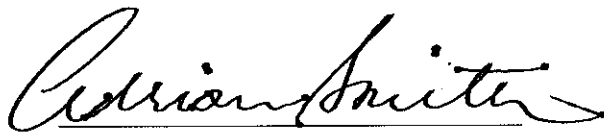
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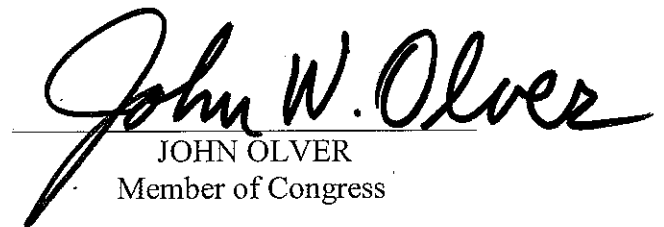
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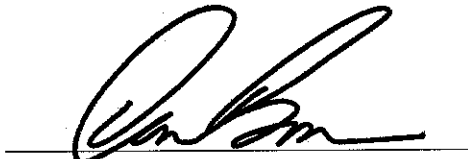
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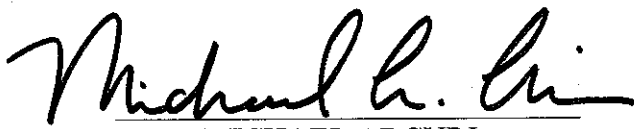
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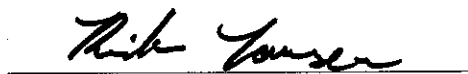

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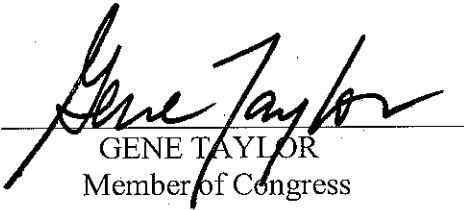

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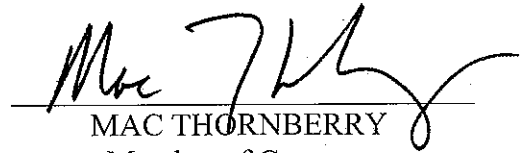
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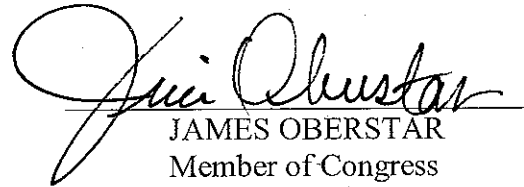
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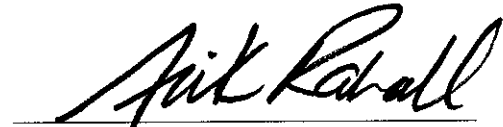
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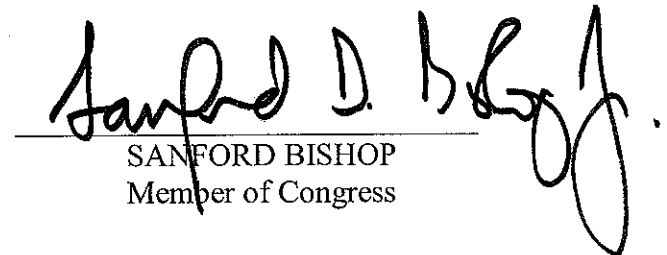
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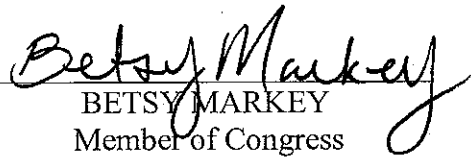
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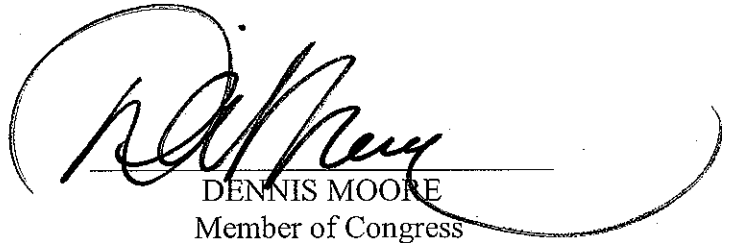
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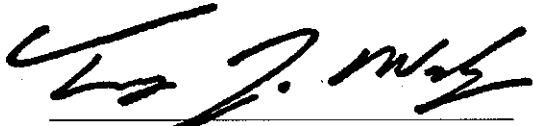
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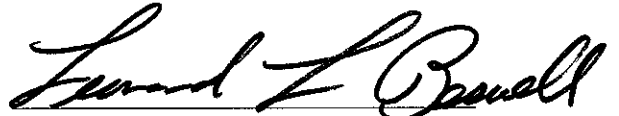
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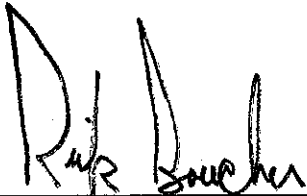
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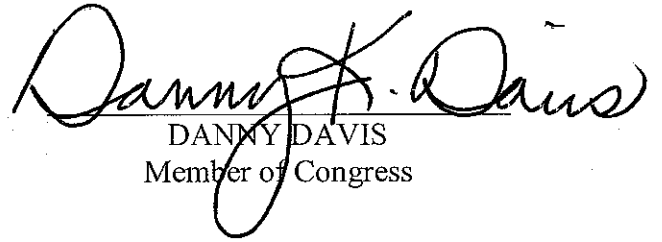
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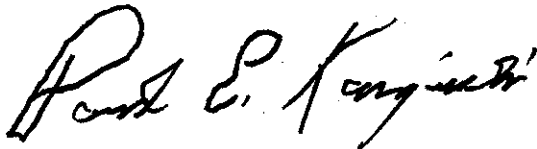
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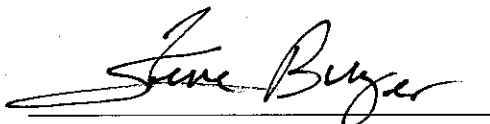
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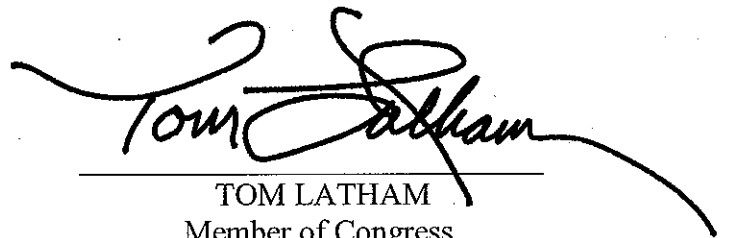
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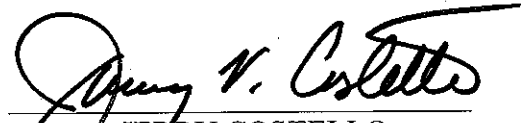



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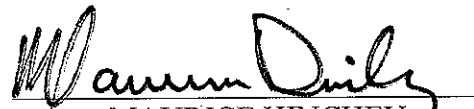



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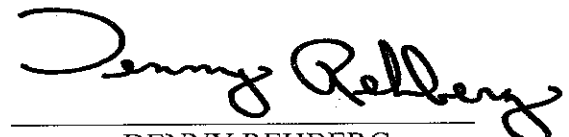

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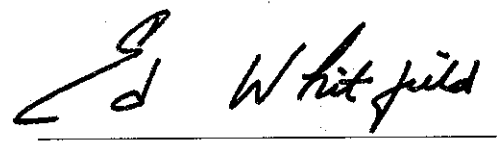

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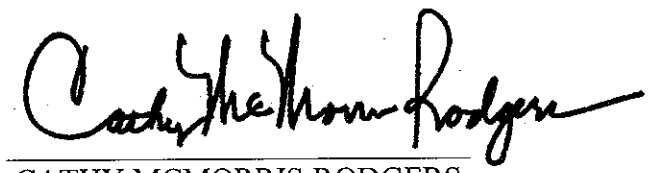

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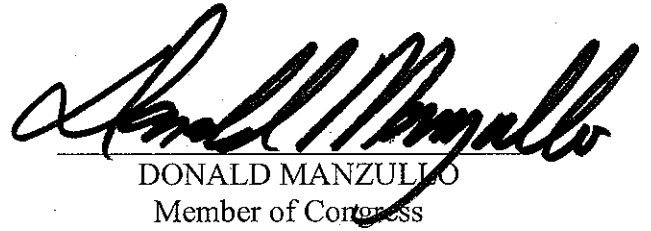

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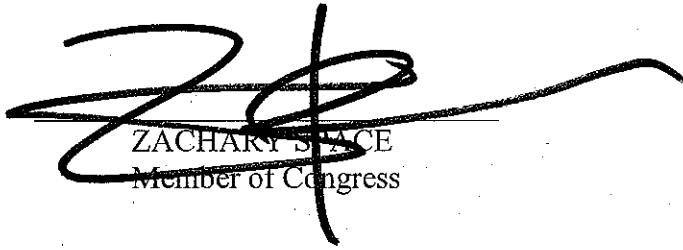

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