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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

February 11, 2011

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The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Dear Secretary Sebelius:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the implementation of the Patient Protection and Affordable Care Act (PPACA) and the federal health care programs. As Ranking Member of the Committee, I consider it part of my responsibility to conduct vigorous oversight of PPACA's implementation and the regulations which are promulgated to effectuate that implementation as well as to closely track all regulations issued related to the federal health care programs.

In reviewing some of the recent proposed and final regulations which have been issued by the Department of Health and Human Services (HHS), I am concerned that HHS and in particular the Centers for Medicare & Medicaid Services (CMS), may have proposed and adopted final regulations:

- Without sufficient policy justification and/or supporting data analysis and discussion;
- That do not comply with Executive Order 12866, Executive Order 13132 (where applicable), and the Congressional Review Act;
- Which contained policies that were not included in the proposed regulations issued for public comment;
- Which did not address or provide complete responses to all public comments submitted; and
- That HHS/CMS has failed to fully implement after they have been issued in final.

Additionally, it appears that HHS and CMS may also be limiting the public's right to comment on regulations by not allowing the public a full 60 day comment period beginning with the date of publication in the Federal Register. I will be asking Administrator Cass Sunstein of the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB) to explain why Agencies are permitted to limit the public comment period by using a variety of dates to start the comment period such as the date of display at the Office of the Federal Register or, in the case of recently released CMS final rule CMS-6028-FC the date that media outlets began reporting the forthcoming display of the proposed rule¹, versus the date of actual publication in the Federal Register.

¹ CMS-6028-P went on display at the Federal Register on September 20, 2010, and the public comment period closed on November 16, 2010, at 5:00 p.m. In response to comments expressing concern about the length of the comment period CMS published the following response: "The Department of Health and Human Services released a press release on September 20, 2010 accessible on its Web site that announced the display

The Honorable Kathleen Sebelius
Page Two
February 11, 2011

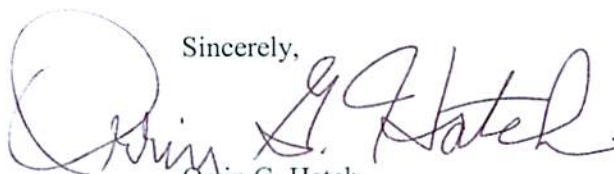
To address the various issues raised in this letter, I request that my office be alerted to all HHS regulations that have an economic impact of \$100 million or more at the same time HHS transmits them to OMB for review. Once the rule has been approved by OMB and before it goes on display at the Federal Register, I am requesting a briefing on the OMB approved rule which should include a detailed discussion of how the economic impact analysis was calculated, what sources were used to determine the economic impact and the stakeholders most impacted by that impact, as well as a crosswalk of the public comments received and how they have been addressed in the regulation.

This is pursuant to the Congressional Review Act (CRA) that requires federal agencies to submit their covered final rules to Congress and GAO before they can take effect. Section 801(a)(1)(A) of the CRA states that: "Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing (1) a copy of the rule; (ii) a concise general statement relating to the rule, including whether it is a major rule; and (iii) the proposed effective date of the rule."

While this request is limited, for now, to regulations that have an economic impact of \$100 million or more, please note that I reserve my right as a Member of Congress and Ranking Member of the Committee to request additional information on any regulation under the jurisdictional purview of the Committee. I shall be paying close attention to the language of the regulations and hope that they live up to the President's Executive Order issued on January 18, 2011, promising government regulations which are "transparent, coordinated and simplified," and that the regulations are not exceeding the laws passed by Congress.

Thank you for your attention to this request. Should you have any questions regarding this letter, please contact Kimberly Brandt with the Finance Committee staff at (202) 224-4515.

Sincerely,

A handwritten signature in black ink, appearing to read "Orrin G. Hatch". The signature is written in a cursive, flowing style.

Orrin G. Hatch
Ranking Republican Member