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# United States Senate

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March 10, 2011

President Barack Obama
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear President Obama:

I write you today to express my sincere appreciation for the Executive Order that you issued on January 18, committing all federal agencies to review regulations and remove any that place unreasonable burdens on our nation's business community and/or impact the ability of our economy to grow. I agree that in light of our current economic crisis, establishing a regulatory environment that promotes growth and job creation should be the number one priority for this Congress and Administration. To that end, I would like to offer some suggested areas related to health care that patients and providers have communicated are of the most concern to them, and would urge you and your Administration to consider these and their impact when implementing your Executive Order.

While the majority of this communication will focus on regulations already on the books, I would also like to take this opportunity to share with you what seems to be an even greater concern within the patient, provider and stakeholder community. When discussing regulations in general and your Executive Order more specifically with my constituents and those representing the patient and provider community, the number one concern that I hear is related to a fear of the impact of *future* regulations. While there is still a large concern with the burden of regulations that have already been issued, I have heard time and time again that there is an even greater concern with the uncertainty of future regulations, especially those regulations for implementing the "Patient Protection and Affordable Care Act" (PPACA) and their potential to have a further and greater impact on jobs and the economy. While I regularly hear concerns about the compounding costs related to implementing any and all of these regulations, the specific areas that are mentioned the most include, but are not limited to:

- Individual Mandate and related penalties
- Employer Mandate and related penalties
- Defining Essential Health Benefits and related coverage mandates
- Accountable Care Organizations

- New taxes and fees including the "Cadillac Tax" and new excise taxes on industries
- 1099 reporting

Additionally, I hear often that patients and providers feel that they do not have a voice in the regulatory process and, more specifically, that a number of regulations are being issued through a shortened process. This shortened process allows limited or no input from those most affected by the regulations, prior to their implementation, and may result in greater costs and economic impact if changes are necessary based on comments that the Administration receives. It is my understanding that the PPACA rules that have been issued as interim final rules, and therefore with limited input are:

- National Provider Identifier
- Web Portal Requirements
- Early Retiree Reinsurance Program
- Coverage of Children to Age 26
- Underserved Rural Communities
- Grandfathered Health Plans
- Pre-Existing Condition Exclusions
- Preventive Services
- Internal Claims/ Appeals and External Review Processes
- Pre- Existing Condition Insurance Plan Program
- Amendment to Grandfathered Health Plans Rule
- Medical Loss Ratio Requirements

While there may have been instances in which a shortened process was necessary or appropriate I would strongly encourage your Administration to limit the use of this regulatory process and take every available opportunity to get feedback from those who would be most affected by these regulations and allow for ample time to review and consider that feedback *prior* to implementing future regulatory priorities. I would also strongly encourage you to review any comments you have received on these regulations for any concerns that indicate a potential to further our economic crisis.

Without fail in my conversations with patients, providers, advocates, and stakeholders,which include my Kansas constituents, I hear about their concerns with the burden of government "red tape" and the impact of regulations on their ability to maintain and grow their businesses. While this is not an exhaustive list, I will share the health care regulations that I have been hearing about the most and would ask you to review them for their potential economic impact and modify or remove them to ensure the least burden on our struggling businesses, individuals, and economy.

It should come as no surprise the regulations that I am hearing the most about are related to the impact of PPACA. Although the full impact of recently passed health care legislation is still uncertain, it is clear that additional employer costs will be substantial, as will the burden of what promises to be extreme complexity in compliance. Already patients, providers and advocates have cited a number of regulations related to PPACA that would have profound impact on jobs and our economy. Specifically:

- The "Preexisting Condition Insurance Plan" and the concern that it is not being utilized efficiently to provide an option for those unable to afford coverage;
- The "Patients Bill of Rights" and the concern that it has resulted in the loss of child-only insurance markets in over 20 states;
- "Grandfathered" health plan regulation and a concern that the regulation is drafted too narrowly to allow businesses to keep their current coverage and maintain current costs of coverage and are too cumbersome and don't allow plans to comply with "the early requirements over a period of time";
- "Medical Loss Ratio" and the concern that the calculation of the standard will increase cost of care for patients and the concern that it will directly result in lost employment and more specifically the omission of health care fraud work as part of ongoing quality improvement activities;
- "Rate Review" and the concern that this requirement will do nothing to control costs and that there are a number of areas within the rule that could cause significant and negative disruption to States and consumers;
- "Annual and Lifetime limits" and the concern over the impact on businesses and individuals the more than 1,000 waivers already issued will have.

Additionally, I have heard that the combination of the regulations being issued to implement the PPACA statute have resulted in an increase in premiums for individuals and businesses, which as you know results in increased costs and tough choices. Related to this, I am deeply concerned by signals from your Administration that regulations being issued to implement the PPACA statute will not be held under the scrutiny of your Executive Order. Iwould strongly encourage your Administration to review all of the regulations that have been issued, past, present and future, while considering their impact on our economy and jobs.

Finally, patients and providers have expressed a number of concerns related to the regulatory burdens that they face. Generally, they have asked that while the Administration may measure indirect benefits for regulatory proposals, that there is a lack of willingness to analyze and make publicly available the indirect costs to consumers, such as higher energy costs, jobs lost, and higher prices and would request that a reasonable estimate of indirect impact and the methodology used in determining those impacts be made available. They would prefer that agencies be accountable for providing a balanced statement of costs and benefits in public regulatory proposals. Also, I have heard that a number of patients and providers are being buried by the paperwork burden of complying with all of the regulations. Specifically, I have heard about the compliance burden of having to adjust to the sheer volumes of changes that the Administration issues every year and the impact on providers to do their jobs and provide care for patients

The regulations that I have been hearing about their negative economic impacts and would suggest you review are:

- The 2011 Medicare Physician Fee Schedule Final Rule, which requires that laboratory requisition forms are signed by the ordering physician. This rule could have potentially serious implications on patient care and business practice. Under this new policy,

laboratories will face a difficult decision when they receive a patient specimen with an unsigned requisition. Laboratories will have to decide not to provide their needed services and therefore be unable to provide a physician the information necessary to make health care decisions - or - provide the services without a guarantee of payment and then work to obtain signatures in order to submit claims to Medicare. As you can imagine, in the former situation, care may be significantly delayed; in the latter scenario the laboratories who serve a high percentage of Medicare beneficiaries could spend a large amount of time contacting providers to gather the required signatures and could see their payments delayed or face the possibility of being unable to receive payment.

- On November, 17, 2010, CMS issued a final rule, as directed by PPACA (P.L. 111-148). The rule conditions payment for home health and hospice services based upon a face-to-face encounter between patients and their physicians or certain non-physician practitioners prior to certification for home health or hospice services. This is resulting in burdensome requirements for our rural home health and hospice patients.

- Physicians Assistants are an important part of care for rural communities especially hospice and palliative care; however, they are often not considered when drafting regulations related to providers allowed to provide services.

- Anti-Switching Rule in Medicare's Competitive Bidding Program (CBP) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Specifically,the proposal to enforce the rule in subsequent rounds of the CBP, but not Round 1, may compromise beneficiary access to appropriate diabetes testing supplies and leave beneficiaries vulnerable to pressure from suppliers to switch testing systems.

- DMEPOS Competitive Bidding implementation continues to be a concern. We originally had over 400 DME providers in KS; however, now that Round 1 has been implemented I am concerned that patients, especially in rural areas, are facing issues related to access.

- Two sets of regulations and guidance – one for hospices and one for rural health clinics – that may have resulted in an oversight in the Medicare billing regulations is creating obstacles for individuals in rural, underserved communities to receive hospice care. In these communities, the primary care physicians are often (and sometimes exclusively) members of Medicare-certified "rural health clinics." However, when a hospice patient's attending physician also happens to be a rural health clinic physician, Medicare is not reimbursing either the physician or the clinic for the physician's services.

- Health IT rules related to implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act which I am hearing are creating uncertainty and confusion, jeopardizing the goal of the rapid adoption of electronic health records. Without policy changes, innovation will be marginalized and job creation threatened.

- Privacy and security regulations adopted by HHS under the Health Insurance Portability and Accountability Act (HIP AA) and the HITECH Act expand the accounting of disclosures requirement to include all disclosures, even daily, routine disclosures. While

patient safety and privacy should be a high priority, businesses are concerned that maintaining detailed records would require an overwhelming amount of information to be stored.

- The short amount of time to comply with new ICDl0 and 5010 coding requirements impose an incredible administrative burden that I am hearing will increase administrative costs significantly.

- CMS regulations that restrict the ability of non-physician practitioners to meeting the CMS requirement for supervision for cardiac and pulmonary rehab. These rules are limiting access to cardiac and pulmonary rehab, particularly in rural and Critical Access Hospitals.

Clearly this is not a comprehensive list, but it represents a number of areas that patients, providers and constituents have expressed concerns on.

Again, thank you for the opportunity to share my recommendations on what rules and regulations pose serious negative consequences to the growth of our nation. As the 112th Congress gets under way, I will continue to identify to your Administration regulations that handicap American businesses and halt American job creation. It is my hope that we can create a regulatory environment that provides American businesses with the necessary tools to hire and thrive in this global market.

Sincerely,

Pat Roberts
United States Senator