United States Senate

WASHINGTON, DC 20510

February 11, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–8013

Dear Dr. Berwick:

We write you today regarding the Centers for Medicare and Medicaid Services (CMS) requirement included in the 2011 Medicare Physician Fee Schedule Final Rule that laboratory requisition forms be signed by the ordering physician. We ask that CMS consider delaying enforcement of the requirement, possibly for an additional nine months.

While CMS' granting of a three-month delay in enforcement of the requirement is appreciated, we believe more time is needed for CMS to work with physicians and the lab community on this rule and to discuss the 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.

We are also concerned with how this requirement will work under varying scenarios. In patient service centers, care may be delayed for patients who report to the facility with an unsigned requisition and are asked to return to the physician to obtain the required signature. In a skilled nursing facility or home health setting, where the attending physician is often not on site, and where some patients require frequent lab tests, the requirement to obtain a signature on a requisition could become increasingly difficult since there could be a significant time lag between the order and the signature. In addition, for more patients needing immediate tests, they could be sent to the emergency room so that they may receive their lab tests quickly. Therefore, we worry about how the rule could affect Medicare beneficiaries where such lab services are necessary for a physician to make critical decisions that affect patients' health and well-being, often under significant time constraints, and urge CMS to consider these situations as they examine this policy.

Additionally, the proliferation of electronic medical records in the coming years has the potential to transform the process and documentation of orders and requisitions, offering CMS access to standardized documentation of the physician's orders. However, challenges currently exist in the electronic ordering systems for lab tests, particularly as some physician systems do not interface with lab computer systems. We encourage CMS to consider using the additional time requested to ensure that efforts to provide consistency in documentation are aligned with its goals for adoption of health information technology systems, which will benefit patients, providers and payers alike.

In light of these issues, we believe that additional time is necessary for CMS to work with the laboratory, physician, hospital and long-term care communities to put in place safeguards to ensure patient care is not negatively affected, allay concerns on possible payment complications stemming from this new requirement, and ensure a streamlined process for health care providers.

Thank you for your consideration of our recommendations. We look forward to hearing from you.

Sincerely,

ROBERT MENENDEZ
United States Senator

PAT ROBERTS
United States Senator