



# American College of Surgeons

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May 5, 2011

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Executive Order 13563: Improving Regulation and Regulatory Review

Dear Secretary Sebelius:

On behalf of the more than 75,000 members of the American College of Surgeons (ACS), we offer recommendations below regarding President Barack Obama's Executive Order 13563: Improving Regulation and Regulatory Review. We view this Executive Order as a step toward improving regulations and easing the regulatory burden on physicians, and we appreciate the Department of Health & Human Services' (HHS) work toward this important goal. As HHS analyzes rules that may be outmoded, ineffective, insufficient, or excessively burdensome and works to modify, streamline, expand, or repeal them in accordance with the direction set forth in the Executive Order, we request that HHS consider our suggestions of ways to streamline and enhance the regulations that we discuss in more detail below.

## Synchronize Reporting Metrics, Periods, and Mechanisms for Incentive Programs

The HHS, through the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology, is in the process of developing or implementing several programs related to physician quality improvement including the Physician Quality Reporting System, the Electronic Prescribing (eRx) Incentive Program, the Medicare and Medicaid Electronic Health Records (EHR) Incentive Program, the Physician Resource Use Measurement and Reporting Program, the Physician Value-Based Payment Modifier, and others. As these various quality and incentive programs progress to more advanced stages of implementation, it is critical that the reporting metrics, reporting periods, and reporting mechanisms be coordinated across the programs.

For example, the Medicare and Medicaid EHR Incentive Program includes an electronic prescribing requirement, which should be coordinated with the eRx

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Incentive Program. The reporting metrics and timeframes for each program should encourage similar action by physicians, and physicians should not be subject to penalties under *both* programs for failure to satisfactorily electronically prescribe. The administrative burden of understanding and complying with these numerous programs is significant, and lack of coordination among the programs would result in unnecessary confusion and duplicative administrative and implementation costs. This, in turn, may impede improvements in quality of care and could even reduce patient access to care or could harm patients, all of which would undermine the intended goals of any quality-related program.

### **Ease the Burden on the Medicare Enrollment Process**

Another area that requires streamlining is Medicare enrollment. Due to limited resources and short deadlines, CMS contractors sometimes struggle to implement agency changes related to Medicare enrollment. Many of our members have experienced frustration with maintaining or updating their enrollment status, and several have even inexplicably had their Medicare billing privileges revoked, most likely due to glitches in the Medicare processing system. Safeguards should be put in place to avoid processing errors such as these, which abruptly and unfairly interrupt patient access to care.

Another problematic aspect of Medicare enrollment is the processing of enrollment in the Internet-based Provider Enrollment, Chain and Ownership System (PECOS). All physicians who order and refer most covered items and services for Medicare beneficiaries must enroll in Medicare and have had their enrollment information in PECOS by April 5, 2011. We appreciate that CMS has postponed the deadline by which physicians must confirm their proper enrollment in PECOS. However, given that the consequence of not being enrolled in PECOS is so high, namely, denial of claims of ordering or referring physicians, it is critical that CMS ensure an efficient mechanism for processing PECOS enrollments and appeals of incorrectly denied claims. Some physicians have spent months attempting to enroll in PECOS, and it is crucial that Medicare contractors are able to handle significant processing issues in a timely manner.

CMS should implement a more clear and direct process for streamlining Medicare enrollment, including identifying and resolving processing errors related to maintaining enrollment and PECOS enrollment. Several of our members have reported to us that they have had great difficulty accessing customer service hotlines in addition to problems receiving correct answers to their enrollment questions. Such hurdles can result in hours taken out of their practices and away from their patients while the physicians attempt to correct processing errors that were perhaps no fault of their own. Without the ability to bill Medicare for even a few weeks, small practices could be significantly disrupted resulting in an adverse impact on



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patient care. We urge CMS to dedicate additional resources to streamlining the Medicare enrollment process, especially during the implementation of new requirements.

### **Create General Surgery Health Professional Service Areas**

Another area requiring a revision of current regulations is the Health Resources and Services Administration's (HRSA) rules related to health professional shortage areas (HPSAs). Section 5501(b) of the Patient Protection and Affordable Care Act (ACA) provides an incentive payment to general surgeons who perform major surgeries in HPSAs. Because the ACA requires this incentive payment to be implemented via Geographic HPSAs, CMS (the agency responsible for implementing section 5501(b)) is required to limit the incentive payment to general surgeons who perform major surgeries in primary medical care or mental health Geographic HPSAs. However, anchoring the incentive to primary medical care or mental health Geographic HPSAs does not appropriately target the general surgery shortage because a general surgery shortage area is not the same as a primary medical care or mental health shortage area.

Consequently, a disconnect exists between the goals of section 5501(b) of ACA and the means by which this provision of the law can be implemented because the current HPSAs are not an indicator of the areas in need of general surgeons. Accordingly, we request that HRSA initiate a process for creating general surgery HPSAs because we believe that this revision of HRSA's regulations related to HPSAs is important to rural patients and patients in underserved areas in need of the services provided by general surgeons.

### **Withdraw Physician Lab Requisition Requirement**

We recommend that CMS withdraw an overly burdensome provision included in the calendar year (CY) 2011 Medicare Physician Fee Schedule (PFS) final rule that would require a physician's signature on requisitions as well as orders for clinical diagnostic laboratory tests paid on the basis of the clinical laboratory fee schedule (CLFS). Currently, a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS, but it must be evident that the physician ordered the services. Due to uncertainty whether some documents are requisitions or orders, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician signature, CMS finalized its proposal to require a physician's signature on requisitions as well as orders for clinical diagnostic laboratory tests paid on the basis of the CLFS.

In our comment to the CY 2011 Medicare PFS proposed rule, we agreed that CMS' proposal would result in a less confusing process, but we disagreed with the assertion that the proposal



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would not increase the burden on physicians. Rather, we believed that this added step would increase the burden on physicians who have already authorized the test at the time it was ordered. We added that if the proposed requirement were due to potential fraud, a better approach would be to identify the groups of providers responsible for fraud rather than imposing this new requirement on all providers. Although CMS finalized its proposal in the November 29, 2010, CY 2011 Medicare PFS final rule, enforcement of this provision was delayed from January 1, 2011, to April 1, 2011. On March 30, 2011, CMS indicated that this provision would not go into effect on April 1, 2011, and that CMS would spend the rest of 2011 focused on changing the regulation that requires signatures on laboratory requisitions. We appreciate CMS' decision not to enforce the signature on laboratory requisitions requirement, and we encourage CMS to formally withdraw the requirement from the regulations because, based on the discussion above, we believe that this policy is overly burdensome.

### **Physicians Enrolled in DMEPOS should not be Categorized as “High” Risk**

In the Medicare, Medicaid and Children's Health Insurance Programs Final Rule on Program Integrity released on February 2, 2011, CMS finalized its proposal to require that enrolled physicians also enrolling as durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers would be classified in a “Moderate” risk category (for revalidating suppliers) or a “High” risk category (for newly enrolling suppliers). Among other things, this means that newly enrolling physicians also enrolling as non-commercial DMEPOS suppliers (e.g., because they desire to furnish DMEPOS, such as crutches, orthotics or post-cataract glasses and lenses, to their own patients), and physicians already enrolled as DMEPOS suppliers but seeking a new DMEPOS location, will need to submit fingerprints and undergo a criminal history record check. We believe this provision is excessively burdensome and should be modified as it relates to physicians who are non-commercial DMEPOS suppliers.

CMS' approach of tiering program providers and suppliers into risk categories and then determining which screening processes to apply based on the risk category seems reasonable, as does the creation of the tiers of “Limited,” “Moderate,” and “High” risk. We are concerned that, given the already high burden on physicians who become DMEPOS suppliers, many physicians will opt out of furnishing DMEPOS to their current patients. To avoid this result, we request that CMS define a process for identifying physicians who have also enrolled as DMEPOS suppliers, functioning as care providers rather than as commercial suppliers, and ensure that those physicians remain in the “Limited” risk category.

Given the history of abuse in the DMEPOS program, we understand the need to apply the stricter screening to those suppliers already in the programs and seeking to participate in the



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programs. However, if physicians functioning as DMEPOS suppliers for their patients are subjected to the additional screening mechanisms associated with the “Moderate” and “High” risk categories, many physicians will simply relinquish the services they provide as DMEPOS suppliers with minimal to no benefit for the waste, fraud, and abuse prevention efforts of CMS. We firmly believe that the licensure efforts in which physicians participate and are cited by CMS as a level of protection against waste, fraud, and abuse should apply to these same physicians when they are functioning as non-commercial DMEPOS suppliers. For these reasons, we believe that subjecting physicians to the additional screening mechanisms associated with the “Moderate” and “High” risk categories is excessively burdensome and that this provision should be modified so that such physicians would only be considered “Limited” risk.

We appreciate the opportunity to offer these comments regarding President Obama’s Executive Order related to the improvement of regulation and regulatory review. If you have any questions about our comments, please contact Bob Jasak in the American College of Surgeons’ Division of Advocacy and Health Policy. He can be reached at [bjasak@facs.org](mailto:bjasak@facs.org) or at (202) 672-1508.

Sincerely,

A handwritten signature in black ink that reads "David B. Hoyt". The signature is written in a cursive style with a large, stylized "H" and "T".

David B. Hoyt, MD, FACS

Executive Director