Alliance of Specialty Medicine

Sound Policy. Quality Care.

March 11, 2011

Honorable Darrell Issa, Chairman
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Issa:

The Alliance of Specialty Medicine (Alliance) is a coalition of 10 national medical specialty societies representing approximately 100,000 physicians and surgeons. We are dedicated to advocacy for the development of sound federal health care policy that fosters patient access to the highest quality specialty care. As patient and physician advocates, the undersigned organizations of the Alliance are responding to your public call to identify existing and proposed regulations that have a negative impact on job growth. The Alliance has identified several regulations that negatively impact jobs in healthcare through increased administrative burdens placed on healthcare providers, which diminishes their ability and time to care for patients, which is the very reason they joined the medical profession. The Alliance respectfully requests that the House Committee on Oversight and Government Reform investigate the following regulations which ultimately restrict patient access, interfere with the physician-patient relationship, and impede the delivery of high quality specialty care. We contend that, if healthcare providers continue to be overburdened with nonessential administrative duties that limit their ability to provide high-quality patient care, individuals in the profession will leave it, and those considering a career in medicine may reconsider.

In addition, we request a meeting with you and your staff to discuss the negative impact of these regulations on specialty medical practices, along with actionable solutions for addressing the issues.

EXECUTIVE SUMMARY

The Alliance has identified proposed and existing regulations that negatively impact the business of specialty medicine. These include:

- ***Independent Payment Advisory Board (IPAB).*** Forthcoming regulations related to the IPAB are of particular concern for specialty physicians. The IPAB receives an inappropriate delegation of Congress' oversight responsibilities and lacks the expertise required to make health care decision that will not only have a negative impact on physician practices, but also the quality of care patients receive.
- ***Accountable Care Organizations (ACOs).*** Soon to be released regulations regarding ACOs are sure to be complex and have a significant impact on specialty physicians and their practices.
- ***Value-Based Payment Modifier.*** The so-called Value-Based Payment Modifier was enacted as part of the Patient Protection and Affordable Care Act (PPACA). Linking Medicare physician payment to patient outcomes through the Value-Based Payment Modifier is not advisable, as both physicians and the agency responsible for implementing this regulation are not prepared to do so.
- ***Quality Improvement Initiatives***. Currently, there are several federal quality improvement initiatives in place, which are fraught with problems and, according to a recent study by the Government

Accountability Office (GAO), must be better aligned to actually achieve improvements in health care quality.

- ***Recovery Audit Contractors (RACs).*** Existing regulations related to RACs need to be reevaluated. The "bounty-hunter" nature of the RAC program places a significant burden on practices and an inappropriate incentive to the RAC contractors to seek out improper payments.
- ***Elimination of Consultation Codes.*** The arbitrary elimination of consultation codes from Medicare has devalued the expertise and collaborative nature of consultative services that specialty medical physicians provide.
- ***Stark & Antitrust Regulations***. In their current form, Stark and antitrust regulations do not allow for the level of care coordination between hospitals and physicians that is necessary to improve health care.
- ***National Coverage Determinations (NCDs).*** Data collection associated with certain NCDs places an undue burden on specialty physicians and does not provide them with any clinically useful information.
- ***Medicare's Physician Enrollment Process.*** Medicare's existing enrollment process is confusing and cumbersome, and must be streamlined.

The Alliance provides more detail about each of these issues in the paragraphs that follow, and looks forward to meeting with you and your staff to discuss meaningful changes to the regulations that will improve the business of medicine and the care provided by specialty medicine providers.

PROPOSED REGULATIONS:

Independent Payment Advisory Board (IPAB)

The Alliance repeatedly noted opposition to the creation of the Independent Payment Advisory Board (IPAB) during the debate over the Patient Protection and Affordable Care Act (PPACA). The IPAB receives an inappropriate delegation of Congress' oversight responsibilities and lacks the expertise required to make health care decisions. This will not only have a negative impact on physician practices, but also the quality of care patients receive.

Under current law, the Medicare's Sustainable Growth Rate formula (SGR) will require physician payment rates to be reduced by more than 40 percent over the next decade. Yet, the IPAB could make additional cuts on top of these SGR payment reductions already built into regulation. As a result, beneficiaries are at risk of losing the doctor of their choice as more physicians are forced to limit the number of Medicare patients they see. The PPACA provisions establishing the IPAB will exacerbate the problem because they permit the IPAB to impose arbitrary cuts in Medicare reimbursement rates for some types of providers while excluding others from their purview. There will be pressure to extract deeper cuts from those providers who fall under the IPAB's jurisdiction. The Alliance also believes that the IPAB lacks the clinical expertise and research capacity necessary to ensure that physician practices and the Medicare beneficiaries who rely on their services are not severely affected.

The IPAB, coupled with the SGR crisis, is a "job killer." It has the potential to drive many physicians out of business, putting thousands of jobs at risk, from the staff that they employ, to those employed by support and referral entities, such as medical billing companies and clinical ancillary services.

Accountable Care Organizations (ACOs)

We expect a notice of proposed rulemaking to be released by CMS on Accountable Care Organizations (ACOs) in coming days. We anticipate there will be a significant impact on specialty medicine providers; therefore, we ask that you maintain a continuous dialogue with the Alliance so we can provide feedback to you once we have analyzed the ACO proposal.

EXISTING REGULATIONS:

Value-Based Payment Modifier

Under PPACA, the Secretary is required to apply a separate, budget-neutral payment modifier to the Medicare physician fee schedule. The modifier would, for the first time, link physician payment to not simply successful reporting of measures, but to a physician's performance on a composite set of measures related to both cost and quality. CMS is authorized to select measures as early as 2012, to define an implementation plan by 2013, and to phase in the payment modifier from 2015 through 2017, with the first performance period beginning in 2014. During debate of the health reform bill, most members of the Senate Finance Committee did not support the value-based modifier and the House leadership successfully kept it out of its version of the bill out of concern that the timeline was too ambitious and could lead to serious unintended consequences if not implemented carefully. CMS also has expressed concern that it is unprepared to implement such a complicated policy. The agency has stated that it needs more time to evaluate, modify and re-evaluate ongoing demonstration projects, such as the physician resource use feedback program, which after only a year demonstrated the serious challenges of defining appropriate resource utilization in a manner that is relevant to the Medicare population and of accurately attributing care to a single physician, particularly in cases of complex care involving teams of physicians.

The Alliance shares these concerns and believes it is ill-advised to move on to a system where pay is based on performance when CMS has not even been able to demonstrate the feasibility and effectiveness of current pay-for-reporting programs, such as the Physician Quality Reporting System (PQRS). It is even more concerning that the value-based payment modifier would result in Medicare physician payment adjustments based not only on quality, but on cost. Both public and private payers continue to struggle with how to accurately define and measure appropriate resource utilization in health care and very few trustworthy risk-adjustment mechanisms currently exist. In fact, the RAND Corporation recently issued a series of studies that questioned the reliability of cost profiling. One study found that physician ratings based on cost of care can be incorrect up to two-thirds of the time for some physician specialties while they misclassify one-fourth of all physicians under the best-case scenario used by most health insurers. RAND ultimately concluded that "current methods of physician cost profiling are not ready for prime time" and that "current cost profiling approaches need to be improved, or new approaches need to be developed."

Although we understand the desire to measure and improve both the quality and efficiency of health care, programs that rely on inaccurate ratings to steer patients to select physicians and to alter physician reimbursement will only restrict patient access to the high value care they deserve. CMS and other stakeholders need more time and resources to test valid measures of cost and quality, as well as mechanisms that accurately adjust for riskier, more complex clinical scenarios, before moving forward with a policy that modifies physician payment based on "value." Furthermore, we are strongly opposed to any policy that is budget neutral and arbitrarily takes from one physician to give to another. The value-based payment modifier, as currently authorized, will only interfere with the physician-patient relationship and impede the delivery of high quality specialty care.

Quality Improvement Initiatives

Our physician members are dedicated to improving the quality and overall efficiency of the care of their patients. However, we are highly concerned about inconsistencies in requirements for CMS's various quality-related programs-- including the Medicare Electronic Prescribing (eRx) Program, the Electronic Health Records (EHR) Program, and the Physician Quality Reporting System (PQRS) -- and their effect on the physician's ability to practice, let alone provide high quality care.

The EHR Incentive Program requires a physician to meet meaningful use criteria, one of which is e-prescribing, in order to qualify for a gradually decreasing incentive payment over the years 2011 through 2014. Starting in 2015, penalties will be imposed for those who do not meet the criteria and will increase over subsequent years. Under the eRx Incentive Program, physicians may qualify for a gradually decreasing incentive payment from 2010 through 2013. Starting in 2012, those who do not meet the requirements of this program will be subject to a penalty, which will increase in subsequent years. In addition to these misaligned timelines, CMS recently determined that while physicians can qualify for both the PQRS and eRx Program incentive payments, they are not eligible to receive incentives from both the eRx and EHR Programs simultaneously. Furthermore, those who qualify for the EHR Incentive Program during the 2011 reporting year are not exempt from the 2012 and 2013 eRx Program penalties. Therefore, physicians who qualify as meaningful users under the EHR Program cannot qualify for the eRx incentive, but still must report separately under the eRx Program in order to avoid the penalty. It makes no sense that physicians who only participate in the EHR Program, which entails immediate adoption of a comprehensive EHR that does more than just e-prescribe, will be subject to penalties for not participating in the e-Rx program even though they cannot qualify for incentives under both programs simultaneously.

Adding to the confusion is the fact that the e-prescribing reporting requirements in the EHR Program are more rigorous than the eRx Program requirements and ask providers to report more detailed information on their use of various e-prescribing capabilities. In yet another misaligned policy, the EHR Program requires providers to adopt and use "certified" EHR systems that meet criteria established by CMS, while the eRx Program does not have a certification requirement. This leaves physicians with no assurance that the systems they invest in will meet the eRx Program requirements and protect them from payment penalties.

Furthermore, CMS has decided to base 2012 eRx Program payment determinations on physician reporting during the first six months of 2011. This announcement was made only in December of 2010, leaving physicians with an unreasonably short amount of time to understand these complicated reporting requirements and for professional societies to conduct outreach to better educate their members.

These inconsistent requirements are administratively confusing, cumbersome and unnecessarily duplicative. Moreover, they are incongruous and contradictory to CMS's stated goal of improving the quality, efficiency, and coordination of care, and they may actually encourage physicians to invest in basic eRx systems rather than more robust and meaningful EHRs.

In mid-February, the Government Accountability Office (GAO) issued a report calling on CMS to address these inconsistencies (GAO-11-159). Considering the hard economic times and the fact that physicians already face the threat of substantial cuts through the SGR, it is simply unreasonable and unfair to expect physicians to be able to provide high quality, patient-focused care while also having to contend with these duplicative demands.. Requirements imposed in the name of advancing quality should be reasonable, should not distract from care delivery, and should be relevant to all affected professionals. We urge Congress and CMS to work to better align the various, overlapping Medicare quality incentive programs in order to minimize confusion and prevent the imposition of unjustified financial and administrative burdens on physician practices.

Specific to the PQRS, the Alliance is concerned with the following:

- **Lack of Measures:** At present, the PQRS program lacks measures for many specialty providers. Specialty and sub-specialty physicians should not be faced with penalties if measures are not available or applicable to the patient populations for which they serve.

- **Lack of Feedback Mechanism:** In the 2011 MPFS Final Rule, CMS stated that it would consider options for providing timely feedback reports to participants; however, the agency has yet to outline a proposal

for how this will be handled. Despite this failure, CMS is already posting information on its web site about participation in the program and will soon post performance data.

- **Lack of Appeals Process:** While CMS has created an informal review process, the timeline for making an appeal is far too short and does not offer a comprehensive process that allows for more than one stage of appeal.

- **Limited Reporting Options:** CMS' development of the group practice reporting option (GPRO) II allows a group practice of 2-199 physicians the opportunity to participate in PQRS; however, CMS has put in place an arbitrary cap on this option, only permitting the first 500 groups that apply to participate. In addition, CMS will only permit claims-based reporting for those who participate in the e-prescribing incentive program.

- **Overly complex program:** According to the 2008 information (latest available), more than 153,000 eligible professionals (e.g., physicians and other health care providers) attempted to participate in the PQRS, which is about a 15% participation rate. Of those who participated, about half (85,000) actually earned a bonus. Further, CMS has no process by which to explain to the participants why they did not succeed in earning the bonus. With such a high failure rate and lack of feedback, it is no wonder that the participation rate has remained low.

- **Public Reporting:** CMS' recent public reporting of physician participation and performance in these programs as part of its Physician Compare web site is of significant concern. So far, many providers have found that Physician Compare does not reflect accurate information about their participation. Physicians are gravely concerned that the data posted thus far can be misused and misrepresents their practices to beneficiaries, who are supposed to be served by this information.

Recovery Audit Contractors (RACs)

The Recovery Audit Contractors (RACs) have been tasked with identifying improper Medicare fee-for-service payments–overpayments and underpayments–and are paid a contingency fee determined by the amount of improper payments they identify and collect. These "bounty hunters" have been made a permanent fixture in the Medicare program with the passage of the Tax Relief and HealthCare Act of 2006 and were extended to the Medicaid program as part of PPACA.

Despite several modifications to the RAC program at the request of the medical community, the Alliance continues to have serious concerns about the impact this program has on physicians. We find that the RAC program is extremely burdensome, prompting our members and their staffs to spend an inordinate amount of time responding to RAC requests, and even more time if an appeal is necessary. Our members already work with multiple CMS contractors to identify and prevent inappropriate payments, and we are unclear of the additional benefits that RACs offer to CMS as the agency attempts to eradicate billing mistakes.

Physicians strive for payment accuracy, and the Alliance is committed to working with CMS to ensure the validity of reimbursements. CMS should consider more useful means of reducing payment errors, such as providing adequate education, training, and clarity on its coding and reimbursement policies to providers, which will go much further toward the prevention of billing errors that currently trigger RAC audits.

Elimination of Consultation Codes

A "consultation" is an evaluation and management service provided by a physician (a) at the request of another physician or medical source, (b) to recommend care or provide an opinion, or to determine whether to take over management of the patient's care, and (c) where both the request for a consultation and the resulting report

must be documented in the patient's record. Consultation codes are used most frequently by specialists after patients are referred to them by primary care physicians. Medicare has provided reimbursement for consultation codes since 1982.

In 2010, the Centers for Medicare and Medicaid Services (CMS) eliminated recognition of consultation codes as part of the Medicare Physician Fee Schedule (MPFS). In the rule, CMS cited confusion over inappropriate use of the consultation codes as the primary driver for the policy change. CMS redistributed the work values in a "budget neutral" manner from the consultation codes to other Evaluation and Management (E&M) (ie, office visit), which are predominantly used by primary care physicians, predicting that no specialty would see Medicare revenues decline by more than 3% as a result of the change. We disagree and believe the impact is far greater for many specialists.

Medical specialty groups and the American Medical Association surveyed physicians on the impact of the elimination of consultation codes. Over 5,500 physicians who completed the survey have been forced to take cost-cutting steps to offset revenue losses associated with the elimination of these codes.

- Three out of every ten (30%) have already reduced their services to Medicare patients or are contemplating cost-cutting steps that will impact care.
- One-fifth (20%) have already eliminated or reduced appointments for new Medicare patients.
- More than one-third (39%) will defer the purchase of new equipment and/or information technology.
- More than one-third (34%) are eliminating staff, including physicians in some cases.

In addition, 42% state that their practice revenues have decreased between 5-15%, which is much higher than CMS estimated.

Furthermore, CMS' decision to eliminate payment for consultation codes suggests that the advanced training and unique care provided by specialists is not valued. The E&M services that specialists must now report do not take into account the level of time, intensity, expertise, and analysis involved in a consultation. In addition, it does not account for the consultants' communication back to the referring physician, which continues to occur despite the elimination of payment for this additional work, as this activity is integral to high-quality, well-coordinated medical care.

Overall, the decision to remove the consultation codes from Medicare payment creates an even larger discrepancy between the cost of providing care to our nation's seniors and what Medicare pays for these services. This continued divergence has prevented, and will continue to prevent, specialty physicians from being a viable business. This results in less investment in new medical equipment, staff and facilities.

Stark & Antitrust Laws

A key component to achieving a high quality health care delivery system is through clinical integration. In their current form, the Stark and Antitrust laws prohibit compensation arrangements between physicians and hospitals that would foster clinical integration. As discussed by other health care stakeholders, compensation arrangements aimed at fostering collaboration between physicians and hospitals should be removed from the definition of financial relationships subject to Stark. Without addressing this issue, it will be difficult for physicians and hospitals to develop clinical integration programs aimed at improving patient care through better care coordination. The Alliance agrees that there are other federal laws that address inappropriate financial relationships. In addition, we support the issuance of clear, unambiguous guidance that assists physicians and hospitals in avoiding any antitrust violations as they develop clinical integration programs.

National Coverage Determinations (NCDs)

While not a specific regulation, Medicare's NCD process is a source of great frustration for many members of the Alliance. Arbitrary and unnecessary documentation requirements make NCDs burdensome for providers. For example, an NCD for carotid stenting mandates the collection and reporting of a limited data set for these procedures, yet the data CMS is asking providers to collect is not useful to the providers themselves, or the agency. The Alliance supports the collection of robust data, and several of our member organizations are collecting this type of data through registries. For example, the Society for Cardiac Angiography and Interventions (SCAI) has developed a robust registry that collects data on carotid stenting procedures. The Alliance seeks assistance from you in ending or modifying agency initiatives and processes that do not promote a more efficient, high-quality health care system.

Medicare's Physician Enrollment Process

Medicare's physician enrollment process, specifically Medicare's Provider Enrollment, Chain and Ownership System (PECOS) is the source of significant problems that distract physicians and their practices from their most important work - providing high quality medical care to patients. The internet-based PECOS system was established in 2003, and requires physicians, including those who have been enrolled in Medicare for years or decades, to re-enroll in the program. In addition, the physician revalidation rules require physicians to resubmit and recertify their enrollment information every 5 years to maintain their billing privileges. Unclear guidance and contractor mishaps that are common in the cumbersome enrollment/re-enrollment process can greatly disrupt a physician's ability to remain in practice. Some practices have reported not receiving Medicare reimbursements for several months, forcing them to take out loans to pay their staff and keep the doors open while the situation is addressed. CMS should streamline the enrollment process to ensure that physicians who aim to provide high-quality care to beneficiaries are not negatively affected while the agency works to keep unscrupulous fraudulent providers out of the program.

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The Alliance appreciates your request for proposed and existing regulations that have a serious negative impact on physicians and the practice of medicine. The specialty organizations represented by the Alliance look forward to meeting with you to discuss how these, and possibly other regulations, harm our patients and our ability to maintain viable business operations. Please contact Vicki Hart at info@specialtydocs.org or 202-441-3515 with any questions or comments.

Sincerely,

American Association of Neurological Surgeons
American Gastroenterological Association
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Heart Rhythm Society
Society for Cardiovascular Angiography and Interventions