Sound Policy. Quality Care.

July 8, 2009

Honorable Charles B. Rangel
Chairman
House Committee on Ways and Means
Washington, DC 20515

Honorable Dave Camp
Ranking Republican
House Committee on Ways and Means
Washington, DC 20515

Honorable Henry Waxman
Chairman
House Committee on Energy and Commerce
Washington, DC 20515

Honorable Joe Barton
Ranking Republican
House Committee on Energy and Commerce
Washington, DC 20515

Honorable George Miller
Chairman
House Committee on Education and Labor
Washington, DC 20515

Honorable Howard McKeon
Ranking Republican
House Committee on Education and Labor
Washington, DC 20515

Dear Representatives Rangel, Waxman, Miller, Camp, Barton, and McKeon:

As the Alliance of Specialty Medicine (Alliance), our mission is to advocate for sound federal health care policy that fosters patient access to the highest quality specialty care and improves timely access to high quality medical care for all Americans. As patient and physician advocates, the Alliance welcomes the opportunity to participate in the debate on Medicare and health care reform during the 111th Congress. We sincerely appreciate your work to produce a Tri-Committee draft legislative text for health care reform, and we would like to take this opportunity to provide feedback on issues of importance to specialty physicians.

Physician Payment Update (section 1121). As your draft legislation acknowledges, Medicare's sustainable growth rate (SGR) formula needs to be replaced with a stable mechanism for updating Medicare fees to continue to assure Medicare beneficiary access to high quality care and also to allow Medicare and the health care system to move forward with important system delivery reform. We strongly support your proposal to avoid band-aid solutions and establish a new baseline for physician reimbursement. We also support your proposal to exclude the costs of prescription drugs administered in the physician's office from the SGR formula calculation. In addition, the Alliance recognizes the importance of improving access to primary care for Medicare beneficiaries and strengthening the role of primary care providers. Vigorous efforts should simultaneously strive to maintain appropriate access to specialty care. We appreciate your efforts to shift health care towards preventive care. Preventive care is routinely provided by specialists in a number of different venues and should be rewarded in the same way as preventive care provided by any physician. We also support your efforts to ensure these rewards are not distributed in a budget neutral fashion. Budget neutral funding does not take into account significant reductions specialists have seen in their fees over time for the services they provide. Since the introduction of Medicare's Resource-Based Relative Value Scale (RBRVS) in 1992, specialists have seen significant reductions in the fees they received for procedural services. Many specialty

medical services were cut in 2008 for a second time during this review because of an additional reduction in work values. Specialists continue to lose more ground in the fees they receive for serving Medicare beneficiaries while their practice costs steadily rise.

Physician Quality Reporting Initiative (section 1124). All member organizations of the Alliance are actively engaged in the process of developing evidence-based and clinically relevant quality measures and establishing data registries through initiatives within their own specialty and/or through the American Medical Association's (AMA)Physician Consortium for Performance Improvement. The commitment is to provide the highest quality specialty care to Medicare beneficiaries in a transparent health care system so as to improve patient outcomes. We appreciate your efforts to further improve and refine the Physician Quality Reporting Initiative (PQRI). In particular, we thank you for including changes to PQRI that would allow physicians to access their data in a timely manner, provide physicians with a reasonable appeals process, and ensure that PQRI is not punitive.

We encourage the Committee to consider establishing a public private partnership to provide long-term support for clinical data registries and measure development currently undertaken solely through the limited resources of medical specialty societies. Additionally, the PQRI program should reward physicians who report clinical data to such registries.

Health Information Technology (section 1124). The Alliance is pleased with your proposal to ensure that the clinical reporting on quality measures for PQRI and "meaningful use" definition included within the recently enacted "American Recovery and Reinvestment Act of 2009" (ARRA) (P.L. 111 -5)be more fully integrated. In addition, we would like to take this opportunity to point out some concerns that we do have regarding the current health information technology (HIT) timelines included within the ARRA and urge you to consider amending the current HIT timelines.

HIT has the potential to increase efficiency, improve patient safety, increase the quality of care, and lower health care costs significantly. We strongly support the development of an electronic health information network that is reliable, interoperable, secure, and protects patient privacy. Congress made significant strides toward the implementation of HIT with the passage of ARRA, and the specialty community is appreciative for the opportunities available for physicians to receive enhanced Medicare payments to support the adoption and effective utilization of HIT. Smaller physician practices, which include the majority of the physicians practicing medicine in this country, continue to face barriers to purchasing HIT systems. In addition, for those practices that manage to adopt HIT, it takes a further investment of significant time and resources to use their systems to the fullest capacity. Funding the operation and improvement of these systems will be difficult without reasonable physician fee updates. Like you, we are closely following the implementation of ARRA. In particular, we still are waiting to hear back from the Secretary of Health and Human Services about the definition of "meaningful user."

We also are concerned that many specialty physicians will not be able to take advantage of the enhanced payments to purchase HIT because of the ambitious timelines and the fact that current specialty systems lack certification and interoperability standards. Further, the current **certified** HIT systems have been developed for primary care settings and have not yet been fully adapted for specialty care. The financial incentives and penalties are based on the adoption and "meaningful use" of certified HIT systems and will have a profound impact on our members and their ability to adopt and become meaningful users. Physicians are hesitant to make the considerable investment until certified systems that meet their unique needs are available.
There are specialties that have made significant accomplishments toward achieving interoperable HIT solutions for their members and have been placed on the Certification Commission for Health Information Technology (CCHIT) -- the only recognized certification body that provides a roadmap for HIT Certification. However, due to the obstacles that must be overcome to be identified by CCHIT as one of the planned expansion areas, and the

lack of CCHIT financing and staff, most specialties are not even in the pipeline. In addition, even those who are on the roadmap are facing challenges in the timelines that have been outlined by the Commission.

As a result and under the current timelines, it will be virtually impossible for the majority of specialty physicians to purchase certified systems that are designed for their specialty, become meaningful users, and qualify for the majority of the vitally necessary financial incentives. We continually strive to provide quality care, and we recognize that HIT can play an important role in achieving and maintaining high performance. Therefore, we urge you to consider amending the current HIT timelines included in the ARRA.

Comparative Effectiveness Research (Subtitle A of Title IV, Division B). The Alliance is pleased that your draft legislation includes a provision to expand comparative effectiveness research (CER). Like the Committees, the Alliance believes appropriately designed CER should enhance information about treatment options and outcomes for patients and physicians, helping them to choose the care that best meets the individual needs of the patient. CER needs to recognize the diversity, including racial and ethnic diversity, of patient populations and subpopulations and communicate results in ways that reflect the differences in individual patient needs. It should not be a vehicle for making centralized coverage and payment decisions or recommendations. The Alliance is concerned, however, that the proposed CER structure would be placed within in the Agency for Healthcare Research and Quality (AHRQ). For a number of reasons, we would prefer that Congress establish an independent CER structure. The Alliance supports the Comparative Effectiveness Research Act of 2009 (H.R. 2502), sponsored by Rep. Kurt Schrader, and the Patient-Centered Outcomes Research Act of 2009 (S. 1213), sponsored by Senators Max Baucus and Kent Conrad, and we urge you to replace the current draft CER provisions with ones based on the framework set forth in these two bills. Finally, the Alliance also strongly urges the House to include medical liability protections for health care providers when they follow practice guidelines recommended by the CER entity.

Physician sunshine (Subtitle D of Title III, Division B). The Alliance is pleased that your draft proposal includes a provision similar to the "Physicians Payment Sunshine Act of 2009" (S.301) introduced by Senators Grassley and Kohl. The Alliance believes that while relationships between physicians and Industry are an important component of advancing medical technologies and improving patient care, uniform procedures for transparent disclosure must be in place to minimize confusion and misrepresentation. The proposals outlined will strengthen transparency in the medical profession and uphold the professional standards that professional medical societies have in place to govern interaction between physicians and the pharmaceutical, biologics, and device industry. The Alliance encourages the Committee to adopt language that would provide physicians with the ability to correct inaccuracies in their report and provide background information on their relationships with industry prior to the public release of this information. In addition, we are extremely concerned with your proposed restrictions on funding of continuing medical education courses, which already are managed for conflict of interest through the accreditation process overseen by the American Council for Continuing Medical Education. There is a legitimate place for ethical partnerships between industry and medical associations and this support has long helped support the advancement of cutting edge science, clinical innovation and continuing medical education. Additionally, the Alliance of Specialty Medicine recommends a provision to pre-empt state law.

Accountable Care Organizations and Medical Homes (section 1301 and 1302). The Alliance appreciates the Committee's efforts to allow groups of providers to voluntarily work together to improve quality and save costs. We support exploration of alternative payment systems, including your proposal for both accountable care organization and medical home pilot programs. Access to specialty care has been inadequately addressed in the current proposals. For these alternative health delivery systems to succeed, we believe specialty medicine must be an integral part of the planning and execution of these various models. We appreciate that the proposed accountable care organizations and medical homes are voluntary, but only the medical home pilot program is inclusive of all providers wishing to participate. As you explore these alternative systems, we urge you to

consider the full cost of the treatment of disease and not focus on a single event. Our vision should remain long term and not result in pressure to save money in the short term for a single event or procedure, only to require additional interventions down the road because of choices made in a vacuum. Therefore, it is important to fully test alternative systems to understand their implications on quality of care and determine whether they achieve their stated goals.

Public Health Insurance Plan Option (Subtitle B of Title II, Division A). The Alliance of Specialty Medicine does not have a specific position regarding the establishment of a public plan option; however, we oppose requiring mandatory participation by Medicare providers to also participate in any public health insurance plan. Such a mandate unnecessarily ties the public health insurance plan option to other, current government health care programs. In talking to your staff, we understand that your proposed legislation is not intended to mandate that physicians participate in the program. However, because the Secretary must establish conditions of participation that ensure that there is an adequate network of providers, we strongly encourage you to include a rule of construction that would clarify Congressional intent that the Secretary cannot mandate participation in creating those conditions of participation. We are further concerned that directly linking the payment mechanisms between Medicare and the public health insurance plan is under consideration, even if the rates are slightly increased above Medicare rates. We appreciate your intent to move away from Medicare payment rates after three years. Finally, we support your goal of ensuring an adequate provider network within the public plan so that beneficiaries can maintain critical access to specialists.

Health Benefits Advisory Committee (section 123). The Alliance is concerned with the proposed composition of the Health Benefits Advisory Committee. Specifically, the concern rests with the language which states "at least one practicing physician or other health professional" shall serve on the Committee. While non-physician health professionals serve an important role in the delivery of care, the Alliance strongly supports explicit language that guarantees that a minimum of three physicians representing different specialties will serve on the Committee. As the language is currently drafted, a situation could arise where physicians are not adequately represented on an advisory committee tasked with recommending necessary benefit standards for their patients. The medical expertise that can only be provided by a physician representative would help to advance Congress' goal of incorporating recent health care innovation in determining essential health care benefits.

Adjusting Reimbursement for Over-Valued Physician Services (section 1122). The Alliance is very concerned about your proposal to address suspected over-valued physician services by having the Center for Medicare and Medicaid Services (CMS) directly evaluate and adjust payment for potentially misvalued physician services because this proposal is unnecessary. Already, as part of the Resource-Based Relative Value Scale (RBRVS), the AMA has established the AMA/Specialty Society Relative Value Scale Update Committee (RUC). The RUC provides recommendations to CMS for the valuation of new and revised codes as well as codes identified as misvalued under the Five-Year Review of Work.

In 2006, the RUC expanded its role by forming the Five-Year Review Identification Workgroup to identify on an on-going basis potentially misvalued services, as well as codes for consideration during future Five-Year Reviews. The Workgroup implemented several screens to facilitate an objective comprehensive review of potentially misvalued services. In addition to identifying codes with high volume growth, the Workgroup also screens for site-of-service anomalies, codes that are inherently performed together, and codes with high intra-service work per unit of time.

In fiscal year 2009, CMS issued a proposed rule to accelerate the review of the fastest growing higher cost procedures, including services with potentially unexplained high RVUs and procedures that have not been reviewed by the RUC since the fee schedule was created. CMS has requested that the RUC begin reviewing the identified codes immediately but anticipates that this process may take a number of years due to the large number of services involved. Therefore, there is already a process in place, which assures physician input from a

variety of disciplines and. to examine potentially misvalued physician services. Therefore, we urge you to delete this section from the draft legislation.

Physician-Owned Hospitals (section 1156). The Alliance believes that physicians should have the ability to treat patients in whichever setting they feel offers patients the highest quality of care available. Ethical referral under the current "Stark laws" provides physicians and their patients the opportunity to determine together which setting is most appropriate for the treatment they require. Further, those requirements laid out in the committee proposal not related to patient referral or disclosure of ownership interest are overly prescriptive and not currently required of other non-physician owned health care entities. We urge the committee not to discriminate against physician-owned hospitals.

Development of a National Workforce Strategy (sections 1502, 1504, 2261, and 2271). The Alliance appreciates your consideration of workforce issues within the context of health reform. In particular, the Alliance supports redirection of unused graduate medical education slots. However, the Alliance is concerned that this provision does not take into account particular specialist shortages. The services specialists provide are an integral part of American medicine, and it takes more than 12 years to produce a specialist. If we do not proceed with caution and federal policy discourages young physicians from entering specialty medicine, we will be unable to quickly correct the problem once it becomes visible. Already, there are shortages in many specialty areas which are projected to get worse.

The Council on Graduate Medical Education (COGME), reported that *"In rural areas, there is a clear need for specialty care."*[1] The report goes on to say that *"Though primary care would be an essential area of medical service and training, subspecialty and surgical disciplines are also sorely needed in underserved areas."*[2]

The Bureau of Health Professions (BHP) has cited significant workforce challenges across the surgical specialties. Between 2005 and 2020, BHP projects an increase of only 3 percent among practicing surgeons – with projected significant declines in a number of surgical specialties. Over the same time period, BHP projects that the number of practicing primary care physicians will increase by 19 percent.

The Association of American Medical Colleges (AAMC) published an updated physician workforce study demonstrating essentially equivalent shortages between primary care and surgery. Specifically, the study projects physician supply and demand through 2025 and finds *that "in terms of the general projected shortage of 124,000 FTE physicians, while 37% of the shortage will be in primary care* [46,000]*, 33% will be in surgery* [41,000]…" In addition, the study projects a shortage of 8,000 medical specialty physicians.[3]

Any national workforce strategy must encourage participation by specialty medicine to ensure a stable, balanced workforce to meet future needs.

Improving Accountability for Approved Medical Residency Training (section 1505). Given Medicare's $9 billion annual investment in graduate medical education (GME), the Alliance appreciates the need for accountability in this system. However, we are very concerned about the provisions of the draft legislation that would (1) establish in statute the goals of medical education and (2) require a GAO study to evaluate residency training programs. The Accreditation Council for Graduate Medical Education (ACGME) has a very dynamic and robust system for ensuring that our nation's training programs are meeting the needs of the 21st Century health care delivery system. The six core competencies that must be incorporated into the curriculum of every residency training program – patient care, medical knowledge, practice-based learning and improvement, interpersonal

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[1] COGME 18th Report: "New Paradigms for Physician Training for Improving Access to Health Care," Sept 2007, page 5
[2] Ibid, page 13
[3] The Complexities of Physician Supply and Demand: Projections through 2025, Michael J. Dill and Edward S. Salsberg, Center for Workforce Studies, Nov 2008

and communication skills, professionalism, and systems-based practice – demonstrate that the profession and medical educators are satisfying the goals of this provision of the draft bill. In addition, the individual specialty societies are also evaluating and reevaluating, on an ongoing basis, GME curricula. Medical education should remain in the purview of the profession and medical educations, and the Alliance firmly believes that the ACGME and specialty societies are doing a superb job in educating and training our Nation's future physicians. We therefore urge you to delete this entire section of the bill.

Imaging (section 1147). We are concerned with your proposal to alter the utilization rates for imaging services, especially because it includes ultrasound and X-ray. We urge you to consider the specific costs of more advanced, expensive imaging services and not catalog all imaging services into one category. The MedPAC recommendation only applied to advanced imaging equipment, with a cost of one million dollars or more. Ultrasound equipment cost on average $40,000 -- far less than MedPAC's recommendation.

Your proposal, which would expand the MedPAC recommendation to all imaging modalities, would have a major negative impact on patient care. Ultrasound is the standard of care for many diagnostic and exploratory procedures and has been for well over ten years. For example, urologists cannot and will not perform a guided needle biopsy for prostate cancer without ultrasound imaging to guide the needle. Diagnostic ultrasound is an imaging modality highly regarded for its efficiency and is a critical component of multiple standards of care. If you reduce patient access to these critical imaging services, patients will be much less likely to obtain the necessary treatment in a timely manner. We urge you to exempt ultrasound and X-ray from the proposed change in utilization rates for imaging services.

Quality Measurement (Subtitle C of Title IV, Division B and Title IV, Division C). Your proposal provides additional authority to Secretary of Health and Human Services, working in conjunction with AHRQ, to further strengthen and improve quality measurement and development processes. The Alliance welcomes this proposal and recommends that these resources be used to fill gaps in clinical research that will allow us to build a better supply of evidence-based clinical practice guidelines, to fund clinical data registries and other innovative quality improvement activities, to develop valid risk adjustment mechanisms that will allow us to take full advantage of clinical outcomes data, and to conduct studies on whether currently used measures have any impact on quality and cost.

We also appreciate that the proposal recognizes the need for measures to focus on a range of important areas, including patient outcomes, functional status, patient experience or satisfaction, and care coordination. However, we urge the committee to carefully consider the implications of measuring efficiency. Cost should not trump quality and information accrued from measures should be presented in a manner that is meaningful and actionable to both physicians and eventually patients.

We have concerns about the proposal's continued heavy reliance on only NQF-endorsed measures. The National Quality Forum (NQF) is certainly the most balanced, structured, and fluid of all the current multi-stakeholder groups. However, its ever-expanding size and scope often make it difficult for the NQF to focus on unique quality improvement activities that are most relevant to smaller specialties, such as outcomes measures that rely on clinical data sources.

Geographic Variation (section 1123). The Alliance would like to further explore with the committee the issue of geographic variation in spending and quality. We are disappointed that your proposed legislation focuses on costs and cost reduction rather than first examining treatment quality. A better focus should be reducing geographic variation in quality. Volume and spending have not proven to be accurate surrogate end points for quality. We agree that it is a challenge to identify inappropriate spending and many demonstration projects are underway to examine different ideas. Congress has struggled for decades with the challenge of defining inappropriate volume only to result in policies that treat all volume the same and fail to recognize when

increased volume may result in quality improvement. It is established that there is geographic variation, but much more needs to be understood about the underlying reasons for these differences, including understanding the difference in patient access to care and the difference in physician supply and mix. It is more effective to understand the source of geographic variation and educate physicians about such differences and the resulting patient outcomes with the purpose of improving overall quality of care.

Modifying Beneficiary Contributions (Title II, Division B). While we do not have a position your proposals to modify beneficiary contributions, we agree with the stated goal of protecting patients by exploring maximum out-of-pocket protection, while restructuring cost-sharing in a way that does not allow individuals to totally be insulated from the cost of health care. Physicians and their patients will benefit from a more cooperative relationship and more information on the cost of various services, while protecting access to necessary care.

Medical Liability Reform. We are discouraged that the draft legislation does not touch on the need to address our broken medical liability system as a strategy to achieve health system savings. As you may be aware, President Obama stated in last fall's New England Journal of Medicine that he would be "open to additional measures to curb malpractice suits and reduce the cost of malpractice insurance." More recently, at the American Medical Association's Annual Meeting, the President also noted that we will not be able to implement changes in our health care delivery system that reflect best practices, incentivize excellence and close cost disparities "if doctors feel like they are constantly looking over their shoulder for fear of lawsuits." We therefore strongly urge you to recognize that a serious effort at comprehensive health care reform must include medical liability reform. Patient access to care and quality of care will continue to be threatened without such reform.

Thank you for commitment and leadership on this issue. Please contact Vicki Hart if you have any questions or would like additional information. Ms. Hart may be reached at 202-441-3515 or vhart@hhstrategies.com.

Sincerely,

American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Heart Rhythm Society
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions