Comments

of the

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American College of Osteopathic Surgeons
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American Society of Breast Surgeons
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American Society of Plastic Surgeons
Congress of Neurological Surgeons
Society for Vascular Surgery
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncologists
Society of Surgical Oncology
The Society of Thoracic Surgeons

on the

Senate Finance Committee Policy Options

Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs

May 14, 2009

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Executive Summary

Sustainable Growth Rate

- To reform Medicare's payment system and find more innovative models of Medicare physician payment, Congress must first immediately eliminate the SGR.
- Surgery does not support another short-term "patch" that only temporarily prevents Medicare payment cuts and does not directly address the problems with the SGR.
- Congress must incorporate a realistic budget baseline that provides physicians with positive updates.
- During the transition period to a new payment system, Congress should replace the SGR with a system of separate service category growth rates (SCGR). The four SCGR categories (primary care; other evaluation and management services; major surgery; and all other physician services) would recognize the differences among the various types of services and account for their varied rates of growth, while providing additional dollars for primary care.

Primary Care and General Surgery Bonus

- Surgery supports increased payments for primary care physicians, however the threshold for determining which providers receive a primary care bonus should be set to ensure that only true primary care services are eligible.
- Surgery opposes any measure that would finance increased payments for primary care and general surgery by an across-the-board reduction in payments for all other services.

Workforce

- In order for surgical residency programs to expand in response to increased patient demand, additional patient and educational resources will be necessary. A redistribution of unused residency training positions may begin to address the workforce shortages in primary care and general surgery. Consideration should also be given to lifting residency caps as an option for addressing the emerging workforce shortages in other medical specialties.

Physician Quality Reporting Initiative (PQRI) Improvement and Requirements

- Surgery supports the proposal to allow physicians who participate in Maintenance of Certification (MOC) programs to qualify for PQRI bonus payments, with the following suggested changes:
    - ABMS member board MOC programs or equivalent should qualify
    - Participation in programs required for obtaining initial board certification should qualify
    - MOC practice assessment must not be limited to NQF approved measures
    - The audit process should not be overly burdensome and costly
- Surgery supports the recommended improvements to the PQRI program including the establishment of an appeals process and more timely feedback reports.
- Quality reporting for physicians should remain voluntary and not be mandatory and surgery therefore opposes the implementation of penalties for those physicians who do not participate in PQRI.

- Surgery urges Congress to expand the PQRI to recognize physicians who prospectively report to a clinical data registry or other similar quality improvement database.

Improving Quality Measurement

- Surgery welcomes the additional resources for quality improvement activities. However, we are concerned about the proposal's continued heavy reliance on only NQF-endorsed measures.
- Cost should not trump quality and Congress should carefully consider the implications for measuring efficiency.
- Surgery recognizes the value of public reporting, but urges Congress to carefully consider the unintended consequences associated with releasing individual physician data to the public.

Encouraging Health Information Technology (HIT) Use and Adoption

- Surgery is concerned about the current HIT timelines for bonuses and penalties established in the American Recovery and Reinvestment Act (ARRA). Given continued problems with interoperability and lack of certified HIT systems, we urge Congress to amend the current bonus and penalty timelines so the entire surgical community can participate fully.

Comparative Effectiveness Research

- Surgery embraces the need for well-designed clinical comparative effective research and supports the proposal to establish a comparative effectiveness research system that builds on the framework laid out in the Comparative Effectiveness Research Act of 2008.

Medicare Shared Savings Program

- Surgery supports the development and testing of shared savings payment models for physician, hospital and other provider services.
- If implemented, participation in shared savings programs should be voluntary, non-punitive and not restrict patient choice.
- Congress should amend the Stark physician self-referral and antitrust laws and/or regulations to allow provider collaboration and flexibility in the development of shared savings programs.

Transparency and Evidence-Based Decision-Making for Imaging Services

- Surgery supports the continued ability of physicians to own, operate and refer patients to in-office imaging services and agree that the Stark in-office ancillary exception should be amended to require the referring physician to provide patients with a written disclosure of financial interests and a list of alternate suppliers.
- In those circumstances involving multiple referrals, after the initial disclosure to a particular patient, physicians should only be required to make a disclosure annually to that patient.
- Surgery is fundamentally opposed to the use of radiology benefit managers (RBMs) or other draconian pre-certification requirements for imaging services in Medicare.
- The timeframe for developing and implementing imaging appropriateness criteria is overly ambitious and needs to be changed.

- Any appropriateness criteria system must also apply to radiologists when they make recommendations for additional imaging tests.
- Surgery supports a non-punitive approach to eliminate unnecessary imaging based on education and confidential feedback programs; however we are opposed to the penalty system outlined in the proposal.

Hospital and Readmission Bundling

- Surgery is concerned with the unintended consequences that a hospital readmission and post-acute bundling policy may carry, particularly the potential avoidance of patients with complex medical conditions.
- When the readmission policy is phased out and the bundled payment policy is implemented, a workable and reasonable readmission policy must remain an essential piece of the initiative.
- Congress must also develop a coherent risk adjustment policy as the primary method for preventing the practice of deselecting patients, addressing the readmission issue, and ultimately providing the highest quality and most appropriate level of patient care with these methods of payment.
- Congress should exclude readmissions for a different diagnosis than the original admission in either the hospital readmission or post-acute bundling policy.

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Physician Payment Sunshine

- Surgery strongly supports disclosure and transparency of physician and industry relationships through a single, federal reporting system that preempts state law.
- Physicians should have the opportunity to review and correct information about their financial relationships before those disclosures are made publically available.
- Congress should not include reporting of industry funding for continuing medical education (CME).

Physician Owned Hospitals

- Surgery believes that physician owned hospitals are an important component of our health care delivery system and Congress should not prohibit their development and further expansion.

Medical Liability Reform

- Congress should incorporate certain medical liability reforms in comprehensive health care reform, including: (1) alternatives to civil litigation, such as health courts and early disclosure and compensation offers; (2) protections for physicians who follow established evidence-based practice guidelines; (3) protections for physicians volunteering services in a disaster or local or national emergency situation; and (4) provisions modeled after the laws in California or Texas.

May 14, 2009

The Honorable Max Baucus
Chairman, Senate Finance Committee
215 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Baucus:

We, the undersigned surgical organizations, write in response to the Senate Finance Committee's proposal entitled *Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs*. We appreciate the leadership that you and your colleagues in Congress have dedicated to enacting comprehensive reform of our nation's health care system and we look forward to working collaboratively with you as more substantive details of the proposal are developed.

Much attention has been paid to the need to provide more Americans with access to health care coverage, to increase Americans' access to care, and to improve the value of care delivered in our health care system. Expanding coverage to more Americans and improving the quality of care will mean little if Americans are not able to access the care they need—particularly in potentially life-threatening situations. Without real reform of our Medicare physician payment system, the reform that our health care delivery system needs cannot be achieved. To that end, the surgical community stands united in the effort to bring fundamental and long-term change to the Medicare physician payment system and overall comprehensive reform.

Sustainable Growth Rate (pgs. 16–17)

The surgical community appreciates the Committee's recognition that the sustainable growth rate (SGR) is a failed system for calculating Medicare reimbursement for physician services. We support this effort to reform Medicare's payment system and to find more innovative models of Medicare physician payment and we believe the first step towards this goal is to immediately eliminate the SGR. During the time necessary to transition out of the SGR to more accountable and integrated models of reimbursement of care, we appreciate your commitment to prevent further cuts in Medicare reimbursement. However, we do not support another short-term "patch" that does not directly address the problems with the SGR and believe a realistic budget baseline for future Medicare payment updates, which accurately reflects the anticipated costs of providing physicians with positive updates under a new update system in lieu of SGR-related cuts, should be incorporated into the federal budget. For full-scale health reform to be successful, Medicare's physician reimbursement system must be set on a path toward full-scale and permanent reform.

While there are many good models that could improve quality, better integrate care, and offer a better value in health care, none have been widely tested, and they will require pilot testing, demonstration projects and further study before broader implementation. As a result, the coming years will be critical. We appreciate the Committee's stated openness to considering other options and to that end, suggest a Medicare payment proposal that we believe should be implemented during the transition from the SGR toward these more innovative models of payment and health care delivery.

As an alternative, interim measure, we propose that Congress replace the SGR with a system of separate service category growth rates (SCGR). The SCGR would recognize the differences among the various types of services that physicians provide to their patients, while providing additional dollars for primary care. Unlike the SGR, which bases reimbursement on the overall spending on all physician services, the SCGR would establish a system that determines reimbursement based on the spending and volume growth among like services. As a result, the SCGR would create four categories based on type-of-service:

1) Primary and preventive care;
2) Other evaluation and management (E/M) codes;
3) Major procedures (10 and 90 day global and related anesthesia services); and
4) All other physician services including minor procedures, radiology services, diagnostic tests, etc.

The SCGR, like the SGR, would base the targets for each category on trends in physician spending, fee-for-service (FFS) enrollment, law and regulations, but unlike the SGR, it would replace the GDP component with a statutorily specified allowance. With the exception of E/M, the annual target allowance for the specific categories should be 3.1 percent; to further promote primary care and preventive care, the target for primary care should be adjusted to 5.1 percent and the target for other E/M should be adjusted to 4.1 percent. The targets for 2010 and following years would be actual spending in the prior year for each service category times the SCGR factors. The surgical community also believes that more than three years is needed to ensure appropriate testing and study of innovative payment models and therefore suggest that the SCGR would sunset after five years in anticipation of Medicare moving into fully-tested innovative payment models at that time.

The surgical community believes that the SCGR would have distinct advantages as a transition model to more innovative reforms. First of all, it recognizes that all physician services are not alike, and lower growth services, such as primary care and surgery, would no longer simply be subject to the blunt cuts of the SGR. Under the second option offered in the options document, we are concerned there would simply be a transferring of this blunt instrument from a national to a more local level, but still treating all physician services the same—just on a smaller scale. Second, under the SCGR, efforts to promote specific services, such as primary care, would be greatly simplified, and the proposal would promote increased payments for primary care without requiring corresponding Medicare cuts for other services. Most importantly, the SCGR would support efforts to promote improved quality and better value by recognizing that these goals will look different and will be achieved in different ways for different services. Also, as Medicare studies various payment models, the SCGR could enable Congress and CMS to study and better understand how these physician quality improvement efforts affect spending for hospitals, skilled nursing, home health and other service areas in the Medicare program. In addition, the SCGR could also provide a mechanism to study alternative payment mechanisms.

While reimbursement does not stand on its own as a determining factor for the professional decisions of physicians, if not appropriately addressed, it will over time exacerbate the growing workforce and access problems we are seeing in surgery. Likewise, if Medicare's payment system is not reformed and set on a path to sustainability, it is hard to envision a scenario where there would be enough physicians and surgeons to cover the need that will present as more Americans are added to the rolls of the insured.

Primary Care and General Surgery Bonus (pg. 10)

The surgical community shares your concern regarding the need for a stable physician workforce in primary care and general surgery—particularly in rural areas. One means toward securing a stable workforce is to ensure more stable and appropriate reimbursement. While we support increased payments for our physician colleagues in primary care, we believe that the threshold for determining which providers receive a primary care bonus should be set at an appropriate level to ensure that only true primary care services are eligible. Furthermore, we oppose any measure that would finance increased payments for primary care and general surgery by an across-the-board reduction in payments for all other services. Such measures, while seeking to promote important physician services, could have a negative effect on patients' ability to access other needed services, including surgical care.

It should be noted that these physicians are not the only ones for whom Medicare reimbursement has failed to keep pace with the rising cost of practicing medicine. In fact, since 1989, Medicare reimbursement for many surgical procedures has been significantly reduced. For example, a three vein coronary artery bypass graft surgery (CPT 33512), for which Medicare paid an average of $3,957 in 1989, is now reimbursed at an average of $2,374—a cut of 40 percent in 20 years. Medicare payment reductions have affected a wide range of surgical care including cataract removal (CPT 66984), removal of spinal lamina (CPT 63047), and total hip replacement (CPT 27130), which have been cut 59.38 percent, 51.15 percent, and 43.96 percent, respectively.

As Medicare payments have continued their steady decline over the past few years, significant steps have been taken to improve reimbursement for primary care. In fact, the most recent five-year review by the AMA/Specialty Society Relative Value Update Committee (RUC), approved by the Centers for Medicare & Medicaid Services (CMS), resulted in more than $4 billion in the fee schedule being shifted to evaluation and management (E/M) codes from other services, including surgical care, in 2007. In addition, the most recent review resulted in a 37 percent increase in the work values associated with an intermediate office visit (CPT 99213), the most frequently billed physician service in Medicare. In its March 2009 report, MedPAC noted that Medicare payments for primary care have increased 10.6 percent between 2006 and 2009, which can be attributed largely to the work of the physician community through its work on the RUC.

The surgical community firmly believes that Medicare payment reform is critical to the larger health reform effort. We also believe that the declining reimbursements are not simply a physician problem, but instead, impact the Medicare program system-wide. Therefore, we suggest that, rather than apply budget-neutrality to only physician services, the Committee should share the burden of the broken payment system across the entire Medicare program. While we acknowledge that cost, at least as calculated by CBO, is great, the surgical community believes the cost of inaction or only partial action could be much greater over the years ahead.

Workforce (pgs. 33-35)

Workforce shortages affect nearly all surgical specialties and occur in both rural and urban areas. The *Archives of Surgery* published an analysis last April that showed a decline of more than 25 percent of general surgeons between 1981 and 2005 in proportion to the U.S. population. Looking to the future, between 2005 and 2020, the Bureau of Health Professions projects an increase of only 3 percent among practicing surgeons, with declines projected in thoracic surgery (–15 percent), urology (–9 percent), general surgery (–7 percent), plastic surgery (–6 percent),

and ophthalmology (–1 percent). Further, according to the Association of American Medical Colleges (AAMC) specialties like cardiothoracic surgery experienced an absolute decline in practitioners and a Government Accountability Office study released May 4, 2009 reports a 40 percent decline in applications for cardiothoracic surgery residency positions from 2004-2008. It should be noted that according to the AAMC October 2008 report, the anticipated physician workforce shortage in 2025 is nearly identical for primary care as surgery, with a projected shortage of 46,000 in primary care and 41,000 in surgery. Some experts believe that had a cap not been imposed on graduate medical education (GME), the U.S. would not be faced with such severe surgical workforce shortages.

Addressing this problem presents a unique challenge for surgery. Physicians entering practice will not grow in spite of an increase in medical school graduates. Residency training is the limiting factor in the pipeline for the shortage. The training is rigorous and lengthy and it will take longer to fill the surgical pipeline than to increase the number of other specialists. In order for surgical residency programs to expand in response to increased patient demand, additional patient and educational resources will be necessary. Quality should be a major factor in determining which education and resident training programs should be funded and how additional residency slots will be allocated. Other factors, such as geographic need and minority participation, are also important considerations.

We agree that efforts to expand the number of insured Americans must be accompanied by proposals that will ensure an adequate health care workforce to meet the anticipated increase in demand for health care services. A redistribution of unused residency training positions will begin to address the workforce shortages in areas like primary care and general surgery. However, consideration should also be given in how to address anticipated workforce shortages in other specialties, like cardiothoracic surgery, and subspecialties such as pediatric neurosurgery. Estimating future workforce shortages is not a perfect science and therefore reallocating unused slots - which those specialties may never regain - has the potential to exacerbate already apparent and emerging workforce shortages in some medical specialties unless an option to lift residency caps is included.

The surgical community encourages the Committee to examine other policy options that will create incentives for medical students to pursue training in specialty areas with demonstrated or anticipated workforce shortages, taking into account the severe workforce shortages in surgical specialties. Such solutions should ensure the quality of surgical training and a workforce that meets our nation's unique geographic and population needs.

Physician Quality Reporting Initiative (PQRI) Improvement and Requirements (pgs. 5-7)

Surgical specialties are committed to providing the highest quality surgical/specialty care to Medicare beneficiaries and have been actively engaged in the process of developing evidence-based and clinically relevant quality measures and establishing clinical data registries through their own specialty and/or through the AMA's Physician Consortium for Performance Improvement (PCPI). We applaud and support the Committee's recommendation to make participation in a qualified Maintenance of Certification (MOC) program a new PQRI reporting mechanism. This represents a major step towards recognizing alternative quality improvement activities. MOC exemplifies continuous advancement of physician quality care by emphasizing self-assessment and practice-based learning to ensure that physicians maintain competencies of patient care, professionalism, and overall medical knowledge.

Despite our support for this option, we have four main concerns that we would like to see addressed. First, your proposal defines a qualified MOC program. We recommend that any final proposal specify that a MOC program created and sponsored by a member board of the American Board of Medical Specialties (ABMS) or equivalent qualify for this PQRI option. Second, not all physicians are required to participate in MOC programs, particularly those physicians who have just graduated from a residency training program but have not yet obtained board certification. We therefore encourage you to recognize clinical data collection and other education requirements related to obtaining board certification as activities that qualify for the PQRI bonus. Third, the proposal states that the MOC practice assessment component must use "NQF measures, where appropriate, to derive a set of clinical metrics that are at least equivalent in both the methods and measures used to those of the PQRI program." We ask the Committee to consider what effect this requirement will have on those participants who choose the MOC reporting option over the more traditional reporting options. Physicians who meet the MOC reporting requirement would be held to much more stringent and burdensome requirements than physicians who choose the basic "three measures reported 80% of the time" option, since they must not only collect data through MOC, but reflect on their results and implement a quality improvement intervention.

We recognize that Congress needs a mechanism to ensure that meaningful, valid metrics are being collected and that physicians are not just getting paid to report low-bar measures. However, requiring these MOC programs to incorporate NQF endorsed measures may pigeon-hole those specialties whose MOC programs already incorporate more robust metrics (many of which rely on clinical data, rather than administrative data). Including the NQF-endorsed measure requirement seems to defeat the whole purpose of moving towards more robust, and more clinically-rich, data sources, since it still relies on the same, limited claims-based measure set. Our final concern involves the MOC audit requirement. While probably necessary to some extent, we ask that the requirement not be so burdensome and costly that it discourages Board participation. In any event, most Boards will need to spend time and resources to put one in place that meets the standards of this program, so these facts must be understood if an audit program is established.

We would like to commend the Committee for including recommendations submitted by the surgical community to establish an appeals process and require CMS to provide more timely reports to providers. However, we remain concerned about the continued administrative burden and the lack of evidence substantiating that the PQRI is having a positive impact on quality and the Committee's proposal to extend the PQRI beyond 2010 with a phase-out of positive incentives and the implementation of penalties for those who do not participate.

Ultimately, the surgical community is concerned about the increasing number of "quality and efficiency" measures imposed on physicians without evidence of improved health outcomes, health status, and reduced system costs. We have found that the administrative burden of participating in PQRI has outweighed the current incentive, a problem that is particularly acute for solo practitioners. The proposal presumes the existence of a functioning and well-developed quality measurement infrastructure that for the majority of physicians is not yet established; rather, it is currently under development. Without acknowledgment of the critical differential between the vast majority of specialties and primary care physicians, hospitals, managed care plans and the like, the expectations embedded in this proposal are premature and will not yield

the kind of reporting and performance sought. Therefore, we maintain that quality reporting should remain voluntary and not punitive.

Because of the detailed clinical data that can be collected through clinical registries, we appreciate recent efforts by CMS to incorporate registries as a reporting mechanism in PQRI. However, we are concerned about the continued overwhelming reliance on claims data for quality improvement and public reporting even though we recognize that claims-based reporting makes it easier for many physicians to participate in the PQRI. Claims data, although based on procedure and diagnosis coding, are limited in scope and are rife with inaccuracies and attribution errors. Claims data also is inadequate in capturing meaningful physician performance if limited to one setting (e.g., inpatient or outpatient). Therefore, we urge the Committee to consider expanding the PQRI, so that it recognizes physicians who engage in other quality improvement activities, such as prospective reporting to a clinical data registry or other similar quality improvement database. Clinical data registries, especially those linked to electronic medical records, offer the benefit of claims data, while also allowing for more accurate attribution and the collection of more detailed data over time, such as quality of life, patient experience, and outcomes data. In addition, continuous data collection through registries also is an excellent method for identifying specific patient characteristics that could serve as predictors of improved outcomes and for identifying and validating meaningful process measures.

Improving Quality Measurement (pgs. 21-23)

Building on the provision set forth in the Medicare Improvements for Patients and Providers Act (MIPPA), the committee proposes to provide additional resources to HHS, working in cooperation with AHRQ and CMS, to further strengthen and improve quality measurement and development processes. Surgeons welcome this proposal and recommend 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/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 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.

Finally, the proposal calls on the HHS Secretary to "develop a strategy for improving the public reporting of quality and performance information." While we recognize the value of public reporting and the need to improve the manner in which information is distributed to various stakeholders, Congress must very carefully consider the unintended consequences associated

with releasing individual physician data to the public prematurely. If measures are not meaningful and data are not adjusted accurately (and few valid risk-adjustment mechanisms currently exist) or presented in an understandable manner, it may create further confusion among patients, limit patients' access to care as physicians avoid high-risk patients or otherwise game the system and/or unfairly harm the reputation of a physician and increase one's exposure to medical liability. Public reporting, if adopted prematurely, creates perverse incentives and discourages the very collaborative spirit and trust that is currently needed among health professionals. Furthermore, the measures on which public reporting would be based have not yet been tested and their true effect on quality/cost is unknown.

Encouraging Health Information Technology Use and Adoption (pgs. 19-21)

Health information technology (HIT) has the potential to increase efficiency and quality of care, and to lower health care costs significantly. The surgical community strongly supports the development of an electronic health information network that is reliable, interoperable, secure, and protects patient privacy. Congress made significant strides towards the implementation of HIT with the passage of the *American Recovery and Reinvestment Act of 2009* (ARRA) (PL11-5), and we are appreciative for the opportunities available for physicians to receive enhanced Medicare payments to support the adoption and effective utilization of HIT. Given HIT's potential positive impact on the health care system, the proposal's recommendation to expand the eligibility for the electronic health record Medicare incentive payments to include nurse practitioners and physicians assistants seems appropriate.

As HIT moves forward within comprehensive health care reform, the surgical community is concerned, however, about the current HIT timelines for bonuses and penalties established in ARRA. Smaller physician practices, which include the majority of the physicians practicing medicine in this country, continue to face barriers to purchasing HIT systems. The financial incentives and penalties are based on the adoption and "meaningful use" of **certified** HIT systems. However, current, certified HIT systems have only been fully developed for primary care settings, and have not yet been fully adapted for specialty/surgical care. Physicians are hesitant to make the considerable investment until the systems are certified and meet their unique needs and appropriate interoperability standards have been developed.

Some surgical specialties are taking steps toward achieving interoperable HIT solutions for their members and have been placed on the Certification Commission for Health Information Technology (CCHIT) roadmap for HIT certification. CCHIT is the only recognized certification body. However, the majority of surgical specialties are not on the roadmap because of the significant 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. Furthermore, due to the time it takes to move through the CCHIT process, even those specialties currently on the roadmap will face significant challenges meeting the HIT timelines.

Because of the existing HIT challenges and limitations, it will be very difficult for the majority of specialty/surgical physicians to purchase certified systems designed for their specialty, become meaningful users, and qualify for the majority of the vitally necessary financial incentives under the currently established timelines. We recognize that HIT will play an important role in achieving and maintaining high quality care and performance and, therefore, urge you to amend the current HIT bonus and penalty timelines included in the ARRA so the entire surgical community can participate fully.

Comparative Effectiveness Research (pgs. 24-25)

The surgical community embraces the need for clinical comparative effectiveness research (CER) and we commend your work to advance legislation on CER. We believe that well-designed comparative effectiveness research can be a valuable tool in meeting our health care challenges and supporting high quality clinical decision-making. Proposals to expand government-supported CER, if appropriately structured, can benefit patients by supporting health care decisions that best meet individual needs, improve overall quality of care and support continued medical progress.

At the same time, such research can be misapplied in ways that restrict patient access to optimal care, undermine physician/patient decision-making, and discourage continued medical progress. We are very pleased that the CER provision in your latest policy options document acknowledges the value of well-designed CER, the importance of continued medical innovation as part of the solution to cost and quality challenges in health care, and the need to ensure that proposals to expand the government's role in CER are centered on patient and provider needs. Surgeons are thrilled that the American Recovery and Reinvestment Act (ARRA) has provided significant "seed" money to begin conducting CER; however we are concerned that there is no appropriate structure or framework in place to oversee the CER enterprise and ensure that this research adheres to certain important principles. We ask that you consider the following principles and ensure that the legislation:

- focuses on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations;
- provides information on clinical value and patient health outcomes, not cost-effectiveness assessments;
- recognizes the diversity, including racial and ethnic diversity, of patient populations and subpopulations and communicates results in ways that reflect the differences in individual patient needs;
- examines all aspects of health care including care management, medical interventions, benefit design, and processes of care for all patients;
- establishes a governance structure that ensures appropriate experts are appointed to research advisory panels (e.g., physicians who are involved in treating the disease or disorder under consideration) and adequate physician representation on any CER Board;
- ensures full transparency and adequate opportunity for surgeons to have input into the development of CER priority topics, research project methodology, and final CER findings;
- provides physicians with certain medical liability protections (e.g., an affirmative defense that the doctor complied with the guidelines and therefore cannot be liable) when they follow clinical practice guidelines that are based on CER recommendations.

The surgical community believes that the Comparative Effectiveness Research Act of 2008 represents a strong starting point that is consistent with organized surgery's principles, and we support the proposal in the Committee's paper to build off this framework as you advance health care reform legislation.

Medicare Shared Savings Program (pgs. 17-19)

The surgical community believes that a reformed health care delivery system should encourage providers to collaborate and provide patient-centered care with the goal of improving quality and creating cost savings and shared savings programs can appropriately align incentives between stakeholders to improve the quality of care for patients leading to reductions in costly complications, the creation of quality guided resource utilization, and the achievement of sustained savings. We support the development of incentive programs that allow physicians to participate in the sharing of savings generated by quality improvement efforts. Care must be refocused around the needs of patients, and systems of delivery should allow and encourage – rather than discourage – collaboration and accountability among health care providers and across sites of care. The surgical community therefore recommends that Congress require the Secretary of HHS or the Government Accountability Office to fully evaluate the shared saving programs and report back to Congress within 5 years of enactment of this provision before a more expanded, permanent shared savings program is implemented.

The term "shared savings" has been used to describe a variety of potential payment models, including accountable care organizations (ACO). The success of the ACO concept will depend largely on how this entity is organized, as well as how the structure would effectively provide care for uncommon, yet costly diseases. The reality is that the incidence of various disease processes in the general population is quite variable, and therefore the "minimum population size" on which an ACO might take risk in an actuarially sound manner varies widely by the type of disease in question. An ACO would have to enroll millions of patients to develop significant expertise in the management of these disease entities, and the structure and financing of ACOs must not provide incentives to retain the care of these types of patients within care organizations without the experience and expertise to provide the best patient care. We recognize the need for improved coordination of care and reduction of resource utilization, but we suggest that improvements in health information technology, particularly interoperability and outcomes data feedback, are central to improved care coordination and more effective resource utilization.

We agree that if implemented, participation in shared savings programs should be voluntary, non-punitive and not restrict patient choice. We also agree with the inclusion in the criteria the requirements that the entity have in place both contracts with a core group of specialist physicians and processes to promote evidence-based medicine, report on quality and costs measures, and coordinate care.

As various shared savings programs models continue to be tested and explored, the surgical community urges the Committee to strongly consider policy changes that will allow for flexibility in the development these programs. Specifically, we support a new, targeted exception to the physician self-referral (Stark) laws to permit provider arrangements, such as those between hospitals and physicians that foster high quality, cost-effective care through economic incentives. Another hurdle is the antitrust laws and/or the enforcement policies of the Department of Justice and Federal Trade Commission. Changes must be implemented to ensure that providers who wish to collaborate by forming an ACO do not run afoul of the antitrust laws. A number of attempts at shared savings programs involving cardiothoracic surgeons, including one sponsored by the Virginia Cardiac Surgery Quality Initiative, have been derailed due to concerns by the Office of the Inspector General and the Department of Justice regarding violations of physician self referral and civil monetary penalty laws. These programs have demonstrated the ability to

generate improved outcomes through reductions in post-operative complications and thus to reduce costs. We believe that it is good public policy to enable these types of programs.

Transparency and Evidence-Based Decision-Making for Imaging Services (pgs. 7-9)

Transparency in Self-Referrals

In order to increase transparency, the Committee proposes to amend the Stark in-office ancillary exception (IOAE) for certain imaging services by requiring the referring physician to provide a written disclosure of financial interests and provide patients with a list of alternate suppliers.

The surgical community agrees that increased transparency is of value to the health care system when the quality and quantity of information provided to patients is *accurate, understandable, and actionable*. We agree that physicians should discuss all options regarding alternative facilities and that the patient should be fully informed of his/her choices and allowed to make the final determination as to where to receive care. Furthermore, the surgical community believes that surgical specialists that are experienced in diagnostic radiologic methods are fully competent to supervise the performance of and interpret imaging studies in their offices for the evaluation and management of certain conditions. Many surgeons perform the immediate and timely interpretation of imaging studies, correlate these studies with clinical findings, and assume the responsibility for determining the treatment of their patients. The quality and accuracy of imaging studies and interpretations performed by these surgeons are consistently high.

As the details of the proposal are further developed, the surgical community urges the Committee members to consider, with respect to frequency of disclosure, the utility and burden of providing patients with a list of alternate suppliers "at the time of referral." In particular, we are concerned about multiple referrals to the same patient, the usefulness of subsequent disclosures, and the burden to the patient and physician. Providing the list to the same patient in multiple instances will neither improve quality nor lower costs, and it risks confusing the patient and adding administrative costs. We propose that, after the initial disclosure to a particular patient, physicians would then be required to make a disclosure annually to that patient. With a clarification regarding the frequency of disclosure and provision of alternate providers to a single patient, the surgical community agrees that transparency and informed decision-making can increase the integrity of our health care system.

Promotion of Adherence to Appropriateness Criteria for Imaging Services

The surgical community understands that imaging services represent one of the fastest growing categories of services in the Medicare physician fee system and this growth is unsustainable and we are therefore committed to working with Congress to identify and reduce unnecessary diagnostic imaging services.

A considerable amount of imaging is utilized because of defensive medicine practices and risk avoidance due to medical liability concerns. Indeed, one study by Elliot Fisher, MD, MPH, concluded that the overuse of imaging services was driven by medical liability fears and was associated with an increase in total Medicare spending of more than $15 billion between 2000 and 2003. This being the case, any legislation aimed at curbing inappropriate imaging services must recognize that the current medical liability system is driving physicians to order more tests to protect themselves, whether the tests are clinically necessary or not.

Another reason for increased imaging utilization relates to the underlying quality of the scan. It is not uncommon for a surgeon to evaluate a patient who comes in with an MRI or other image only to discover that the scan is of poor quality. This then requires the surgeon to order another scan before he or she can make a definitive decision to proceed or not with a particular surgical procedure. We are hopeful that the imaging accreditation provisions of the Medicare Improvements for Patients and Providers Act (MIPPA) will adequately address the gaps in quality of imaging equipment, which we believe will require surgeons to order fewer scans due to poor quality.

With regard to the specific options outlined in the paper, we have the following comments. At the outset, the surgical community is fundamentally opposed to the use of radiology benefit managers (RBMs) or other draconian pre-certification requirements for imaging services in Medicare. Surgeons are already burdened with enough paperwork and mind numbing regulations, and to add yet another layer of rules, requirements and hoops through which a surgeon must jump to care for his or her patient is unacceptable. We therefore appreciate that the options paper recognizes a different approach to managing medical imaging volume.

Having said that, however, we have a number of concerns and questions that we believe need to be addressed before this new system becomes law:

- The timeframes for implementing this new program are overly ambitious.

  - One year is simply not enough time for the national standards organizations, physician specialty societies and other stakeholders to develop valid appropriateness criteria, the process by which physicians would report their use of imaging and a system to ascertain whether they have adhered to such criteria. This could not be accomplished until the end of 2011 at the earliest.
  - While we certainly favor a confidential education and feedback program, the program should not begin until 2013, which would allow the appropriateness criteria to be developed and available for use in 2012.
  - We are opposed to the penalty structure outlined in the proposal, but should Congress nevertheless implement such a structure, penalties cannot be imposed until 2014 at the earliest until physicians have had the opportunity to reflect on their confidential feedback and adjust their ordering patterns.

- How will physicians access the appropriateness criteria and report required data? Who are the vendors? Which registries will be used? Will individual specialty societies that have created their own clinical data registries be able to incorporate this in their own systems or will physicians be expected to report to yet another data management system? Congress must keep in mind that not every physician has the necessary EMR/HIT system to participate.

- Who determines which criteria apply, particularly if there are different opinions offered by different specialties?

- Will the appropriateness criteria and penalties also apply to radiologists who often make additional imaging recommendations to encourage the ordering physician to do additional

(and usually more expensive) tests? When this happens, the ordering surgeon may not agree that an additional test is necessary, but if he or she fails to follow the advice of the radiologist the surgeon may face a potential medical liability problem.

- As stated above, surgeons support a non-punitive approach to help eliminate unnecessary imaging and we support the proposal to establish an education and confidential feedback program on patterns of imaging and adherence to appropriateness criteria. Organized surgery is fundamentally opposed to the 5 percent reduction on all outlier physicians' fees. If a penalty system is put in place, it should be altered and somehow only tied to the value of the imaging services, rather than all services ordered by an individual physician. In addition, the penalty should not be for an entire year, but rather for a shorter period of time, particularly if tied to an education and feedback program.

- Because, as stated above, surgeons are sometimes forced to order scans that may not be deemed clinically appropriate, we suggest that any data collection and education and feedback program also seek additional information from the ordering physicians such as whether or not they ordered the test for defensive medicine reasons and/or because the quality of the original scan was poor, necessitating an additional test.

The surgical community is willing to assist Congress in finding an appropriate mechanism to reduce unnecessary diagnostic imaging. At the same time, however, we need to make sure that the solutions to this problem do not unduly interfere with physician and patient treatment decision making in a way that delays or restricts patient access to necessary services.

<u>Hospital and Readmission Bundling (pgs. 13-16)</u>

The surgical community understands that current methods of reimbursement by government programs and private insurance offer little incentive to help control the cost of delivering care and supports efforts of all stakeholders to develop and evaluate payment methodologies that will incentivize coordination of care among providers and help curb health care inflation. However, the surgical community is concerned with the unintended consequences that a hospital readmission and post-acute bundling policy may carry.

The patient must be the focal point of any initiative and therefore the system must not create incentives to treat healthier patients and limit access to sicker patients. One possible consequence is deliberate deselecting of complex or risky patients. As is already occurring, we are concerned that physicians may find it even more difficult to treat their most complex, vulnerable patients. We are also concerned that physicians may be subjected to facility pressure to discharge a patient earlier or later than medically necessary and/or to an inappropriate post-acute setting. We encourage the Committee to ensure that the payment policy facilitates a provider's ability to decide the most appropriate facility in which the patient should receive care.

Additionally, when the readmission policy is phased out and the bundled payment policy is implemented, a workable and reasonable readmission policy must remain an essential piece of the initiative. Unavoidable, planned, scheduled, or extreme cases of high risk readmissions will still need to be addressed in the development of a bundled payment methodology between the hospital and post-acute provider. Developing a coherent risk adjustment policy is the primary method for preventing the practice of deselecting patients, addressing the readmission issue, and

ultimately providing the highest quality and most appropriate level of patient care with these methods of payment.

The surgical community applauds the Committee's recognition of the need for risk adjustment to adequately account for a "patient's severity of illness and differences in case types" when calculating the readmission benchmark and the recognition of readmissions that are planned, scheduled, unavoidable, and/or related to extreme cases of high risk. We encourage the Committee to include provisions for both readmissions and bundled payments that require risk-adjustment for patient demographics, co-morbidities, severity of illness, and procedure-specific characteristics that account for the differences that contribute to outcome and costs of treatment. The surgical community understands that risk adjustment is a costly and complicated task and, therefore, proposes that the Committee require the federal agencies to work with the individual specialty societies when developing, implementing, and evaluating the metrics for risk adjustment. As is always the case, when stakeholders are involved in the decision making process, the support and participation follows.

The surgical community would like to highlight the importance of excluding readmissions for a different diagnosis than the original admission in either the hospital readmission or post-acute bundling policy. It is important to avoid the unintended consequences of restricting choice and/or encouraging denial of care based on a payment policy. We encourage the Committee to ensure that an all-cause approach to readmissions and bundled payments is not taken.

Ultimately, we must have safeguards to protect both the patient and the equity and role of providers. Policies should not create a system where each entity is imputing blame on the other. Before proceeding with hospital readmission and post-acute bundling policy, we urge the Committee to consider the necessary resources, structure, and cultural changes necessary to reasonably implement such a policy.

Necessary Safeguards to Protect Patient Access to Quality Care:

- The patient should be the primary focus of all initiatives.
- The patient should be empowered to be a fully participating stakeholder in their health care process.
- The patient's access to quality care should always be a priority over cost savings.
- No stakeholder should be incentivized to limit care or provide unnecessary care.
- The physician should be the patient's primary advocate for their unique medical needs.
- All stakeholders should disclose potential conflicts of interest when providing patient care.
- Patients should maintain access to a variety of necessary providers and facilities.

Necessary Safeguards to Protect and Facilitate Provider Alignment:

- One provider should not have control over another provider.
- The burden to improve quality and affect cost savings should be on all providers and stakeholders.
- The process should be transparent so that all financial incentives and any revisions are known by all stakeholders.
- The initiative should align providers to collaboratively work together.
- All stakeholders should be represented when developing initiatives to align payment and incentives.

- The payment should be agreed upon prior to delivering care.
- All stakeholders should be represented when creating a method of distribution for payment.
- The compensation for work should be fair and reasonable for all providers.
- Payment should be risk adjusted for patient and procedure specific characteristics.
- The implementation should be equitable for all patients and providers.
- Competition should be maintained in the health care system.
- A provider should have the autonomy to provide care that addresses each patient's unique medical needs.

Physician Payment Sunshine (pgs. 25-27)

The surgical community strongly supports disclosure and transparency of physician and industry relationships and believes that a reliable system of transparency will reinforce ethical standards that have long governed the practice of medicine. We support the Committee's requirement that the reporting and disclosure requirements would preempt state law. To reduce reporting errors and minimize public confusion, the surgical community believes that a national standard of reporting is preferable to the patchwork of state laws that would be created should the requirements allow states to go beyond what would be covered under federal law. The surgical community believes it is critically important that physicians have the opportunity to review and correct information about their financial relationships before those disclosures are made publically available. To that end, we support the Committee's provision that allows the submission of corrections and requires stakeholder input on the development of the reporting procedure. Finally, we believe the proposal should not be expanded to include reporting of industry funding for continuing medical education (CME). CME has long advanced the educational foundations and cutting edge science of our medical system, and issues relating to disclosure have not been thoroughly vetted. The complexity of this issue was evident during MedPAC's deliberations last year and we believe this issue must be thoughtfully considered and debated.

Physician-Owned Hospitals (pgs. 27-29)

The surgical community believes that physician-owned hospitals are an important component of our health care delivery system. Physician owners in physician-owned hospitals have greater control over the facility and the quality and efficiency of care (e.g., scheduling of surgeries, surgical equipment, staffing, etc.) which lead to higher quality patient care. Furthermore, these facilities tend to have greater patient satisfaction, reduced costs, and lower infection rates.

While the document contains a number of thoughtful options to reform our health care delivery system, it proposes language that will have significant and harmful affects on the 218 existing physician-owned hospitals and the eighty-six projects under development. Significantly, it will prevent physicians from owning hospitals in this country in the future.

Currently, hospitals that have physician ownership are located in 31 states across the country and provide diversity of location, specialty, and ownership. Of the 218 hospitals that are currently active, 18 are general acute-care facilities, 150 are multispecialty (includes surgical, women's and children's hospitals), 18 are rehabilitation hospitals, 19 specialize in cardiac care and 13 focus on orthopaedics. More than half (117) are joint ventures with not-for-profit, general acute

care hospitals and health systems. The remaining entities are a mixture of joint ventures with for-profit hospitals and corporate investors or are owned entirely by physicians. Although the debate over physician ownership may have started with specialized facilities in a few states, it now affects hospitals of all variations. Because of this wide geographic impact, the proposed legislation will disrupt access to medical care in many communities.

Resulting from a study of physician-owned hospitals required by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, the Federal government in 2005 reported that structural measures of quality, such as staff specialization, clinical staff per patient, and complication rates, all suggest good performance on the part of physician-owned hospitals and demonstrate very high quality of care. Mortality rates were also shown to be significantly lower in physician-owned hospitals than in other community hospitals. For all medical procedures analyzed by the U.S. Department of Health and Human Services (HHS), there was a measurable statistical significance. In addition, complication rates at physician-owned hospitals are measurably lower than at general hospitals. According to the HHS study, patients are 3 to 5 times more likely to experience complications at general hospitals than at physician-owned hospitals. All of the HHS results were adjusted for patient acuity.

In a survey conducted in 2008 by Lake Research Partners, an independent third party, it was determined that "The American public believes doctors would do a good job running hospitals in their community, and they want doctors to make decisions about patient care and how hospitals are run. They believe doctors should be allowed to own hospitals where they work and that Congress ought to vote to allow this practice to continue." Two-thirds (67 percent) of the American public believes physicians would do an excellent or good job running a hospital in their community. Additionally, physicians are the American public's first choice (over hospital administrators) of the person(s) they would prefer to see in charge of hospitals in their communities. (March 2008 telephone survey of 1,000 adults nationwide, conducted by Celinda Lake of Lake Research Partners).

Not only do physician-owned hospitals deliver high quality medical care to the patients they serve, they also provide much needed jobs, pay taxes, and generate significant economic activity for local businesses. In its 2005 study, HHS concluded that, considering uncompensated care and tax payments, physician-owned hospitals returned a net community benefit as a percent of total revenue almost 8 times higher than non-profit hospitals, averaging 7.23 percent in net benefit as compared to .87 percent for non-profit hospitals. Physician-owned hospitals have a huge economic impact at the national, state, and local levels.

The surgical community believes legislation limiting physician ownership is bad for health care, bad for business, and bad for Medicare beneficiaries who receive care at the many physician-owned and operated hospitals throughout the country and urge the Committee to not include any legislative language that would discriminate against physician-owned hospitals.

Liability System Reform

While the surgical community is acutely aware of the current challenges in passing federal medical liability reform legislation, we nevertheless believe that there are a number of approaches that would be worthwhile to pursue. To alleviate the medical liability crisis and ensure patient access to surgical services, the Committee should consider incorporating the following medical liability reform ideas in comprehensive health care reform legislation:

- Studying alternatives to civil litigation, including: early disclosure and compensation offers; the administrative determination of compensation model; and health courts;
- Providing medical liability protections for physicians who follow established evidence-based practice guidelines;
- Protections for physicians volunteering services in a disaster or local or national emergency situation; and
- Modeled after the laws in California or Texas, which includes reasonable limits on non-economic damages.

Reform of our nation's health care system covers a range of important issues, from covering the uninsured to expanding patient access to care, from improving the quality of care to containing the growth of our nation's rising health care costs. A myriad of problems and challenges calls for not one but many steps and solutions to put us on the path to extending the possibility and promise of quality health care to all Americans. We must proceed deliberately and thoughtfully to ensure that the policy changes we make today do not lead to unintended consequences that could undermine Americans' access to quality care. The surgical community looks forward to working with the Committee in the weeks to come to reform our nation's health care system and to preserve and improve Americans' ability to access high quality surgical care and health care services.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American College of Osteopathic Surgeons
American College of Surgeons
American Osteopathic Academy of Orthopedics
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society for Metabolic & Bariatric Surgery
American Society of Plastic Surgeons
Congress of Neurological Surgeons
Society for Vascular Surgery
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncologists
Society of Surgical Oncology
The Society of Thoracic Surgeons