

July 20, 2005

The Honorable Nancy L. Johnson
Chair, Subcommittee on Health
Ways and Means Committee
U.S. House of Representatives
Washington, DC 20515

Dear Mrs. Johnson:

The undersigned surgical specialty organizations are grateful for your leadership in developing and promoting reforms to the Medicare physician payment system. In particular, we appreciate your efforts to balance calls for restructuring current physician payment incentives with the need to eliminate the sustainable growth rate system that has destabilized the program and now threatens the financial viability of physician practices and patient access to care.

As the Ways and Means Health Subcommittee continues to review these issues, especially the many practical concerns involved in developing a meaningful value-based purchasing program, it is important to keep in mind the diversity of physician practices and services. In particular, it seems that much of the discussion to-date has focused on ambulatory services such as chronic disease management and preventive care, with little acknowledgement of the very different concerns associated with acute care procedures or hospital-based care. Even within surgery, there are substantial differences between hospital and ambulatory services that must be taken into account. The implications and the strengths associated with such diversity must be assessed carefully if the changes that are being considered for the Medicare physician payment system are truly aimed at improving the quality and processes of patient care.

With that in mind, surgery offers the attached framework for consideration if Congress is to develop a broad-based quality improvement program for Medicare. Like your draft legislation, this framework envisions a phased approach that begins with broadly applicable and relevant measures that can be reported by physicians through administratively simple means. The starter set of five potential surgical measures addresses key patient safety goals and can be implemented promptly. Over time, more complex specialty- and service site-specific measures and systems—including but not limited to those described in the document—can be developed to ensure broad applicability and participation across specialties and across sites of service.

Thank you again for your leadership and your support. We all look forward to working with you further on developing effective Medicare payment system reforms.

Sincerely,

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 Surgeons
American Society of Cataract and Refractive Surgery
American Society of General Surgeons
American Society of Plastic Surgeons
American Urological Association
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

cc: Members of the Ways and Means Committee

DEVELOPING A QUALITY IMPROVEMENT FRAMEWORK FOR SURGICAL CARE

Surgical organizations have long stood for quality and safety. They were among the first to champion peer review reporting in morbidity and mortality conferences, and were at the forefront of developing standards for the facilities in which surgical care is provided. Although surgeons continue to advance evidence-based care, surgical specialists and the research and processes they have developed have largely been omitted from recent debates on ways to report and measure healthcare quality in a Medicare pay-for-performance program. Instead, the focus has been principally on public health and primary care services, and on processes that are relatively simple to measure through ambulatory service claims. If policymakers begin to pursue the development of pay-for-performance, surgical participation is vital.

It is important to highlight key distinctions in surgical quality improvement from preventive and chronic care quality measures. For example, surgery is more episodic and less focused on chronic disease management, preventive services, and screening. In surgery, the ultimate outcome produced by a specific intervention is much more immediate and clear than disease management strategies that may span many years. As a result, surgery lends itself much more readily to rigorous clinical outcome measurement. And, while it is typical for generalist physicians to see a wide array of patients, surgeons tend to have more focused areas of practice that make it difficult to apply broad quality measurement sets. Administrative records other than the operative report—such as claims records—provide much less useful information about processes of care because of the way surgery is packaged and billed. Finally, successful patient management in a primary care setting generally results in increased utilization of preventive services. In surgery, “more” rarely means “better” care. For surgery, the best measures focus on elaborate decision-making processes that call for direct action to determine the right procedures, at the right time, for the right patient. Surgical quality initiatives limit acute complications and provide immediate cost savings, with enhanced outcomes and improved operational efficiencies through process development.

Of course, individual physicians and specialties are in different stages of preparedness for participation in meaningful pay-for-performance programs. Some individuals do not have access to sophisticated information technology that facilitates participation, and some specialties have yet to develop the rigorous clinical evidence that is needed to identify processes of care that improve patient outcomes. Nonetheless, there is general consensus among leading surgical societies on an overall framework for any program intended to promote high-quality surgical care.

We envision a phased approach that will afford a process of continuous improvement in the overall quality of surgical patient care while allowing further progress on the development, testing, and refinement of new measures.

First Phase

Phase I would essentially implement a “pay for reporting” system focusing on administratively simple, self-reported information about processes that are widely accepted and promoted for their contribution to improving patient safety and advancing the principle of patient-centered care—which are among the aims included in the Institute of Medicine’s framework for improving the health care system, *Crossing the Quality Chasm*. In this phase, which can be implemented through claims-based reporting, we envision a set of standards that assures the surgeon’s role in improving quality and safety. These standards might include the following:

- **Confirmation of Operative Site and Side.** While rare, wrong-site or wrong-patient operations do occur. A wide range of physician organizations and specialty societies, along with other provider groups, payers, and accreditation organizations have not only called on surgeons but also on surgical team members and patients to ensure that the operative site is appropriately signed and confirmed by either the patient or a representative for the patient. So-called “sign your site” programs have been endorsed by the Joint Commission on the Accreditation of

Healthcare Organizations (JCAHO), Agency for Healthcare Research and Quality (AHRQ), Department of Veterans Affairs (VA), American Academy of Orthopaedic Surgeons, American College of Surgeons (ACS), and other national organizations representing surgical specialists and perioperative nurses.

- **Pre-Operative “Time-Out.”** When errors do occur in the operating room, poor communication among surgical team members is often cited as a key cause. In addition, after signing the site for surgery, a variety of circumstances, such as a change in scheduling or operating rooms, can occur and potentially lead to a wrong-site or wrong-patient procedure, or to an operation for which the surgical team lacks the necessary tools or equipment. For these reasons, a broadly-endorsed technique known as the surgical “time-out” --a checklist type process based on airline safety practices—should occur prior to making the surgical incision. This process is currently endorsed and promoted by JCAHO, AHRQ, the VA, and a variety of national organizations representing members of the operating room team, including ACS.
- **Immediate Post-Operative Documentation.** In addition to improving communication through a pre-operative time-out for the surgical team prior to surgery, an important aspect of patient care is to prevent so-called “hand-off” errors by ensuring that those who provide post-operative care have essential information about the patient’s condition. Prompt documentation in a brief post-operative report by the surgeon that includes any specific directives for care can help ensure that the post-operative health care team is prepared for potential complications that may need to be monitored or addressed. This practice fulfills one of JCAHO’s 2006 National Patient Safety Goals across various care settings.
- **Post-Operative Pain Management.** Pain management is an important but sometimes neglected component of a patient’s treatment and important in speeding recovery. Surgeons need to incorporate into their post-operative care processes discussions with their patients about the level of their pain, followed by appropriate pain management. The Centers for Medicare and Medicaid Services (CMS) included pain management in its demonstration project for cancer patients undergoing chemotherapy; in addition, the CMS and AHRQ Hospital CAHPS venture surveys patients regarding the management of pain provided by their hospital.
- **Appropriate Post-Operative Care.** As important as the care the patient receives in the hospital is the care and the directives for care that the patient receives upon discharge. These follow-up steps may include: 1) scheduling post-operative visits with the surgeon or other relevant providers; 2) prescribing medications with the necessary instructions; 3) counseling for particular patient lifestyle choices, such as smoking cessation;

4) directives for patient representatives regarding care for the patient at home; and 5) any other directives appropriate to the patient’s condition, such as wound care.

These measures are broadly applicable across surgical specialties and across sites of services, and should be reportable through relatively straightforward administrative mechanisms. In addition, they are likely to have an immediate positive impact on the quality of care and, taken as a group, will produce little if any increase in service utilization. Indeed, collectively they may well produce system cost savings by preventing complications.

Second Phase

Phase II of Medicare’s pay-for-performance program could call more directly for surgeons to “pay for participation,” and involve targeted goals that rely on more complex process and outcomes measures that are applicable to broad service categories. For surgical care provided in the hospital setting, a widely endorsed set of measures that is applicable to most surgical specialties is incorporated into the Surgical Care Improvement Program (SCIP). SCIP addresses the following surgery-related quality and safety issues:

- **Surgical site infections** (SSIs) account for 14 to 16 percent of all hospital-acquired infections and are a common complication of care, occurring in 2 percent to 5 percent of patients after clean extra-abdominal operations and up to 20 percent of patients undergoing intra-abdominal procedures. Among surgical patients, SSIs account for 40 percent of all hospital acquired infections. By implementing projects to reduce SSIs, hospitals could recognize a savings of \$3,152 and reduction in extended length of stay by seven days on each patient developing an infection. Among the practices known to prevent surgical site infections are timely administration and proper duration of antibiotics, glucose control, and proper hair removal.
- **Adverse cardiac events** are complications of surgery occurring in 2 to 5 percent of patients undergoing non-cardiac surgery and as many as 34 percent of patients undergoing vascular surgery. Certain perioperative cardiac events, such as myocardial infarction, are associated with a mortality rate of 40 to 70 percent per event, prolonged hospitalization, and higher costs. Current studies suggest that appropriately administered beta-blockers reduce perioperative ischemia, especially in patients considered to be at risk. It has been found that nearly half of the fatal cardiac events could be preventable with beta-blocker therapy.
- **Deep vein thrombosis** (DVT) occurs after approximately 25 percent of all major surgical procedures performed without prophylaxis, and **pulmonary embolism** (PE) occurs in 7 percent of operations conducted without prophylaxis. More than 50 percent of major orthopaedic procedures are complicated by DVT, and up to 30 percent by PE, if prophylactic treatment is not instituted. Despite the well-established efficacy and safety of preventive measures, studies show that prophylaxis is often underused or used inappropriately.
- **Postoperative pneumonia** has been associated with high fatality rates, according to the Centers for Disease Control and Prevention (CDC). Postoperative pneumonia occurs in 9-40 percent of patients and has an associated mortality rate of 30-46 percent. Studies have found that many of the factors that can lead to post-operative pneumonia respond favorably to medical intervention and so are preventable. A conservative estimate of the potential savings from reduced hospitalization due to postoperative pneumonia is \$22,000 to \$28,000 per patient per admission. Again, SCIP proposes tests that can be applied to test whether prevention strategies for postoperative pneumonia have been followed.

The SCIP measures were proposed in a partnership that includes CMS, AHRQ, CDC, VA, JCAHO, ACS, and other national organizations representing members of the surgical team.

Employing the SCIP criteria in a pay-for-performance program would involve coordinated efforts with hospitals and with Medicare's quality improvement organizations. Indeed, since hospital adherence to the SCIP protocols depends on surgical leadership, one way to align hospital and physician incentives in the payment system would be to pay "bonuses" to surgeons who refer their patients to hospitals participating in the SCIP.

Of course, because SCIP measures focus on hospital care, other widely-accepted and clinically relevant goals, processes, and measures must be developed that are appropriate for physicians and surgeons whose practice is narrower in scope and those who practice in non-hospital settings. Participation by the relevant professional organizations is key to this effort, as is adequate time for pilot testing and implementation.

Third Phase

Phase III, the most forward reaching effort, would place greater emphasis on the outcomes of surgical care. Such quality initiatives will require large infrastructures to house and analyze data and to provide the professional expertise to define, refine, and report on quality and outcomes. This phase will also involve professional review of outcomes data that, in turn, will produce new performance processes that will further improve care. It may be possible during this stage to benchmark performance of individual surgeons for the purpose of public reporting.

Surgery generally accepts the principle that reporting on outcomes provides the first step in a multi-step process toward quality improvement. Once risk-adjusted outcomes are identified, we can define opportunities for improving care and even highlight areas of exceptional care, and then use expert panels of clinicians to identify the processes that are involved in high-quality care delivery.

Various patient databases can be used to launch this effort, including some developed in the private sector by surgical organizations such as ACS and the Society of Thoracic Surgeons (STS). The National Surgical Quality Improvement Program (NSQIP), developed first by the VA and now under development in the private sector by ACS, as well as the STS National Database for cardiac surgery, hold promise for providing the data and measures needed to identify the processes that improve patient care.

Again, it is important to keep in mind that specialties are in various stages of preparedness in developing and adopting such systems, and this must be accounted for in any pay-for-performance framework that is ultimately adopted. This is particularly true for office-based practices and those in smaller communities where resources are more limited. Further, adequate time for developing and pilot testing new measures and processes is essential, because of the considerable risks associated with implementation of poorly constructed data collection and reporting systems.

For this phase, in particular, the administrative investments will be significant and the potential for Medicare program costs savings outside the physician fee schedule can be substantial. So, alternative means of financing performance awards (e.g., shifting unspent funds from Medicare Part A to Part B, broader allowance of so-called gain-sharing, and so forth) must be developed.

Pay-for-Performance

It will be challenging to produce payment incentives that are fair for all physicians and across specialties and service settings. Nonetheless, surgery generally agrees that a Medicare performance-based payment system should incorporate the following principles:

- The primary goal of pay-for-performance programs must be improving health quality and safety.
- Physician participation in pay-for-performance programs must be voluntary, and a non-punitive audit system should be implemented to ensure the accuracy of data.
- Because of differences across specialties and in the federal government's ability to collect and analyze meaningful data, any Medicare pay-for-performance program must be pilot tested across settings and specialties and phased-in over an appropriate period of time.
- Practicing physicians and their professional organizations must be involved in the design of Medicare pay-for-performance measures and programs.
- Physician performance measures used in Medicare pay-for-performance programs must be evidence-based, broadly accepted, and clinically relevant. The metrics must be fair and balanced across specialties and developed using evidence-based work or consensus panels of expert physicians. They must also be kept current to reflect changes in clinical practice.
- Physician performance data must be fully adjusted for case-mix composition including factors of sample size, age/sex distribution, severity of illness, number of co-morbid conditions, and other features of physician practice and patient population that may influence the results. The program should foster the patient-physician relationship, and must not discourage physicians from treating patients with significant health problems or complications out of fear that they will have a negative influence on quality scores and reimbursement. There also must be a mechanism for exceptions to pay-for-performance compliance metrics for clinical research protocols, and in situations where measures are in conflict with sound clinical judgment.

- Performance measures should be scored against both absolute values and relative improvement in values, as appropriate.
- Medicare must positively reward physician participation in pay-for-performance programs, including physician use of electronic health records and decision support tools. Pay-for-performance programs must also compensate physicians for any administrative burden for collecting and reporting data.
- Pay-for-performance programs must not be budget neutral within the Medicare physician payment system or be subject to artificial Medicare payment volume controls such as the sustainable growth rate mechanism. Pay-for-performance programs should not penalize physicians for factors beyond their control.
- For surgical procedures performed in the hospital setting, the processes that improve care frequently involve a surgeon-led team approach. Many of these processes are directed toward preventing costly complications, reducing length of stay, and avoiding readmissions, which substantially reduce hospital costs covered under Medicare Part A reimbursements. Mechanisms must be established to allow performance awards for physician behaviors in hospital settings that produce cost savings outside the physician fee schedule.
- Physicians must have the ability to review and correct performance data, and those data must remain confidential and not subject to discovery in legal proceedings.