Testimony of Mark B. McClellan, MD, Ph.D. Administrator, Centers for Medicare & Medicaid Services Before the Senate Committee on Finance Hearing on Physician-Owned Specialty Hospitals May 17, 2006

Chairman Grassley, Senator Baucus, distinguished Committee members, thank you for inviting me to testify today about the Centers for Medicare & Medicaid Services' (CMS) role in ensuring its beneficiaries have access to quality health care. Through our payment systems and quality efforts, CMS is working to promote a level playing field for all health care providers, including both community hospitals and physician-owned specialty hospitals.

At CMS our chief concerns are the quality of care for people with Medicare and Medicaid and the efficiency of Medicare and Medicaid spending. We make no differentiation in the application of our quality standards whether a facility is rural or urban, or for-profit or not-for-profit. Through Medicare's conditions of participation requirements and the survey and certification process, CMS monitors and enforces quality requirements for all hospitals. If necessary, CMS has the authority to terminate a hospital's participation in the Medicare program; and, CMS recently used this authority to put a facility in Oregon on track for such action.

CMS also is actively working to ensure payments for services promote quality and accurately reflect the cost of providing care. As you know, how Medicare pays for medical services can significantly impact quality and medical costs for our beneficiaries and our overall health care system. With a reimbursement system based on admissions and procedures and not outcomes or efficiency, the current system may pay for services that are ineffective, inefficient and out-of-date, instead of recognizing and encouraging quality care that prevents complications and errors. Moving toward a performance-based

payment system could potentially enhance fair competition across health care settings. By leveling the financial playing field for all hospitals, Medicare payments to hospitals will more accurately reflect actual resource needs. This can be achieved, in part, for example, by reconfiguring payments to better recognize severity of illness. CMS also is considering ways to improve patient safety and the Medicare payment system by addressing "never events," which are serious, preventable medical errors.

Public disclosure of hospital pricing and quality data also has the potential to spur quality improvements at all hospitals. Quality and cost information is increasingly available and being used by patients to create a health care system that is more transparent. We hope that this will eventually provide every patient with an opportunity to get a clear idea of the quality of providers and the price of treatment options available to them and will help them to make an informed choice about their own health care. And people may find more opportunities to save when they use such information effectively.

In addition to promoting quality at all hospitals and improving the accuracy of Medicare's payment systems, CMS has responded to questions raised by Congress regarding physician-owned specialty hospitals. Last year, CMS completed a study on referral patterns and quality in physician-owned specialty hospitals, finding that certain specialty hospitals delivered high quality care that was as good as or better than their competitor hospitals. CMS also implemented a moratorium for new specialty hospitals included in the Medicare Modernization Act (MMA). This moratorium began on December 8, 2003 and ended on June 8, 2005. During that period of time, new physician-owned specialty hospitals (excluding those physician-owned specialty hospitals that were found to be "under development" as of November 18, 2003) were unable to take advantage of the "whole hospital exception" of the physician self-referral statute. In other words, these physician-owned specialty hospitals were prohibited from billing Medicare for services furnished to patients referred to the specialty hospital by a physician-owner. The moratorium did not prevent such hospitals from opening and receiving a Medicare provider number. It also did not absolutely prevent the physician-owned specialty hospital from billing Medicare during the moratorium for

services furnished to patients referred to the specialty hospital by non-owner physicians. Following this moratorium, CMS went even further, suspending the enrollment of new specialty hospitals, while reviewing the Agency's enrollment procedures. The Deficit Reduction Act (DRA) built on this action, continuing the enrollment suspension until CMS developed a strategic and implementing plan regarding physician investment in specialty hospitals.

CMS' On-Going Quality Assurance Operations

CMS has had responsibility for ensuring the quality of hospital care from the inception of the Medicare program in 1965. In order to participate in the Medicare program, all hospitals, regardless of whether they are general or specialized, must meet the Conditions of Participation (CoPs), as laid out in regulation.

These minimum health and safety standards cover a broad range of operational requirements and represent the foundation for improving quality and protecting the health and safety of Medicare beneficiaries. Every hospital seeking a Medicare billing number must pass an in-depth survey to demonstrate that it meets all applicable Conditions of Participation.

Hospitals have two options when it comes to the survey. They can seek accreditation from an approved body such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or they may apply directly to CMS for a review. Reviews for CMS are carried out by individual State Survey Agencies, under contract with CMS.

Hospitals choosing accreditation through accrediting organizations must undergo on-site surveys by such organizations at least every three years to maintain their accreditation. As of 2006, these surveys are made on an unannounced basis. Surveys include evaluation of care processes throughout the hospital, meetings with senior management and selected caregivers, a review of medical records and a physical inspection of the hospital building.

The surveys ascertain whether a provider/supplier meets applicable requirements for participation in the Medicare and/or Medicaid programs, and evaluate the hospital's performance and effectiveness in rendering safe care of an acceptable quality. Each survey also examines a provider's efforts to prevent environmental hazards due to contagion, fire, contamination, or structural design and maintenance problems. It also ascertains that the responsible provider officials and key personnel are effectively doing all they must do to protect health and safety.

If the hospital is surveyed by the State Survey Agency or an accrediting body other than JCAHO, such survey organization officially recommends its findings regarding whether health care entities meet applicable legal and regulatory definitions and requirements. Based on such information, CMS then makes a decision as to initial certification and issuance of a provider number. Pursuant to statute, JCAHO-accredited hospitals are automatically deemed to be in compliance with CMS standards.

As a general rule, State Survey Agencies and accrediting bodies do not have Medicare determination-making functions or authorities; those authorities are delegated to CMS' Regional Offices. However, they provide the crucial evidence relied upon by the Regional Offices in approving health care entities to participate in the Medicare program.

When CMS receives a credible report of the existence of potential threats to the health and safety of patients, the Agency authorizes the State Survey Agency to conduct a complaint investigation. In FY 2005, for example, 4,876 such complaint investigations were conducted by State Survey Agencies in general hospitals, 143 complaint investigations were conducted in Critical Access Hospitals, and 32 complaint investigations were conducted in specialty hospitals. CMS encourages anyone with information regarding a quality concern to refer the matter to one of our ten Regional Offices for investigation.

An institution that fails to comply with every condition cannot participate in Medicare.

If the State Survey Agency or accrediting body discovers deficiencies in a hospital's operations, it prepares a certification of such finding for the CMS Regional Office and sends the institution a "Statement of Deficiencies" form. Unless an immediate jeopardy deficiency is found, the institution is given 10 calendar days in which to respond with a Plan of Correction for each cited deficiency, and enters this response on the form containing the statement of deficiencies.

If the institution has not come into compliance with all Conditions within the time period accepted as reasonable, the State Survey Agency certifies noncompliance, notwithstanding a Plan of Correction. At this point, CMS may begin termination procedures to revoke the institution's Medicare billing number. If an immediate jeopardy deficiency is found, the institution's Medicare agreement is terminated within 23 days, unless prior to the scheduled termination the following occurs: the immediate jeopardy situation is corrected, the CMS Regional Office receives an acceptable Plan of Correction from the institution, and compliance is achieved and documented through onsite verification during a full survey of all Medicare Conditions of Participation.

As part of ongoing quality monitoring activities for all hospitals that treat Medicare patients, CMS recently found significant quality concerns with a Portland Oregon hospital, and has placed it on a termination track. Termination of a hospital's enrollment in Medicare can have severe adverse impacts on access to health care in a community, as well as resulting in loss of employment for hospital staff. Consequently, hospitals usually undertake significant responses to improve quality and safety when these steps are taken by CMS. CMS' first emphasis is on bringing a hospital into compliance, with termination occurring when that proves impossible.

CMS Focuses on Improving Quality of Care at All Hospitals

CMS recognizes the potential of the Medicare payment system to encourage and reward quality care in the hospital setting. This is particularly important, as it provides an opportunity to address quality concerns proactively. Therefore, CMS has worked with a number of key stakeholders, including hospital representatives and consumer groups,

through the Hospital Quality Alliance to develop a shared national strategy for improving the quality of care provided at all hospitals, including physician-owned specialty hospitals. Since 2003, CMS has supported and advanced the Hospital Quality Alliance, which is an unprecedented public-private partnership that has helped develop strategies that improve quality, promote health, and prevent complications and duplicative or unnecessary services.

The Hospital Quality Initiative is designed to stimulate improvements in hospital care by standardizing hospital performance measures and data transmission to ensure that all payers, hospitals, and oversight and accrediting entities use the same measures when publicly reporting on hospital performance. Although hospitals are not mandated to submit clinical performance data to CMS, the Medicare Modernization Act (MMA) gives CMS the authority to pay hospitals the full market basket update – a 0.4 percentage point differential – upon submission of performance data for a "starter set" of 10 quality measures. This payment adjustment resulted in near-universal reporting of the measures.

The reporting requirements were further expanded through the Deficit Reduction Act (DRA) to include the reporting of additional measures in FY 2007. Failure to report on this expanded set of measures will result, effective for FY 2007, in a reduction of 2 percentage points in hospital payment. Importantly, the DRA will, for the first time, allow CMS, beginning in FY 2008, to begin to adjust payments for hospital acquired infections. Currently, infections acquired in any hospital can trigger higher Medicare payments because these cases are assigned to higher paying diagnosis related groups. CMS intends to use this new provision, as well as a growing set of measures related to patient satisfaction and outcomes, to ensure that our payment system encourages all hospitals to treat patients efficiently and effectively.

For example, two quality measures endorsed by National Quality Forum for heart failure patients include placing the patient on blood pressure medications and beta blocker therapy. Here too, these therapies have been shown to lead to better health outcomes and reduce preventable complications. Together, diabetes and heart failure account for a

large share of potentially preventable complications. Measures of effectiveness and safety of some surgical care at the hospital level have been developed through collaborative programs like the Surgical Care Improvement Program (SCIP), which includes the American College of Surgeons. Preventing or decreasing surgical complications can result in a decrease in avoidable hospital expenditures and use of resources. For example, use of antibiotic prophylaxis has been shown to have a significant effect in reducing post-operative complications at the hospital level. This measure is well developed and there is considerable evidence that its use could not only result in better health but also avoid unnecessary costs. These post-operative complication measures, which are in use in our Hospital Quality Initiative, are being adapted for use as physician quality measures. Application of this type of post-operative complication measure at the physician level has the potential to help avoid unnecessary costs as well as improve quality.

Transparency of Quality Data Aids Consumer Choice

The data from the "starter set" of 10 quality measures, as well as additional voluntarilyreported data on other quality measures are available to the public through the Hospital Compare website at http://www.hospitalcompare.hhs.gov. This website provides information on hospital quality of care for consumers to use to select a hospital. It further serves to encourage consumers to discuss the quality of care provided with their doctors and hospitals, thereby providing an additional incentive to improve the quality of that care. In addition to the Compare website, CMS is working on ways to provide even more comparative information to drive improvements in the quality of care. This includes the Hospital CAHPS (HCAHPS) survey, which provides a standardized instrument and data collection methodology for measuring patients' perspectives on hospital care.

CMS is implementing a number of demonstration projects aimed at encouraging quality care and designed to lay the groundwork for performance-based payments in the future. These include the Physician Group Practice Demonstration, the Premier Hospital Quality Incentive Demonstration, the Health Care Quality Demonstration, and the Care Management Performance Demonstration. These projects are helping us to examine our

current systems to better anticipate patient needs, especially for those with chronic diseases, and explore whether incentives lead to better results -- across-the-board improvements in quality, fewer complications, and reduced costs.

CMS is using the Premier demonstration as a pilot test of the effectiveness of quality incentives and is considering ways to apply this concept to additional hospitals, and to other types of providers. The Premier Hospital Quality Incentive Demonstration recognizes and provides financial rewards to hospitals that demonstrate high quality performance in a number of areas of acute care. Under the demonstration, top performing hospitals will receive bonuses based on their performance on evidence-based quality measures for Medicare patients with: heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements. Poorly performing hospitals are participating voluntarily in the demonstration. For the first year of the program, hospitals received incentive bonuses totaling \$8.9 million. The first year's bonus incentive payments ranged from \$900 to \$847,000.

CMS also is examining the concept of "value-based purchasing," which may use a range of incentives to achieve identified quality and efficiency goals, as a means of promoting better quality of care and more efficient resource use in the Medicare payment systems. In considering the concept of value-based purchasing, CMS is working closely with stakeholder partners, including health professionals and providers. In addition, CMS is developing a plan to implement a value-based purchasing plan beginning in FY 2009 for Medicare hospital payments. This plan, as required by the DRA, will address issues regarding quality measures, data infrastructure, incentive methodology, and public reporting.

CMS Investigates Ways to Prevent Serious Medical Errors

In a March 2001 report, "Crossing the Quality Chasm," an Institute of Medicine (IOM) committee proposed six aims for improving health care quality, and CMS has adopted the six aims in our Quality Improvement Roadmap. Safety is the first of those aims. Very

simply, care that is intended to help patients should never injure them. Unfortunately, patients all too often suffer injuries caused by medical errors. Another IOM committee issued the landmark "To Err Is Human" report in November 1999. That report found that as many as 98,000 Americans die each year as a result of medical errors. Both reports recommended a systems approach to quality improvement, called for a nationwide mandatory adverse event reporting system, and recommended that public and private purchasers use incentives to encourage providers to improve patient safety.

During the six years since "To Err Is Human" was released, some progress has been made in combating medical errors. However, our progress in the struggle against medical errors has been slow. Medical errors continue to be a common cause of death in the United States, and we certainly have not met the IOM report's challenge of a 50 percent reduction in medical errors over five years. A number of obstacles hinder improvement in patient safety. Some of these obstacles, such as the overall complexity of health care, may not be readily amenable to the promises of a value-based purchasing program. However, value-based purchasing may help overcome other obstacles, including the lack of commitment to safety, a lack of safety measures, underreporting of errors and the role of fear in undermining reporting, and the perverse payment incentives that may result from paying more for the complications caused by errors.

Based on the experiences CMS has had with the voluntary reporting of quality measures, our demonstration programs that are testing important concepts for value-based purchasing programs, and our new authority to address hospital acquired infections, CMS is considering ways to facilitate even greater safety and improvement in the Medicare payment system by addressing "never events," which are serious, preventable medical errors, such as medication errors, surgery on wrong body parts or mismatched blood transfusions. For example, in 2005, 84 wrong site surgeries were reported to JCAHO. Hospital payments should be based on the premise of supporting higher quality and efficiency. Paying for "never events" – and in many cases, paying more for such events – is contrary to this goal. As a necessary step toward encouraging better care and lower

overall heath care costs, we support further steps such as eliminating payments for "never events" and want to work with the Congress to take such steps.

CMS Proposes to Level the Financial Playing Field for All Hospitals

In addition to the above mentioned long-range plans and goals for improving the quality of care provided at all hospitals, CMS also has taken more immediate steps designed to improve quality and tailor its payment systems to more accurately reflect the cost of care. CMS has undertaken a number of activities to improve the quality and efficiency of care delivered to Medicare beneficiaries, but also recognizes the ability of Medicare payment systems to promote quality and more accurately reflect the costs of providing services to our beneficiaries. Currently, there are several different fee-for-service payment systems under Medicare that are used to pay health professionals and other providers based on the number and complexity of services provided to patients. In general, all providers to which a specific Medicare payment system applies receive the same amount for a service, regardless of its quality or efficiency. As a result, Medicare may often pay more to hospitals that deliver care that is not of the highest quality or include unnecessary services.

CMS Developing Refinements for Hospital Inpatient Services

In the April 12, 2006 notice of proposed rulemaking, CMS has proposed a number of regulatory changes that would lead to significantly more accurate payments for acute care furnished to hospital inpatients, with a particularly important impact on specialty hospitals. Specifically, one proposal would restructure the diagnosis-related groups (DRGs) that serve as the basis for payment to reflect a patient's actual cost of care more accurately. These reforms also further CMS' quality goals, as more accurate payments may encourage better care for patients. Currently, DRG payments are set to reflect the average resource use of treating a patient with a particular diagnosis. In general, when hospital costs are less than the DRG payment, the hospital keeps the difference. However, hospitals absorb the loss if costs are more than the DRG payments.

CMS is moving toward the most significant revision of the DRG payment methodology since its introduction in the 1980s. In the hospital inpatient prospective payment system (IPPS) final rule for FY 2006, we found a sound analytical basis for revising nine cardiovascular DRGs that account for nearly 700,000 cases to better recognize severity in the DRG system. Further changes as recommended by Medicare Payment Advisory Commission (MedPAC) are proposed in the FY 2007 IPPS proposed rule. In that proposed rule, CMS' analysis suggests that the current, charge-based weights and the current DRG classifications result in notable distortions between payments and the relative cost of care. The proposed rule for FY 2007 includes two major types of reforms. First, the proposed payment changes would assign weights to DRGs based on estimated hospital costs, rather than reported charges. Second, the DRGs would be reconfigured to better recognize severity of the illness. These changes are expected to reduce incentives for hospitals to "cherry pick" or treat only the most profitable patients, and ensure that whether services were furnished in a specialty hospital or a community hospital, the payment would more closely reflect the costs of treating the patient, in light of the severity of illness. This would eliminate potential financial incentives for overinvestment in treating less complex but more profitable case, which often reduce the support available to the more severely ill and more costly patients.

CMS Developing Revisions to Ambulatory Surgical Center Payment System

In its 2005 Report to Congress, CMS found that many orthopedic and surgical specialty hospitals were more similar to ambulatory surgical centers (ASCs) than to acute care hospitals. Despite the similarity in the care provided, difference in payments for the same services encourages providers to enroll what are essentially ASCs as specialty hospitals.

To address this problem, CMS is developing revisions to the list of procedures eligible for payment in ASCs to include most surgical procedures performed in hospital outpatient departments. The basic structure of the payment rates for ASCs has not been updated since 1990 and CMS is considering revising the payment methodology in ASCs to align more closely with the payment rates in other payment systems for the same procedures, which would remove much of the incentive for physicians and other investors to form orthopedic and surgical specialty hospitals in order to take advantage of the typically higher payments under the inpatient and outpatient hospital prospective payment systems.

Both the expansion to the list of procedures eligible for payment in ASCs and the payment revisions are expected to be in effect by January 1, 2008. When implemented, Medicare payments to ASCs are expected to better reflect the resources required to perform specific surgical procedures and to be similar to payments under other payment systems.

CMS Clarifies EMTALA Responsibilities in Proposed Rule

Many specialty hospitals, especially orthopedic and surgical hospitals, do not have emergency departments. As a result, there has been some confusion regarding whether these facilities are required under the Emergency Medical Treatment and Labor Act (EMTALA) to accept an appropriate transfer of an individual from a requesting hospital. The FY 2007 IPPS proposed rule clarifies that all hospitals (including specialty hospitals) with specialized capabilities must accept, within the capacity of the hospital, appropriate transfers of unstable individuals covered by EMTALA, without regard to whether the hospital has an emergency department. This clarification of current policy may result in an increase in the number of specialty hospitals accepting transfers of individuals with emergency conditions on nights and weekends. This clarification was recommended by the Secretary's EMTALA Technical Advisory Group. The community hospital associations have supported this position. Public comments on the proposed rule are due by June 12, 2006.

CMS Examines Process for Hospital Participation in Medicare

In addition refining Medicare's payment systems and clarifying emergency requirements under the program, CMS is more closely scrutinizing whether specialty hospitals meet the definition of a hospital. Under existing law, a hospital, for Medicare purposes, must be, among other requirements, primarily engaged in furnishing services to inpatients. Although CMS has not promulgated a regulatory definition of "primarily engaged" in

furnishing services to inpatients, we have studied whether specialty hospitals (and other hospitals) are primarily engaged in furnishing services to inpatients. Based on an analysis of inpatient and outpatient claims data regarding community hospitals and specialty hospitals, our research indicates that cardiac specialty hospitals resemble full-service community hospitals in many ways. Orthopedic and surgical specialty hospitals, which typically have far fewer beds than cardiac hospitals, are probably no less engaged in furnishing care to hospital inpatients than are some community hospitals, including some small rural hospitals.

We have not yet identified any quantitative method, such as percentage of services or ratio of inpatient to outpatient services, which could gauge whether a facility is primarily engaged in furnishing services to inpatients without disqualifying both community hospitals and specialty hospitals. As a result, CMS does not currently intend to define by regulation the statutory requirement that a hospital is an entity that is "primarily engaged" in furnishing services to hospital inpatients for the purpose of differentiating specialty hospitals from community hospitals. Instead, CMS will continue to interpret "primarily engaged" on a case-by-case basis as it continues to explore other options for addressing this issue. For example, CMS recently denied a provider agreement to an entity that intended to create an emergency department with 25 bays and an inpatient area with two beds. In addition, CMS terminated the provider agreement of an Arizona hospital following an action by the State prohibiting any inpatient stays at the hospital.

CMS Enforces Payment Restrictions for New Specialty Hospitals

The MMA's 18-month "specialty hospital moratorium" prohibited physicians from referring Medicare patients to specialty hospitals in which the physicians had an ownership interest. In addition, the moratorium prohibited specialty hospitals from billing, and Medicare from paying, for inpatient and outpatient hospital services that were furnished as a result of a physician owner's referral. The moratorium did not apply to physician owner's referrals to (and claims billing by) specialty hospitals that the Secretary determined were in operation, or "under development," as of November 18, 2003. However, the MMA prohibited these hospitals from increasing the number of

physician investors or the number of beds, or changing the type of specialty services provided by the hospital. Recently, CMS identified two hospitals that billed Medicare for services in violation of the specialty hospital restrictions imposed under the MMA moratorium. We have initiated procedures to recover improper Medicare payments made to these hospitals.

To obtain a determination regarding whether it was "under development," as of November 18, 2003, a specialty hospital could request an advisory opinion from CMS using the procedures already set forth in CMS's physician self-referral regulations. In processing advisory opinion requests, CMS reviewed financial and other information relating to the requesting specialty hospital. The advisory opinions were reviewed by HHS's Office of the General Counsel. CMS also consulted, where necessary, with the Office of Inspector General (OIG) and the Department of Justice.

CMS Suspends Enrollment of Specialty Hospitals

Separate from the moratorium on payments to new specialty hospitals, CMS temporarily suspended the processing of new provider applications for specialty hospitals in order to comprehensively review the procedures used to determine if these hospitals qualify for participation in the Medicare program. This suspension, which was continued by section 5006 of the DRA, does not apply to specialty hospitals that already had provider agreements or those specialty hospitals that had requested an Advisory Opinion from CMS prior to June 8, 2005.

Currently, the Medicare enrollment application does not contain a separate category for specialty hospitals. If, based on the continued review of the issues identified in the DRA, it is determined that requirements specific to physician-owned specialty hospitals are warranted, CMS would be prepared to change the enrollment application form to identify such hospitals. However, the enrollment form without a separate category for specialty hospitals may be a potential advantage for purposes of implementing the current suspension of enrollment of new specialty hospitals. Any entity seeking to enroll as a hospital does not have the opportunity to self-select and specify that it is not a specialty

hospital. Therefore, should an applicant identify itself as any type of hospital, the fiscal intermediary must investigate further as to whether the applicant will be a specialty hospital. If enrollment requirements specific to specialty hospitals were implemented, it may be necessary for CMS to provide formal guidance as to what constitutes a "specialty hospital."

In contrast to the current suspension on enrollment of new specialty hospitals, the moratorium on physician referrals to specialty hospitals imposed under the MMA did not restrict specialty hospitals from obtaining a provider agreement, or from billing Medicare for services furnished to patients referred by physicians who did not have an ownership interest in the specialty hospital.

CMS Begins Development of Strategic Plan Regarding Physician Investment in Specialty Hospitals

In connection with the recently released Secretary's Interim Report to Congress, CMS sent a survey to approximately 130 specialty hospitals and 270 general acute care hospitals seeking information about physician investment interests and provision of care to low income and charity patients. The information gained from the survey will be used to develop the final report and the Strategic Plan that will be released later this year.

The survey is designed to provide comprehensive information on how physician investment arrangements are structured. For example, the survey asks hospitals to identify their physician investors, the returns on their investments, whether the physicians have stop losses or other types of limitations on liability available to them, whether the physicians received a loan from the hospital to purchase their investment interest, and whether the physicians have or have had a compensation arrangement (such as a management contract) with the hospital or an entity related to the hospital.

CMS also anticipates that this survey will provide much more information about the provision of charity care and care to Medicaid patients by specialty hospitals and their general acute care hospital competitors than has previously been obtained. That is, the

survey also asks questions about the hospital's number of Medicaid patient discharges, its revenue from Medicaid patients, and the amount of charity care it provides.

To ensure a high quality survey, we sought and received input from the American Surgical Hospital Association, National Surgical Hospitals Incorporated, the MedCath Corporation, the Federation of American Hospitals and the American Hospital Association. Because CMS would not want to make recommendations to Congress without thorough, timely information, all of these hospital organizations have committed to contacting their member hospitals to encourage their participation in the survey.

CMS Supports Enforcement against Improper Investment Activities

In addition to developing factual information about investments in specialty hospitals, CMS is very interested in public comment on how best to support enforcement against inappropriate investment, which is an issue that is different from our usual mandate and capacities to promote quality care and to pay appropriately for care provided to our beneficiaries. In conjunction with the hospital survey, we also are assessing how we can best promote the availability of accurate and relevant information on physician investments in hospitals. In addition, we are continuing to assess the extent to which relevant State and other Federal agencies have jurisdiction over issues related to whether investments are bona fide and result in "appropriate" return on investment.

CMS has program responsibility for the physician self-referral statute under section 1877 of the Social Security Act. The HHS Office of Inspector General (OIG) has authority to impose civil monetary penalties for knowing violations of section 1877. The statute's "whole hospital exception" permits a physician to refer a patient to a hospital in which the physician has an investment or ownership interest, so long as the investment is in the whole hospital, and not just the department or subdivision of the hospital, provided that certain other conditions are satisfied. During the period of the MMA specialty hospital moratorium, the exception applied only if the physician's ownership interest was not in a specialty hospital as defined under the MMA. Now that the moratorium has expired, the exception applies without regard to whether the hospital is a specialty hospital or some

other type of hospital. Presently, there are no additional restrictions in the physician selfreferral statute and regulations with respect to whether a physician's investment is "proportional" or "bona fide."

In some circumstances, physician investments in specialty hospitals may implicate the Federal anti-kickback statute, a criminal law enforced by the Department of Justice (DOJ) and the OIG. If we uncover evidence of possible violations of the anti-kickback statute, or evidence of potential knowing violations of the physician self-referral statute, we refer those cases to the OIG for appropriate action. Importantly, CMS works collaboratively with the OIG and DOJ to ensure that allegations of potential fraud and abuse, whether arising in the context of specialty hospitals or otherwise, are handled in an appropriate manner, using the full range of tools available to the government.

CMS recognizes that there are different opinions regarding physician-owned specialty hospitals. Physician-owned specialty hospitals are legal under the existing whole hospital exception to the physician self-referral law and elimination of the exception cannot be done administratively.

Conclusion

Mr. Chairman, thank you for this opportunity to discuss CMS' efforts to promote quality care in all hospitals. Regardless of the setting of care, CMS is committed to improving the quality of patient care and to increasing the efficiency of Medicare spending. CMS has proposed reforms to Medicare's payment systems that would improve quality, while at the same time more accurately reflect the cost of providing care. In addition, transparency of hospital pricing and quality data will help to allow consumers to make more informed choices on where they receive care, furthering our quality efforts by promoting competition. CMS also is considering ways to further patient safety and improve the Medicare payment system by addressing "never events." CMS looks forward to working with this Committee to ensure Medicare and Medicaid beneficiaries continue to have access to high quality care. I thank the Committee for its time and would welcome any questions you may have.