United States Department of Health and Human Services

Final Report to the Congress
and Strategic and Implementing Plan
Required under
Section 5006 of the Deficit Reduction Act of 2005

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Executive Summary

I. Introduction

Section 5006(a)(1) of the Deficit Reduction Act of 2005 (DRA), enacted on February 8, 2006, requires the Secretary of Health and Human Services (the Secretary) to develop a "strategic and implementing plan" to address certain issues relating to physician investment in "specialty hospitals." The specific issues the Secretary is required to address, as described in section 5006(a)(2) of the DRA, are the following: (1) proportionality of investment return; (2) *bona fide* investment; (3) annual disclosure of investment information; (4) the provision by specialty hospitals of (i) care to patients who are eligible for Medicaid (or who are not eligible for Medicaid but who are regarded as such because they receive benefits under a section 1115 waiver) and (ii) charity care; and (5) appropriate enforcement. A "specialty hospital" is defined by the DRA as a hospital that is exclusively or primarily engaged in the care or treatment of one of the following categories: patients with a cardiac condition; patients with an orthopedic condition; or patients receiving a surgical procedure.

The DRA requires the Department of Health and Human Services (HHS) to issue, within 3 months of its enactment, an interim report on the status of the development of the strategic and implementing plan and, within 6 months of its enactment, a final report or certification of failure to complete the report. In addition, the DRA extends the administrative suspension on enrollment of new specialty hospitals until the earlier of the date the Secretary submits the final report or 6 months after enactment of the DRA. If the Secretary does not submit the final report within the 6-month period, the suspension on enrollment is extended for 2 additional months. On May 9, 2006, the Secretary issued his interim report (the Interim Report). This is the final report, which contains the strategic and implementing plan required by the DRA.

II. Study Methods

We carefully reviewed the HHS and MedPAC studies required under section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and their findings concerning physician financial incentives, rates of return on investments, the provision of care to Medicaid patients, and uncompensated care. In addition, we reviewed the information submitted by hospitals in connection with their requests for advisory opinions as to whether they were excepted from the MMA moratorium because they were "under development" as of November 18, 2003. Some of the requestors furnished information describing the funding of the hospital, physician investors, the entities that were part of the venture, and the projected rates of return. Although we were able to use that information, we concluded that, in order to obtain a more complete depiction of the proportionality of physician investment return and *bona fide* investment in specialty hospitals, we needed to supplement this with additional data. Therefore, the Centers for Medicare & Medicaid Services (CMS) created a survey to be sent to both specialty and competitor acute care hospitals.

We selected two groups of hospitals for our analysis – the universe of specialty hospitals as we know it to exist and a sample of competitor acute care general hospitals. For specialty hospitals, we began with the universe of 76 specialty hospitals identified in the HHS MMA Study. Building upon those specialty hospitals, we added the 49 specialty hospitals that had requested an advisory opinion, regardless of case volume criteria or having filed a cost report, and additionally, we identified other hospitals as specialty hospitals based on Medicare claims data. The above steps in our selection process resulted in our identifying 130 physician-owned specialty hospitals for inclusion in our survey.

In order to identify the acute care hospitals that are competitors of specialty hospitals, we first identified the markets in which specialty hospitals are located. We identified the health referral regions (HRRs) in which each of the cardiac specialty hospitals was located by using the Dartmouth Atlas for Healthcare. We also identified the hospital service areas (HSAs) in which each of the orthopedic and surgical hospitals are located. We then identified competitor acute care hospitals for each of the HRRs and HSAs in which specialty hospitals are located by employing the same criteria used by GAO in a previous report.

III. Survey Results and Other Findings

In summary, the data we received on physician investment have not revealed, on their face, any disproportionate or non-*bona fide* arrangements that require CMS to institute a drastic shift in our enforcement approach. However, because many hospitals did not respond to our survey questions on investment interests and compensation arrangements (or did not respond completely), we are sufficiently concerned about potential tainted relationships and will begin seeking financial disclosure with those hospitals and will implement a regular disclosure process. As part of this data collection and analysis initiative, we will analyze survey data received after July 14, 2006 as well. (*See* Strategic and Implementing Plan, section V.D.1, below.) Failure to disclose timely the information sought in this effort can result in civil monetary penalties of up to $10,000 for each day beyond the deadline established for disclosure (which in all cases must be at least 30 days).

In addition, we obtained substantial data with respect to Medicaid and charity care patient populations and on the relative characteristics of specialty and competitor hospitals. This data has confirmed our determination to continue making improvements to payment systems and to issue further guidance regarding what we expect of hospitals with emergency departments (*See* Strategic and Implementing Plan, section V.A-C, below.). This data adds to and enhances the information that the Congress is already considering on issues relating to care provided in these settings.

Our specific findings include the following.

A. Investment in Specialty Hospitals

Bona Fide Investment

The DRA required us to examine issues related to whether the investment in specialty hospitals by physicians was *bona fide*. For purposes of this report, we considered a *bona fide* investment to be one in which the capital contributed by a physician does, in fact, represent an investment for which the physician is at risk. That is, we would not consider an investment to be *bona fide* if, for example, a physician made a 5 percent capital contribution, but some or all of that contribution was funded by another person or entity that did not expect repayment. We also considered additional factors, described in detail in section IV.D.1.

Loans to Physicians

Our survey identified few instances where specialty hospitals reported making loans or loan guarantees to physician-investors. Only one specialty hospital reported making direct loans to physician-investors. Other specialty hospitals reported the existence of commercial loans from third party lenders that indicate the existence of loan guarantees; however, the hospitals did not provide information as to the terms or recipients of any guarantees for these loans.

Investor Selection and Retention

In determining whether a joint venture is *bona fide*, one should closely review how investors are selected and retained. We found that for specialty hospitals responding to our survey, cardiac hospitals reported that, when investment was offered to non-physicians, it was always offered on terms similar to those offered to physician-investors. In contrast, orthopedic and surgical hospitals did so at a reduced rate (70.6 percent and 80.0 percent, respectively). Although not explicitly given by the hospitals as a criterion for selecting investors, it appears that the volume of referrals and/or revenue generated may have been a significant factor for some hospitals in determining which physicians were permitted to invest.

In analyzing the total percentage of physician ownership versus non-physician ownership and the amount of revenue generated by the physician-owners and non-owner physicians who refer patients to specialty hospitals, we found that the percentage of revenue generated by physician-owners generally was greater than the corresponding percentage of physician ownership in the hospital.

Initial Investment and Subsequent Distributions

We collected information related to initial physician investment, classes of stock (if any), whether there had been any independent valuation of the stock, and subsequent distributions. Of the 21 specialty hospitals that responded to our question, 11 hospitals had one class of stock, and 10 had two or more.

Proportionality of Investment

All specialty hospital respondents reported returns consistent with physician investment. We note, however, that 34 out of 64 responding specialty hospitals (53.1 percent) did not complete this portion of the survey and, thus, we are unable to determine at this point with great reliability whether the physician-investors in such hospitals received proportionate returns on their investments or had *bona fide* investments.

Structure of the Business Enterprise

One important component of making the determination as to whether a joint venture appears to be compliant with applicable law is to analyze the structure of the enterprise. Therefore, we requested information concerning the hospital's ownership and structure. We found that 31 specialty hospitals reported joint ventures between an entity or entities and physicians, and 1 specialty hospital reported a joint venture between physicians only.

Previous Affiliation as an Ambulatory Surgical Center

Some specialty hospitals have come about as a result of a conversion of another facility type to a hospital, especially ambulatory surgical centers (ASCs). This is often attributed to the fact that Medicare does not pay facility fees for procedures in ASCs that require overnight stays. Of the 64 reporting specialty hospitals, 14 were previously organized as another type of entity. All but two of the 14 were previously organized as ASCs.

B. Compensation Arrangements

Our survey requested information concerning other compensation arrangements between hospitals and physician-investors. Of the hospitals that reported, 53.1 percent reported compensation arrangements with physicians (not including payments to entities such as real estate companies, equipment leasing entities, and management companies). The services for which compensation was paid were largely for medical directors, on call coverage, administrative (non-Board) services, and clinical services such as diagnostic test interpretations.

C. Medicaid Information

CMS was required by the DRA to examine issues related to the provision of care to patients who are eligible for medical assistance under a State plan approved under title XIX of the Act, including patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under Title XI of the Act (commonly referred to as a "section 1115 waiver"). CMS has examined two types of data from responding hospitals: patient revenues generated for services provided to Medicaid beneficiaries, and Medicaid patient admissions or visits as a percentage of total admissions or visits.

Our survey found that Medicaid inpatient discharge rates averaged 18.4 percent of total inpatient discharges for competitor acute care hospitals, whereas specialty hospitals averaged only 3.6 percent. We found the differential was less pronounced for outpatient services. Medicaid outpatient visits averaged 12.3 percent of total outpatient visits at competitor acute care hospitals. Comparatively, reporting specialty hospitals averaged 6.1 percent overall (6.7 percent for cardiac hospitals, 4.3 percent for orthopedic hospitals, and 7.7 percent for surgical hospitals).

We also analyzed reported Medicaid revenue data for the responding hospitals. For competitor acute care hospitals responding to our survey, we found that Medicaid revenues averaged 7.0 percent of total net patient revenues for those hospitals, whereas the specialty hospitals averaged only 2.3 percent. The distinction is even greater for cardiac hospitals: only 1.1 percent of their revenues were generated from services provided to Medicaid patients; surgical and orthopedic hospitals had Medicaid revenues of only 3.4 percent and 1.7 percent, respectively.

D. Charity Care

The DRA required us to address the provision by specialty hospitals of care to charity patients. There is no Medicare statutory or regulatory definition of "charity care," and hospitals define charity care in many ways. For purposes of the survey and the strategic and implementing plan, we considered charity care to be medical treatment furnished to hospital patients with no expectation of receiving payment for all or a portion of the care provided.

Our survey solicited data on charity care provided to Medicare, Medicaid and other patients for fiscal years (FYs) 2004 and 2005. We found that competitor acute care hospitals provided a substantially higher amount of charity care to patients than did specialty hospitals. Competitor acute care hospitals averaged 7.9 percent (as a percent of net patient revenue), while reporting cardiac specialty hospitals averaged 3.9 percent, reporting orthopedic specialty hospitals averaged 1.0 percent, and reporting surgical specialty hospitals reported 0.2 percent on this measure.

E. Payer Mix

Although payer mix was not identified in the DRA specifically as an issue for report by HHS, our survey was designed to solicit information on both the patient and the payer mix of specialty hospitals and their competitors. We have analyzed the payer mix of specialty and competitor acute care hospitals, both in terms of patient discharges/visits, and in terms of revenues generated therefrom.

Our survey found that, for responding competitor hospitals, Medicaid revenue averaged 7.0 percent, Medicare revenue averaged 31.2 percent, and other sources constituted 61.8 percent of total net patient revenue for combined FY 2004 and FY 2005. In contrast, Medicaid revenue averaged 2.3 percent, Medicare revenue averaged 22.5 percent, and

other sources constituted 75.2 percent of total net patient revenue for combined FY 2004 and FY 2005 for responding specialty hospitals.

F. Inpatient versus Outpatient Services

We designed our survey to allow us to examine the relative characteristics of specialty hospitals and their competitors in terms of inpatient and outpatient services provided. Our survey indicates that: (1) cardiac hospitals provide substantially higher rates of services to inpatients than other specialty hospitals reporting to us; and (2) orthopedic and surgical hospitals focus slightly more on the provision of outpatient services than do competitor acute care hospitals.

G. Emergency Rooms

We are aware that some are concerned that specialty hospitals may be less likely than competitor acute care hospitals to operate a dedicated emergency department, which, in turn, may impact disproportionately Medicaid and uninsured patients, and which may serve to direct such patients to competitor acute care hospitals.

Accordingly, we designed our survey to allow us to examine the relative characteristics of specialty hospitals and their competitors in terms of emergency departments. Our survey results are consistent with previous studies showing that: (1) competitor acute care and cardiac hospitals are much more likely to have emergency departments than are orthopedic and surgical hospitals; and (2) orthopedic and surgical hospitals have smaller emergency departments, if they have them at all. We have also found that orthopedic and surgical hospitals have lower admission rates through the emergency department than do competitor and cardiac hospitals.

IV. Strategic and Implementing Plan

Our plan for addressing administratively issues related to specialty hospitals, including the specific issues identified in section 5006 of the DRA, is summarized below. We are not making legislative recommendations at this time.

A. Continue Making Improvements in the DRG and ASC Payment Systems

We continue to believe that the most effective way to deal with perceived unfair competition by specialty hospitals in the form of selecting more profitable diagnosis related groups (DRGs) and more profitable patients (that is, less severely ill) within those DRGs, is to make the DRG payment system more accurate. As MedPAC noted in its MMA Study, this would reduce or remove the incentive for cherry-picking cardiac cases by specialty hospitals by providing equitable and accurate payment across all cases.

Similarly, community hospitals have complained that orthopedic and surgical specialty hospitals more closely resemble ASCs than “real” hospitals and that they unfairly take advantage of higher outpatient prospective payment system (PPS) rates for procedures

that can be performed in ASCs. We continue to believe that reforms to the ASC fee schedule are necessary to better reflect the resources required to perform specific surgical procedures, and so that they are similar to payments under other payment systems to the extent that similar procedures and use of resources are involved. We further believe that these reforms may discourage physicians and other investors from forming orthopedic and surgical specialty hospitals simply to take advantage of the typically higher payments made under the payment systems for inpatient and outpatient hospital services.

With recently issued regulations, we are now implementing these major reforms in the hospital and ASC payment systems.

B. Align Physician and Hospital Incentives

We believe that closer alignment of physician and hospital incentives has the potential to reduce physicians' motivation for creating specialty hospitals and to improve patient outcomes and the efficiency of care delivery. CMS currently is pursuing demonstration projects, under the authority of section 5007 of the DRA and section 646 of the MMA, to explore ways for physicians to participate meaningfully in the governance and management of hospitals, as well as to benefit financially from operating the clinical enterprise more efficiently. Alignment of value-based purchasing incentives will allow physicians and hospitals to work together to share in rewards that reflect their joint activities in improving care.

C. Issue Guidance on Patient Safety Measures

We believe it is appropriate to issue further guidance on what we expect of hospitals without emergency departments with respect to the evaluation, treatment, and, where appropriate, transfer of patients with emergency medical conditions. Also, we proposed to clarify in the FY 2007 inpatient PPS rule that hospitals with specialized capabilities (including hospitals without emergency departments) are required under the Emergency Medical Treatment and Labor Act to accept appropriate transfers of unstable patients. We have finalized that proposal in the final FY 2007 inpatient PPS rule.

D. Promote Transparency of Investment

1. Required Disclosure of Investment and Ownership Information

We will require hospitals to provide us information on a periodic basis concerning their investment and compensation relationships with physicians, pursuant to 42 CFR § 411.361. We are not limiting our requirement to information concerning physician investments in specialty hospitals for three reasons. First, all physician ownership in hospitals potentially implicates the physician self-referral statute. Second, physician investments in any type of hospital raise potential issues concerning compensation arrangements that can be associated with the investment. Third, other types of compensation arrangements, that is, those that do not arise from an investment interest

per se, implicate the physician self-referral statute (and, depending on the circumstances, potentially the anti-kickback statute).

Because we are unable to determine at this point whether the hospitals that did not respond to our survey questions on investment and compensation relationships had tainted relationships or whether their non-response was for other reasons, we will begin our required disclosure initiative with those hospitals. We will also implement a regular disclosure process. We have not yet designed the process, but will consider such issues as whether we should (1) survey all hospitals annually, (2) stagger our survey so that all hospitals are queried but not all in the same year, and/or (3) focus our inquiry on certain types of relationships or certain hospitals. We will also consider whether, having once provided information, hospitals need submit only updated information on a yearly or other periodic basis.

2. Disclosure to Patients of Physician Ownership in Hospital

We believe that a well-crafted disclosure requirement, which, at a minimum, would require hospitals to disclose to patients whether they are physician-owned, and if so, the names of such physician-owners, is consistent with our approach that hospitals should be transparent as to their pricing and their quality outcomes. We are exploring whether to seek a change to our regulations on hospital conditions of participation or on provider agreement requirements to best achieve this.

3. Changes to Enrollment Form to Capture Type of Hospital

Currently the provider enrollment form, the CMS-855A, does not distinguish between specialty hospitals and other types of hospitals. We will propose changing the CMS-855A to capture whether the applicant hospital is, or is projected to be, a specialty hospital. In advance of any change to the CMS-855A, we will instruct our contractors to begin capturing data through contacting those hospitals that check the hospital box on the CMS-855A, and inquire whether they are, or plan to be, a specialty hospital.

E. Enforcement

1. Enforcement Against Arrangements Involving Disproportionate Returns or Non-*Bona Fide* Investments

Although our survey results did not reveal, on their face, any disproportionate or non-*bona fide* arrangements, we will take appropriate action against any such arrangements that we discover, including through our initiative of requiring information about investment and compensation arrangements.

The physician self-referral statute and regulations require that each financial arrangement that exists between a physician (or his or her immediate family member) and an entity furnishing designated health services must be protected by an exception in order for the entity to submit claims for Medicare services referred to it by the physician. Therefore, if

a physician has both an investment interest in, and a compensation arrangement with, a hospital, the physician would need to have an exception covering the investment interest, as well as an exception covering the compensation arrangement.

The denial of payment provisions of the physician self-referral statute are administered by CMS, and the civil monetary penalty and exclusion provisions for knowing violations are administered by OIG. Consistent with current practice, if CMS learns of a credible allegation of a knowing violation of the physician self-referral statute (including, but not limited to one involving disproportionate returns or non-*bona fide* investment), it will forward such information to OIG for appropriate action. CMS will work with OIG and other law enforcement agencies to support the investigation and prosecution of fraud and abuse cases including, without limitation, cases involving violations of the physician self-referral statute. In addition, and also consistent with current practice, CMS will refer credible allegations of improper referral payments to OIG for potential investigation under the anti-kickback statute.

2. Continued Enforcement of the MMA Moratorium

As noted in the Interim Report, CMS investigated and determined that two hospitals that did not seek advisory opinions as to whether they were excepted from the MMA moratorium were, in fact, specialty hospitals, and were subject to the moratorium. Overpayment notices were sent to both hospitals. Both hospitals are expected to appeal CMS' determinations.

CMS also attempted to ascertain whether there were other hospitals that did not seek an advisory opinion as to whether they were subject to the MMA moratorium but which in fact were specialty hospitals and which may have violated the moratorium. Information submitted by four hospitals indicates that they were subject to the MMA moratorium. Overpayment letters were sent, demanding repayment of approximately $12 million.

F. Charity Care and Care to Medicaid/Section 1115 Waiver Patients

We are not making a recommendation at this time for the Congress to require specialty hospitals or other hospitals to furnish minimum levels of charity care, or care to Medicaid or section 1115 waiver patients. Rather, we hope that the findings from our survey as to the amount of care provided to these patient populations by specialty hospitals and competitor hospitals, and other studies of the tax contributions of specialty hospitals, will assist the Congress in addressing questions about the responsibilities for-profit and nonprofit hospitals bear with respect to serving the indigent, the uninsured, and the underinsured.

Final Report

I. Introduction

Section 5006(a)(1) of the Deficit Reduction Act of 2005 (DRA), enacted on February 8, 2006, requires the Secretary of Health and Human Services (Secretary) to develop a "strategic and implementing plan" to address certain issues relating to physician investment in "specialty hospitals." The specific issues the Secretary is required to address, as described in section 5006(a)(2) of the DRA, are the following: (1) proportionality of investment return; (2) *bona fide* investment; (3) annual disclosure of investment information; (4) the provision by specialty hospitals of (i) care to patients who are eligible for Medicaid (or who are not eligible for Medicaid but who are regarded as such because they receive benefits under a section 1115 waiver) and (ii) charity care; and (5) appropriate enforcement. A "specialty hospital" is defined by the DRA as a hospital that is exclusively or primarily engaged in the care or treatment of one of the following categories of patients: patients with a cardiac condition; patients with an orthopedic condition; or patients receiving a surgical procedure.[1]

The DRA requires the Department of Health and Human Services (HHS) to issue, within 3 months of its enactment, an interim report on the status of the development of the strategic and implementing plan and, within 6 months of its enactment, a final report or certification of failure to complete the report. In addition, the DRA extends the administrative suspension on enrollment of new specialty hospitals until the earlier of the date the Secretary submits the final report or 6 months after enactment of the DRA. If the Secretary does not submit the final report within the 6-month period, the suspension on enrollment is extended for 2 additional months. On May 9, 2006, the Secretary issued his interim report (the Interim Report). This is the final report, which contains at section V the strategic and implementing plan required by the DRA.

Proponents of physician-owned specialty hospitals[2] claim that by offering a limited range of services and by giving physicians more control over the delivery of care, these hospitals can provide care more effectively, more efficiently, and with greater patient satisfaction. Supporters also contend that the innovations in care cause competitor hospitals to make comparable improvements. Opponents of physician-owned specialty hospitals assert that they engage in "cream-skimming" or "cherry-picking" by selecting those patients who are in need of more profitable procedures and whose conditions are less severe, thus disadvantaging competitor hospitals, which rely on the more profitable

[1] The DRA referenced the definition of specialty hospital contained in section 1877(h)(7)(A) of the Social Security Act (the Act), 42 U.S.C. § 1395nn(h)(7)(A), as added by section 507(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

[2] Unless otherwise noted, this report is limited to and focused on those specialty hospitals that are physician-owned. Other studies have taken different approaches and may include non-physician owned specialty hospitals in their analyses.

cases to offset their less profitable cases. Detractors also say that the physician-owned specialty hospitals do not contribute enough to community needs by providing emergency services or care to the poor and uninsured.[3] In the few years prior to 2003, physician-owned specialty hospitals, though small in number, began to grow at a rapid rate.[4]

II. Background

A. The Physician Self-Referral Statute, the Medicare Prescription Drug, Improvement, and Modernization Act Moratorium, and the Hospital Fair Competition Act of 2005

1. The Physician Self-Referral Statute

Under the physician self-referral statute, section 1877 of the Social Security Act (the Act) (42 U.S.C. § 1395nn),[5] a physician cannot refer a Medicare patient for designated health services (DHS) to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies.[6] Section 1877 of the Act also prohibits the entity furnishing the DHS from submitting claims to Medicare, or billing the beneficiary or any other entity, for Medicare DHS that are furnished as a result of a prohibited referral. Inpatient and outpatient hospital services are included as DHS.[7] A financial relationship includes both ownership/investment interests and compensation arrangements. The statute and regulations enumerate various exceptions, including exceptions for physician ownership or investment interests in hospitals (known as the "whole hospital" exception) and rural providers (known as the "rural provider" exception).

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[3] *Report to the Congress: Physician-Owned Specialty Hospitals*, Medicare Payment Advisory Commission (March 2005) at 3.

[4] A report prepared for the Centers for Medicare & Medicaid Services (CMS) by Research Triangle Institute (RTI) states that the number of physician-owned specialty hospitals treating Medicare beneficiaries more than quadrupled, from 21 in 1998 to 92 in 2004. Three of the 21 specialty hospitals in 1998 were cardiac hospitals, 13 were orthopedic, one was surgical, and the remaining four, either because of very low Medicare volumes or surgery shares, could not be classified. By 2004, there were 20 physician-owned cardiac specialty hospitals treating Medicare patients, 43 orthopedic hospitals, 12 surgical hospitals, and 17 low-volume or low-surgery hospitals that generally were too new to classify. RTI Report at 152. *See* www.cms.hhs.gov/reports/downloads/cromwell3.pdf. For purposes of this report, we identified 130 physician-owned specialty hospitals.

[5] Section 1877 of the Act was added by the Ethics in Patient Referrals Act of 1988, H.R. 5198, 100th Cong. (1988), and is commonly known as the "Stark" law, after the bill's principal sponsor, Representative Fortney "Pete" Stark.

[6] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. Social Security Act, section 1903(s), 42 U.S.C. § 1396b(s).

[7] A complete list of DHS is found at section 1877(h)(6) of the Act.

2. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Prior to the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), the "whole hospital" exception at section 1877(d)(3) of the Act allowed a physician to refer Medicare patients to any hospital in which the physician (or an immediate family member of the physician) had an ownership or investment interest, provided that the physician was authorized to perform services at the hospital and the ownership or investment interest was in the entire hospital and not merely in a subdivision of the hospital. Section 507 of the MMA added an additional criterion to the whole hospital exception, specifying that for the 18-month period beginning on December 8, 2003 and ending on June 7, 2005, physician ownership and investment interests in "specialty hospitals"[8] would not qualify for the whole hospital exception. Section 507 further specified that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers at section 1877(d)(2) of the Act would not apply in the case of specialty hospitals located in rural areas.

Excepted from the MMA moratorium on referrals of patients by physician-investors[9] were hospitals determined by the Secretary to be in operation or "under development" as of November 18, 2003 and for which: (i) the number of physician-investors did not increase at any time on or after that date; (ii) the specialized services furnished by the hospital did not change since that date; and (iii) any increase in the number of beds occurred only on the main campus of the hospital and did not exceed the greater of five beds or 50 percent of the beds in the hospital as of that date.[10]

Hospitals that sought a determination that they were excepted from the moratorium – either because they were not (or were not projected to be) exclusively or primarily engaged in the care or treatment of patients with a cardiac or orthopedic condition, or patients undergoing a surgical procedure, or because they were "under development" as of November 18, 2003 and met the other requirements of section 507 of the MMA – did so by requesting an advisory opinion from the Centers for Medicare & Medicaid Services (CMS). CMS issued a one-time notification on March 19, 2004 that instructed specialty hospitals on the procedures for requesting an advisory opinion as to whether they were "under development." Regulations on the advisory opinion process appear at 42 CFR §§ 411.370-411.389. In accordance with Section 507 of the MMA, hospitals that sought an advisory opinion that they were "under development" were required to submit information concerning whether architectural plans were complete, funding was received, zoning requirements were met, and necessary approvals from appropriate State agencies

[8] The MMA and DRA definitions of "specialty hospital" are the same. *See* note 1.

[9] For purposes of this report, the terms "physician-investor" and "physician-owner" are used interchangeably and refer to physicians who have an investment or ownership interest in a hospital.

[10] MMA, section 507(a).

were received. After the moratorium expired, CMS advised those hospitals that had requested an advisory opinion but had not yet opened that CMS would not issue an advisory opinion for them. CMS advised such hospitals that they could either withdraw their request for an advisory opinion or have it placed on inactive status (to address the possibility that the moratorium would be reenacted and given retroactive effect).

3. The Hospital Fair Competition Act of 2005

On May 11, 2005, Senators Charles Grassley and Max Baucus introduced S.1002, entitled "The Hospital Fair Competition Act of 2005." The bill makes permanent the moratorium enacted by the MMA, with retroactive effect. That is, notwithstanding the expiration of the MMA moratorium on June 8, 2005, the bill amends sections 1877(d)(2)(B) and 1877(d)(3)(B) of the Act by striking "effective for the 18-month period beginning on the date of enactment of the [MMA]" and inserting "on and after December 8, 2003".

The bill also amends the grandfather protection of the MMA that allowed certain physician-owned specialty hospitals in operation or under development before November 18, 2003 to continue to bill Medicare for services rendered to patients referred to the hospital by physician investors, provided they met certain requirements intended to limit their growth or expansion. The bill prohibits grandfathered specialty hospitals from increasing their overall investment by physicians in the hospital beyond the amount held on June 8, 2005, and prevents individual physician-owners from increasing their individual ownership stake beyond that held on June 8, 2005. The bill also prohibits grandfathered specialty hospitals from increasing the number of operating rooms and beds after June 8, 2005.

In addition to extending the moratorium, the bill adopts many of the payment refinements that were recommended by MedPAC in its report on specialty hospitals required by section 507 of the MMA. That is, the bill requires: (i) the use of estimated costs rather than charges in establishing the DRG weights; (ii) establishment of DRG weights at the hospital level for use in calculating aggregate factors at the national level; (iii) adjustments to DRG weighting factors to reduce outlier payments; and (iv) establishment of classification of inpatient discharges to capture severity differences in patients. The bill phases in these payment provisions over a three year period, beginning in fiscal year (FY) 2007.

Also in line with MedPAC's recommendations, the bill expressly authorizes gainsharing, a program in which physicians and hospitals share in the savings from cost-reduction efforts coordinated between physicians and hospitals. The gainsharing provisions of the bill were written as a specific exemption from the Secretary's civil money penalty authority, and direct the Secretary to establish requirements for gainsharing that include quality of care protections, minimization of incentives that could affect physician referrals, and ongoing monitoring of gainsharing arrangements. The bill also establishes

an exception to the anti-kickback statute[11] and the physician self-referral statute for gainsharing arrangements that meet the requirements set out in the exemption to the Secretary's civil monetary penalty authority.

The bill was referred to the Senate Finance Committee on May 11, 2005, and no further action has been taken on it to date.

B. Specialty Hospital Reports and Studies

Physician-owned specialty hospitals have been the subject of reports issued prior to, during, and after the MMA moratorium by the Government Accountability Office (GAO), the Medicare Payment Advisory Commission (MedPAC), and HHS. We summarize below the findings of each of these studies. Each of the studies is available on the internet at the addresses provided in Appendix V.

1. The April 2003 GAO study

Prior to the MMA, the House Committee on Ways and Means requested that GAO study the impact of specialty hospitals on the healthcare system generally and on competing general acute care hospitals in particular. In its April 18, 2003 report, GAO concluded that specialty hospitals represented a small but growing share of the national hospital market; that approximately 70 percent of the specialty hospitals in existence or under development had some physician-owners; and that patients at specialty hospitals tended to be less sick than patients with the same diagnoses at general hospitals (although it did not determine the clinical or economic significance of this finding).[12] For purposes of its report, GAO considered a hospital to be a specialty hospital if the diagnosis-related group (DRG) classification for two-thirds of its Medicare patients (or two-thirds of all of its patients where such data were available) fell into no more than two major diagnosis categories (MDCs), such as diseases of the circulatory system, or if at least two-thirds of its patients were classified in surgical DRGs. Based on these criteria, it identified a total of 92 specialty hospitals as of February 2003 – 17 cardiac hospitals, 36 orthopedic hospitals, 22 surgical hospitals, and 17 women's hospitals.

2. The October 2003 GAO Study

GAO supplemented the findings in its April 2003 report in a report released later the same year.[13] In its October 2003 report, GAO found that specialty hospitals (which, for

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[11] The provisions of the Federal anti-kickback statute set forth at section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b), are summarized at section V.E.1.b.

[12] *Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served,* GAO Report, GAO-03-683R (April 2003).

[13] *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance,* GAO Report, GAO-04-167 (October 2003).

purposes of its analysis were again cardiac, orthopedic, surgical, and women's hospitals) tended to be concentrated in certain geographic areas, where State policy or local demographic conditions were favorable to hospital growth. Specifically, although specialty hospitals were located in 28 States, approximately two-thirds of the 100 specialty hospitals identified by GAO were located in the following seven States: Arizona, California, Kansas, Louisiana, Oklahoma, South Dakota, and Texas.[14] GAO further found that all of the 26 specialty hospitals under development that it identified, and 96 percent of those that opened in 1990 or later, were located in States where hospitals may add beds or build new facilities without first obtaining State approval (referred to as certificate of need or "CON" requirements).[15] GAO stated that 83 percent of all specialty hospitals, 55 percent of general hospitals, and 50 percent of the population of the United States were located in States without CON requirements.

The 100 specialty hospitals studied by GAO included both physician-owned and non-physician owned, and both for-profit (74) and nonprofit (26) hospitals. Some of the GAO's findings related to all 100 specialty hospitals it identified, whereas other findings related to a sample of 26 specialty hospitals located in six States, identified through Healthcare Cost and Utilization Project (HCUP) data for all patient discharges in 2000.

Relative to general hospitals, specialty hospitals were much less likely to have emergency departments. Specifically, 72 percent of the cardiac hospitals, 33 percent of the orthopedic hospitals, and 39 percent of the surgical hospitals were found to have dedicated emergency departments, whereas GAO stated that 92 percent of general hospitals had dedicated emergency departments.

Faster growing counties were somewhat more likely than slower growing counties to have had a specialty hospital open since 1990; however, there did not appear to be a consistent relationship between specialty hospital location and a relative abundance or shortage of local health care resources, as measured by physicians per capita or hospital beds per capita. Eighty-five percent of the specialty hospitals were located in urban areas, which was roughly proportional to that of the population of the United States.

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[14] As of this writing, 93 of the 130 physician-owned cardiac, orthopedic, and surgical specialty hospitals that we identified for purposes of the DRA survey, or 71.5 percent, are located in these seven States.

[15] Federal legislation enacted in 1975 to promote comprehensive planning and development of hospitals and other health care resources conditioned funding to States on their establishment of CON requirements. National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641. Following the repeal of this requirement in 1986 through the Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, several States dropped their CON requirements. GAO noted that, as of 2002, 27 States had CON requirements for acute care facilities. A State's adoption of a CON requirement does not prohibit necessarily a specialty hospital from locating in that State; however, GAO found that 83 percent of all specialty hospitals were located in States without CON requirements. *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, GAO Report, GAO-04-167 (October 2003) at 15.

Although specialty hospitals were much smaller on average than general hospitals in terms of the number of inpatient beds, GAO found that cardiac hospitals in its HCUP data sample generally were not smaller than general hospitals when the comparison was based upon the number of patients treated for specific conditions. Each of the seven cardiac hospitals in GAO's HCUP sample treated more patients than the median general hospital's cardiac practice in the specialty hospitals' market areas, and six of the eight orthopedic hospitals in the sample treated more patients than the median general hospital's orthopedic practice in the specialty hospitals' market areas. However, two of the three surgical hospitals in the sample performed fewer inpatient surgical procedures relative to the general hospitals in their markets.

GAO found that specialty hospitals in its HCUP data sample treated smaller percentages of Medicaid inpatients than did general hospitals located in the same urban areas. Medicaid inpatients comprised 3 percent of the patients at cardiac hospitals, but 6 percent of the cardiac inpatients at the area general hospitals; 8 percent of the orthopedic inpatients at orthopedic hospitals, but 10 percent of the orthopedic inpatients at the area general hospitals; and 1 percent of the surgery inpatients at surgical hospitals, but 5 percent of the surgery inpatients at the area general hospitals.

GAO also found that specialty hospitals derived a smaller percentage of their total revenues from inpatient services (as opposed to outpatient services) than did general hospitals. General hospitals derived 57 percent of their revenues from inpatient services, compared to 36.5 percent for orthopedic hospitals and 25 percent for surgical hospitals. However, cardiac hospitals derived 85 percent of their revenues from inpatient services.

Specialty hospitals tended to perform about as well as general hospitals did on their Medicare inpatient business for Federal fiscal year 2001 (the most recent year for which GAO had information). Medicare inpatient margins averaged 9.4 percent for the four types of specialty hospitals[16] and 8.9 percent at general hospitals. These figures pertain to both for-profit and nonprofit specialty hospitals and general hospitals. With respect to for-profit hospitals, average Medicare inpatient margins were 12.4 percent for the four types of specialty hospitals and 14.6 percent for general hospitals. When revenues and costs from all lines of business and all payers were considered, the average financial performance of specialty hospitals (6.4 percent margin) exceeded that of general hospitals (3.1 percent margin).

3. The May 2005 GAO Study

Shortly before the MMA moratorium ended, GAO issued a third report, in which it attempted to estimate the potential growth in physician-owned specialty hospitals.[17] In this report, GAO took a two-fold approach to its analysis. It first obtained information

[16] The GAO report does not break down margins by type of specialty hospital.

[17] GAO Report, GAO-05-647R, *Specialty Hospitals: Information on Potential New Facilities* (May 19, 2005).

from CMS on the number of hospitals that had requested an advisory opinion as to whether they were excepted from the MMA moratorium. It then noted that 12 of these hospitals were given a favorable advisory opinion, while 25 hospitals' requests were pending. It therefore concluded that if the moratorium were extended, at least the 12 hospitals that were given favorable advisory opinions, and perhaps as many as 37 (12 plus 25) physician-owned specialty hospitals could be completed and opened within a "year or two."

Second, GAO attempted to estimate the number of additional physician-owned specialty hospitals (that is, those not already accounted for in the 37 mentioned above) that would open in the near future if the MMA moratorium were not extended. GAO was uncertain as to how many hospitals fell into this latter category. It received information from the American Hospital Association (AHA), the Federation of American Hospitals (FAH), and others pointing to an additional 52 potential physician-owned specialty hospitals that were under development. GAO found, however, that only six of the 52 were physician-owned specialty hospitals under development, whereas it did not have sufficient information concerning an additional 17 of the 52 to make a determination as to whether they were physician-owned specialty hospitals or whether they were under development. Thus, according to GAO, based on information it had at the time of its report, the maximum number of additional physician-owned specialty hospitals (that is, in addition to the 37 mentioned above) that could open soon after the moratorium expired was 25 (six identified as physician-owned specialty hospitals under development, 17 potential physician-owned specialty hospitals under development, and two physician-owned specialty hospitals that sought advisory opinions that they were exempted from the MMA moratorium but were denied). However, GAO also noted that it spoke with specialty hospital representatives and that most of the representatives expected that any growth in the number of physician-owned specialty hospitals following the expiration of the MMA moratorium would likely be both modest and gradual. Among other reasons given to GAO, the continued uncertainty regarding future Federal restrictions was said to dampen interest in developing new specialty hospitals and make it difficult to obtain the necessary financing.

4. The MedPAC and HHS Studies Required Under Section 507 of the MMA

Section 507 of the MMA required both MedPAC and the Secretary to issue reports to Congress on specialty hospitals. MedPAC was required to study: differences in the costs of health care furnished to patients by physician-owned specialty hospitals; the extent to which specialty hospitals treat patients in certain DRGs relative to competitor acute care hospitals; the financial impact of specialty hospitals on competitor hospitals; how the current DRG system should be updated to better reflect the cost of delivering care in a hospital setting; and the proportions of payments that specialty hospitals and competitor hospitals received by type of payer.

HHS was directed to: determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest; determine the referral patterns of physician-owners, including the percentage of patients they

referred to local full-service competitor hospitals for the same condition; compare the quality of care furnished in specialty hospitals and competitor hospitals for patients with similar conditions, and patient satisfaction with such care; and assess the differences in uncompensated care between specialty hospitals and competitor hospitals, and the relative value of any tax exemption available to such hospitals.

a. The MedPAC MMA Study

MedPAC surveyed 48 physician-owned specialty hospitals (12 cardiac, 25 orthopedic and 11 surgical), as well as 78 peer hospitals (that is, non-physician owned hospitals providing specialized services). MedPAC found that physician-owned specialty hospitals: (1) do not have lower costs thus far for Medicare patients than competitor hospitals, although their patients have shorter lengths of stay; (2) treat patients who generally are less severe cases (and hence are expected to be relatively more profitable than average) and concentrate on particular DRGs, some of which are relatively more profitable; and (3) tend to have lower shares of Medicaid patients than competitor hospitals. MedPAC also found that many specialty hospitals do not have dedicated emergency departments, whereas 93 percent of competitor hospitals do. MedPAC also reported that the financial impact on competitor hospitals in the markets in which specialty hospitals are located has been limited thus far, and those acute care hospitals competing with specialty hospitals have demonstrated financial performance comparable to other competitor hospitals. Specialty hospitals had an average all-payer margin of 13 percent (with many specialty hospitals exceeding 20 percent), compared to between 3 and 6 percent for competitor hospitals.

MedPAC also examined the issue of whether physician-owned cardiac hospitals increased utilization during the period 1996 through 2002. MedPAC found that cardiac surgeries as a whole increased during the study period by 5.5 surgeries per 1,000 Medicare beneficiaries in markets with physician-owned cardiac hospitals and by 4.4 surgeries per 1,000 Medicare beneficiaries in markets without physician-owned cardiac hospitals, and that the difference was not statistically significant. MedPAC also found that although there was a decline in all markets in the growth of higher profitable coronary arterial bypass grafting (CABG) surgeries, the decline in growth was slower in markets with physician-owned cardiac hospitals, and the difference was statistically significant. MedPAC noted that the small changes in utilization were always in the direction that would be predicted by looking at financial incentives.[18]

MedPAC cautioned that its findings were based on the small number of physician-owned specialty hospitals that have been in existence long enough to generate Medicare data, and that because the industry is in its early stages, some of its findings could change as the industry develops. MedPAC said that it did not know yet if physician-owned hospitals will increase their efficiency and improve quality, and that it also did not know

[18] A detailed treatment of MedPAC's utilization study is set forth in Stensland, J., and Winter, A., *Do Physician-Owned Cardiac Hospitals Increase Utilization*?, Health Affairs (January-February 2006).

if, in the longer term, they will damage competitor hospitals or unnecessarily increase use of services.

b. The HHS MMA Study

The HHS study released on May 2, 2005 (the HHS MMA Study) was based on site visits by Research Triangle Institute (RTI) to 11 specialty hospitals in six markets (Dayton, Ohio; Fresno, California; Rapid City, South Dakota; Hot Springs, Arkansas; Oklahoma City, Oklahoma; and Tucson, Arizona). The 11 hospitals constituted 16.4 percent of the 67 cardiac, orthopedic, and surgical specialty hospitals.[19] The study also included findings based on Medicare claims data from the entire population of physician-owned specialty hospitals. HHS found in its study that physician-owners refer or admit the majority of Medicare patients in most specialty hospitals; however, these physicians do not refer their patients exclusively to the specialty hospitals that they own, but also refer them to local competitor hospitals.

The HHS MMA Study determined that, overall, the Medicare cardiac patients treated in competitor hospitals were more severely ill than those treated in cardiac specialty hospitals at the six study sites (the number of cases was too small to draw conclusions for orthopedic and surgical hospitals). Further, the study reported that quality of care at cardiac hospitals was at least as good as, and in some cases better than, care provided at the local competitor hospitals (the numbers of cases were too small to draw conclusions for orthopedic and surgical hospitals), and patient satisfaction was very high in both cardiac hospitals and orthopedic/surgical hospitals. The study also determined that, overall, the proportion of net revenue that specialty hospitals devote to both uncompensated care and taxes significantly exceeds the proportion of net revenues that competitor hospitals devote to uncompensated care.

Medicare patients account for two-thirds of the patients in cardiac specialty hospitals and about 36 percent in orthopedic and surgical specialty hospitals.

5. The April 2006 GAO Study

In an April 2006 report, GAO found that actions taken by general hospitals to remain competitive largely were without regard to whether the competition came from a physician-owned specialty hospital (cardiac, orthopedic, or surgical) or some other type of facility.[20] GAO surveyed 603 general hospitals during August and September 2005, and received responses from 401 of the surveyed hospitals.

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[19] Subsequent to the HHS MMA Study, RTI prepared a report for CMS, entitled *Specialty Hospital Evaluation*, which is a more detailed presentation of the research RTI conducted on behalf of HHS for the HHS MMA Study. *See* www.cms.hhs.gov/reports/downloads/cromwell3.pdf.

[20] GAO Report, *General Hospitals: Operational and Clinical Changes Largely Unaffected by Presence of Competing Specialty Hospitals* (April 2006).

GAO surveyed a sample of general hospitals in regional markets with at least one specialty hospital that had opened since the beginning of 1998. It also surveyed a comparison sample of general hospitals in regional markets where there were no specialty hospitals. General hospitals in both groups were asked to describe the extent of competition within their markets in 2005 (choosing between very or extremely competitive, somewhat competitive or competitive, or not competitive), and to indicate the operational changes and clinical service changes they made from 2000 through 2005 to remain competitive in their markets. The 72 potential operational changes listed in the survey included, for example, increasing income guarantees to recruit physicians. The 34 potential clinical services that hospitals could have reported are adding, expanding, reducing or eliminating included services such as cardiac care. GAO analyzed the survey responses to determine whether there were significant differences between the group of general hospitals with at least one specialty hospital in each market and the group of general hospitals with no specialty hospitals in their markets. This analysis was conducted separately for urban general hospitals (that is, those located in a metropolitan statistical area (MSA)) and rural general hospitals (that is, those located outside of an MSA).

GAO reported that nearly all of the general hospitals that responded to the survey reported making operational and clinical changes. GAO found that there was little evidence to suggest that general hospitals made substantially more, fewer, or different types of changes if some of their competition came from a specialty hospital. Whereas the majority of the respondent hospitals indicated that competition had increased from other general hospitals, a larger percentage of respondents (91 percent of urban general hospitals and 74 percent of rural general hospitals) reported increases in competition from limited service facilities.[21] The category of limited service facilities includes specialty hospitals; however, it also includes many other types of facilities such as ambulatory surgical centers, imaging centers, urgent care centers, and gastroenterology centers, which, collectively, far outnumber specialty hospitals.

GAO found that 100 percent of the respondent hospitals reported implementing at least one operational change; 97 percent of the respondents reported adding at least one new clinical service or expanding an existing service; and 32 percent of the respondents reported eliminating at least one clinical service or devoting fewer resources to it. GAO concluded that there were no substantial differences in the average number of operational and clinical service changes made by general hospitals in markets with specialty hospitals as compared to changes made in markets without specialty hospitals, and for the vast majority of the potential changes included in the survey, there was no statistical

[21] A recent article states that, although public policy attention has focused on specialty services provided by physician-owned specialty hospitals, the provision of specialty services in all types of hospitals is a more pervasive development. The authors conclude that the development of specialty service lines shows early signs of increasing health care costs and as-yet-unquantified effects on the quality of care. Berenson, R., et al., *Specialty-Service Lines: Salvos in the New Medical Arms Race*, Health Affairs July 25, 2006).

difference between the two groups of hospitals with respect to the specific changes they reported making.

6. Testimony from the April 2006 MedPAC Meeting[22]

On April 19, 2006, MedPAC supplemented its 2005 report issued pursuant to section 507 of the MMA with a public meeting to discuss new findings related to specialty hospitals. MedPAC staff noted that MedPAC's 2005 report was based on the limited set of specialty hospitals operating for all of 2002, and that MedPAC had indicated that it might revisit its findings when more data were available. The findings discussed at the public meeting are based on two additional years of data (2003 and 2004) and relate to specialty hospitals' cost of inpatient care, the share of Medicaid patients served by specialty hospitals, whether market entry of physician-owned cardiac hospitals is associated with an increase in cardiac surgeries, and the impact of physician-owned cardiac hospitals on competing community hospitals. MedPAC staff testified that, in general, the new findings based on the two additional years of data were similar to those in its 2005 report, but that the expanded data set allowed MedPAC to have more confidence in the statistical significance of its findings.

MedPAC staff testified that specialty hospitals' costs were not less than those of competing community hospitals. Cardiac specialty hospitals had inpatient costs that were comparable to competing community hospitals. Orthopedic and surgical specialty hospitals tended to have inpatient costs per discharge that were 20 to 30 percent higher than those of competitor hospitals (which was statistically significant). Some of the higher costs per discharge may be explained by higher capital costs (such as depreciation and lease costs) due to the new plant and equipment of specialty hospitals, but the most important factor explaining higher costs per discharge appears to be the low inpatient volume at which specialty hospitals (particularly orthopedic and surgical hospitals) operate, and their chronically underused capacity.

Cardiac, orthopedic, and surgical specialty hospitals all typically served a lower percentage of Medicaid patients than competitor hospitals. MedPAC staff noted that the higher percentage of Medicaid patients served by competitor hospitals may be explained by the services offered, such as obstetrics. However, staff testified that physician-owned specialty hospitals also have a slightly lower Medicaid share than "peer hospitals," that is, hospitals with similar levels of specialization that are not physician-owned.

MedPAC staff testified that MedPAC examined the issue of utilization. Staff noted that, historically, when physicians have invested in imaging centers or diagnostic labs, the investments were followed by an increase in utilization of imaging and clinical laboratory services, but that it is not clear that physician investment in cardiac hospitals has led to an increase in cardiac surgery. MedPAC tested whether utilization increases, and whether a

[22] MedPAC is currently preparing a report of its findings. We have reviewed a draft of the report, but are not citing to the draft report; rather, our citations are only to the testimony at the April 19, 2006 public meeting.

shift in surgical volumes toward more profitable surgeries (such as CABG or surgery on less severely ill patients) occurs when a physician-owned cardiac hospital enters the market. It compared utilization from 1996, a year prior to the opening of cardiac hospitals, to 2004. By comparing the rate of increase in cardiac surgeries in markets without physician-owned cardiac hospitals to the rate of increase in cardiac surgeries in markets with physician-owned cardiac hospitals, MedPAC staff said the overall rate of cardiac surgeries increased by roughly 6 percent following the entry of a typically-sized physician-owned cardiac hospital into the market.

There was also a statistically significant increase in CABG surgeries and an increase that was not statistically significant in moderately profitable angioplasties and low- or no-profit defibrillator implants. The ratio of more profitable, low-severity surgeries to less profitable, high-severity surgeries did not increase significantly faster in markets with physician-owned cardiac hospitals. Because both highly profitable and less profitable surgeries increased with the entry of a physician-owned cardiac hospital, the increase in cardiac surgeries associated with physician-owned cardiac hospitals may be entirely due to the increased surgical capacity associated with building a new cardiac hospital. In conclusion, staff testified that physician-owned cardiac hospitals do appear to cause an increase in utilization. The increase may be purely due to surgical capacity, but financial incentives cannot be ruled out as having some effect. If physicians' incentives are causing a shift toward more profitable surgeries, the magnitude of the shift is too small to be detected.

Finally, staff testified on the effect of physician-owned cardiac hospitals on competitor hospitals. Increased utilization accounted for roughly 6 percent of the median physician-owned cardiac hospital's 26 percent market share. The cardiac hospitals obtained roughly 80 percent of their patients from competitor hospitals. However, the cardiac hospitals had a limited impact on competitor hospitals. Although the entry of physician-owned cardiac hospitals into markets shared by competing community hospitals had a negative effect on the latter's growth, the competitor hospitals were able to make adjustments to compensate for the lost revenue. There was no statistically significant net impact on competitor hospitals' total revenue or total margins. The median competitor hospital reported a total margin that was in line with the national average.

C. CMS Recommendations in Response to the MedPAC and HHS MMA Studies

CMS Administrator Mark B. McClellan, M.D., PhD, testified before the House Committee on Energy and Commerce on May 12, 2005 and presented four key recommendations regarding specialty hospitals.[23] First, Dr. McClellan stated that CMS would analyze MedPAC's recommendations to improve the accuracy of the payment rates for inpatient hospital services and that CMS expected to adopt significant revisions in FY 2007. Second, CMS would reform payment rates for ambulatory surgical centers

[23] In addition to the May 12, 2005 hearing, the Congress has held several other hearings on issues related to specialty hospitals. References to these hearings are found in the bibliography at Appendix V.

to reduce incentives to form a specialty hospital simply to take advantage of higher payment rates under the Medicare outpatient prospective payment system (PPS). Third, CMS would engage in closer scrutiny of whether specialty hospitals meet the definition of a hospital in section 1861(e) of the Act. Fourth, CMS would carefully review its criteria for enrolling new specialty hospitals into the Medicare program.

Recommendation 1: Reform Payment Rates for Inpatient Hospital Services through Diagnosis Related Group (DRG) Refinements

In general, CMS agreed with MedPAC that the accuracy of the inpatient hospital prospective payment system rates should be improved, and the emergence of specialty hospitals clearly illustrated the need for such a change.

a. Refine DRGs to More Fully Capture Differences in Severity of Illness

CMS stated that it would propose changes to the DRGs to better reflect severity of illness. There is a standard list of diagnoses that are considered complications or co-morbidities (CC). These conditions, when present as a secondary diagnosis, may result in payment using a higher weighted DRG. CMS's analysis indicated that the majority of cases assigned to these DRGs fell into the "with CC" DRGs. CMS stated its belief that it is possible that the CC distinction has lost much of its ability to differentiate the resource needs of patients for two reasons: (1) the length of time since the original CC list was developed, and (2) the incremental nature of subsequent changes in an environment of major changes in the way inpatient care is delivered.

CMS said that it also was considering a selective review of specific DRGs, such as cardiac, orthopedic, and surgical DRGs, that are alleged to be overpaid and that may create incentives for physicians to form specialty hospitals. CMS stated that it would selectively review particular DRGs based on statistical criteria such as the range or standard deviation among charges for cases included within the DRG. CMS noted that it was possible for specific DRGs to have high variation in resource costs and that a better recognition of severity would reduce incentives for hospitals to select the least costly and most profitable patients within these DRGs. CMS also stated that it would evaluate the use of alternative DRG systems, such as the all-patient refined diagnosis-related groups (APR-DRGs), in place of Medicare's current DRG system. APR-DRGs have a greater number of DRGs that could relate payment rates more closely to patient resource needs, and thus reduce the advantage of selecting healthier patients.

b. Base DRG Weights on the Estimated Cost of Providing Care Rather Than Hospital Charges

MedPAC recommended that CMS base the DRG relative weights on the estimated cost of providing care rather than on charges. CMS noted that it did not have access to any information that would provide a direct measure of the costs of individual discharges, but that claims filed by hospitals provided information on the charges for individual cases and accordingly, at present, it uses this information to set the relative weights for the

DRGs. CMS stated that, although it obtains information on costs from the hospital cost reports, this information is, at best, at the department level and, thus, does not include information about the costs of individual cases. Consequently, the most straightforward way to estimate costs of an individual case would be to calculate a cost-to-charge ratio for a group of claims (for example, for a hospital's radiology department), and then apply this ratio to the charges for that department. CMS noted that this procedure has disadvantages. Assignment of costs to departments is not uniform from hospital to hospital, particularly given the variability of hospital accounting systems, and cost information is not available until a year or more after claims information is available. In addition, the application of a cost-to-charge ratio that is uniform across any group of claims may result in biased estimates of individual costs if hospital charging behavior is not uniform.

c. Base DRG Weights on Hospital-Specific Estimated Cost of Providing Care

MedPAC recommended that CMS base DRG relative weights on the national average of hospitals' relative values in each DRG. CMS stated that it set the relative weights using standardized charges (adjusted to remove the effects of differences in area wage costs, indirect medical education, and disproportionate share payments). In contrast, MedPAC proposed that Medicare set the DRG relative weights using non-standardized hospital-specific charges. Each hospital's non-standardized charges would become the basis for determining the relative weights for the DRGs for that hospital. These relative weights would be adjusted by the hospital's case-mix index when combining each hospital's relative weights to determine a national relative weight for all hospitals. This adjustment is designed to reduce the influence that a single hospital's charge structure could have on determining the relative weight when it provides a high proportion of the total nationwide number of discharges in a particular DRG.

CMS stated that it would analyze the possibility of moving to hospital-specific relative values while conducting the analysis outlined above in response to the MedPAC recommendations regarding improved severity adjustment and using charges adjusted to estimated cost to set the relative weights.

d. Adjust DRG Weights to Account for Differences in Prevalence of High-Cost Outlier Cases

MedPAC also recommended that CMS adjust DRG weights to account for the prevalence of high-cost outlier cases. Under current Medicare policy, CMS includes all the charges associated with high-cost outlier cases to determine the DRG relative weight. CMS stated that it believed that MedPAC's recommendation arose from a concern that including high-charge outlier cases in the relative-weight calculation results in overvaluing DRGs that have a high prevalence of outlier cases. However, CMS believed that excluding outlier cases completely in calculating the relative weights would be inappropriate. Doing so would undervalue the relative weight for a DRG with a high percentage of outliers by not including that portion of hospital charges that is above the

median but below the outlier threshold. It said that it would be preferable to adjust the charges used for calculating the relative weights to exclude the portion of charges above the outlier threshold, but to include the charges up to the outlier threshold.

e. Provide a Transition for These Changes

MedPAC recommended that a transition period be included for adopting any changes. CMS stated that, before proposing changes to the DRGs, it would need to model the impact of any specific proposal to determine whether changes should be implemented immediately or over a period of time. CMS noted that replacing the existing DRG system with a revised DRG system that fully captures differences in severity likely would involve unique complexities in creating a transition from one DRG system to the other. CMS's payment would be a blend of two different relative weights that would be determined by using two different DRG systems. The systems changes and legal implications of such a transition or any other major change to the DRGs could be significant.

Recommendation 2: Reform Payment Rates for Ambulatory Surgical Centers

Physicians may be participating in the ownership of small orthopedic or surgical hospitals, in part, to take advantage of payment differences between hospital outpatient departments and ASCs. An important goal of Medicare's planned reform of the ASC fee schedule is to reduce divergences of payment levels between these settings when resource costs consumed in producing the same service in the two settings are similar. CMS noted that, as a group, surgical and orthopedic hospitals are different from cardiac hospitals. The cardiac hospitals tend to have more inpatient beds and to more closely resemble competitor hospitals (for instance, by participating in community emergency medical service protocols).

Section 626 of the MMA requires and sets parameters for a revision to the ASC fee schedule. The existing fee schedule is comparatively crude, especially relative to recent changes in outpatient medical practice, with only nine payment rates used for approximately 2500 different services. Consequently, each payment cell spans a broad set of clinically heterogeneous services. In addition, the basic structure of rates has not been updated since 1990. This has resulted in a situation in which payment rates for particular services in ASCs differ significantly from those in hospital outpatient departments, for which Medicare pays using the more differentiated and current outpatient PPS. In many instances, the payments for particular services are significantly higher in hospital outpatient departments. Insofar as these divergences do not reflect real differences in the needs of patients treated in the two settings or the resources used in treating them, they create incentives for the development of specialty hospitals, where the outpatient services are paid under the outpatient PPS. Reforming the ASC fee schedule to (1) use the same payment categories in the two settings so payments can be compared, and (2) adjust payment rates where the resource costs consumed in providing the same services are similar can materially reduce these divergences and mitigate incentives that now favor the proliferation of specialty hospitals.

Recommendation 3: Closer Scrutiny of Whether Entities Meet the Definition of a Hospital

CMS stated that it would examine closely the question of whether some specialty hospitals did not meet the definition of a "hospital." Section 1861(e) of the Act provides that, in order to be a "hospital," an institution must be primarily engaged in providing care to inpatients. CMS stated that the results of the HHS Study suggested that some entities providing specialty care may concentrate primarily on outpatient care and consequently did not meet the definition of "hospital" in section 1861(e) of the Act. CMS stated that applicant specialty hospitals could be denied a provider agreement if it were determined that they did not meet the definition of a "hospital," and that specialty hospitals operating under an existing Medicare provider agreement could have such agreements terminated if they did not satisfy the definition of a "hospital."

Recommendation 4: Review of Procedures for Approval for Participation in Medicare

CMS said that, in addition to its concern that some specialty hospitals may not meet the definition of a "hospital," it wanted to be assured that, given their limited focus, specialty hospitals meet such core requirements that CMS determines are necessary for the health and safety of Medicare beneficiaries. To address these concerns, CMS stated that it would review its current standards for approval for participation and payment to determine whether additional or different standards should apply to specialty hospitals in light of the focused nature of their services. CMS said that it planned to confer with State survey and certification units, and the organizations that accredit hospitals (that is, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA)). CMS also stated that it would assess whether revisions to its standards for enrolling specialty hospitals would be appropriate based on the requirements of the Emergency Medical Treatment and Labor Act (EMTALA). Finally, CMS stated that, while it was looking at the procedures for enrolling new specialty hospitals, it would instruct its regional offices not to issue new specialty hospital provider agreements or authorize an initial survey by the State survey agency for new specialty hospitals. Medicare fiscal intermediaries would be instructed to refrain from processing further new provider enrollment applications for specialty hospitals during a six-month period.

III. Interim Report and Comments

A. Contents of the Interim Report

On May 9, 2006, we released the interim report required by section 5006 of the DRA (the Interim Report). The Interim Report gave an update on the four recommendations that CMS offered in response to the MedPAC and HHS MMA Studies required by section 507 of the MMA, and outlined the steps we planned to take for issuing the final report and strategic and implementing plan. We summarize below some of the key provisions of the Interim Report. The Interim Report is reproduced in its entirety at Appendix IV.

1. Reform Payment Rates for Hospital Inpatient Services

The Interim Report described the progress CMS has made with respect to refining the DRG payment system. In response to the FY 2006 inpatient PPS proposed rule, CMS received comments indicating that cardiac surgery DRGs have high relative profitability ratios, and recommending refinement of cardiac surgery DRGs. For the final rule for FY 2006, CMS performed an extensive review of the cardiovascular DRGs, particularly those DRGs that are commonly billed by specialty hospitals. CMS identified conditions that would lead to a more complicated patient stay requiring greater resource use. Using this approach, CMS found a sound analytical basis for revising nine cardiovascular DRGs, and, in the inpatient PPS final rule for FY 2006, we replaced those nine cardiac DRGs with 12 new DRGs that better recognize severity of illness. *See* 70 FR at 47289-92. The Interim Report stated that CMS believes the new cardiac DRGs are an improvement over the existing DRG structure because they better recognize a patient's severity of illness and, accordingly, permit higher payments for more severely ill patients who require more resources while lowering payments for less severely ill patients and less resource-intensive patients. The Interim Report noted that CMS was currently studying other DRGs, including those for orthopedic and surgical procedures, to better identify subgroups of more severely ill patients who use greater hospital resources.

2. Reform Payment Rates for Ambulatory Surgical Center Services

The Interim Report noted that CMS is developing revisions to the list of procedures eligible for payment in ASCs to take effect by July 1, 2007 and expects to include most outpatient hospital surgical procedures in the ASC fee schedule by 2008. As a result, CMS stated, Medicare payments under that system will: (1) better reflect the resources required to perform specific surgical procedures, and (2) be similar to payments under other payment systems to the extent that similar procedures and use of resources are involved.

3. Definition of a Hospital

The Interim Report noted that the issue of how to determine whether a facility was primarily engaged in furnishing services to inpatients was discussed at a September 30, 2005 Special Open Door Forum. Representatives of both community and specialty hospital associations opposed the adoption of a fixed definition of "primarily engaged in furnishing services to inpatients." Some associations recognized that, given advances and improvements in medical technology, many procedures that previously could be performed on an inpatient basis only can now be safely performed on an outpatient basis. Community hospital associations opposed a fixed standard because some small rural hospitals might not meet new requirements. The Interim Report stated that CMS has not yet identified any quantitative method, such as percentage of services or ratio of inpatient-to-outpatient services, that could be used without disqualifying both community hospitals and specialty hospitals. Therefore, CMS currently did not 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.

4. Changes to the Enrollment Procedures

The Interim Report stated that, largely because CMS did not intend to define hospital by regulation, it had not identified any needed changes to the enrollment process.

5. EMTALA

The Interim Report stated that CMS considered many aspects of the application of EMTALA to specialty hospitals. The Interim Report disclosed that, after taking into account the EMTALA technical advisory group's (TAG) deliberations and public comments following the EMTALA TAG meeting and the Special Open Door Forum, CMS did not intend to recommend currently to Congress or require, as a condition of Medicare participation, that all hospitals must have an emergency department. The community hospital associations, including FAH and AHA, supported CMS's position in their comments before the EMTALA TAG. However, the Interim Report stated that CMS proposed in the FY 2007 inpatient PPS proposed rule that all hospitals (including specialty hospitals) with specialized capabilities must accept appropriate transfers of unstable patients, regardless of whether the hospital with specialized capabilities has a dedicated emergency department.

Part III of the Interim Report set forth our strategy for obtaining the necessary data for the physician investment and Medicaid/charity care issues that section 5006 of the DRA requires us to address. Based upon the analysis of information available to CMS (including data collected as part of the MedPAC and HHS MMA Studies required by section 507, the GAO reports, and the applications of specialty hospitals seeking advisory opinions concerning whether they were excepted from the MMA moratorium), we stated that it was necessary to secure additional information on each component of the Strategic Plan. We explored possible ways to obtain this information and held numerous meetings with various specialty and community hospital groups. We stated that CMS developed a survey to collect information to supplement the data we already have. We stated that our goal in collecting data was to make transparent the investments of physician-owners of specialty hospitals and to present a picture of the Medicaid population served by, and charity care practices of, specialty hospitals in context with their primary competitors, the community hospitals.

B. Public Comments on Interim Report

The American Hospital Association (AHA), the Federation of American Hospitals (FAH), and the Ohio Hospital Association (OHA) commented on the Interim Report.

1. Hospital Payment Reforms

AHA and OHA addressed the hospital payment reforms discussed in the interim report. AHA stated that, although it supports a move to cost-based DRG weights, it is not clear which of several ways of accomplishing this best improves payment accuracy. Therefore, it recommended a one-year delay to enable further analysis and development of workable approaches. It also stated that more analysis is required to assess the need for, and to develop approaches for, severity adjusted payments. OHA stated that, although it too supported the planned reforms, any reexamination of DRG weights and payment rates should be performed in tandem. It asserted that phasing in these reforms will only result in dramatic and expensive overhauls of hospital billing and payment systems year after year. OHA contended that all changes should be implemented at the same time and only when CMS is confident that it has adequately studied the impact and understands the full effect of the reforms.

2. Ambulatory Surgical Center Payment Reforms

AHA stated that it was concerned that the Interim Report suggested that CMS plans to simply increase payments to ASCs so that they more closely approximate outpatient hospital payments. According to AHA, ASCs and hospital outpatient departments play different roles, are subject to different regulatory standards, have different underlying costs, and serve different populations. Therefore, hospital outpatient departments should be paid higher rates than ASCs.

3. Whole Hospital Exception and Conflict of Interest

AHA and FAH stated that the hospital and ASC payment reforms planned by CMS systems do not adequately address conflict of interest concerns that are inherent in physician ownership of specialty hospitals. AHA continues to support a permanent ban on physician self-referral for specialty hospitals. According to AHA, research has clearly shown that self-referral increases the use of services but does not reduce cost. AHA opined that no patient should have to question whether his or her physician is acting in the interest of patient care or in the physician's best financial interest. At a minimum, AHA argued, CMS should recommend that Congress require transparency of physician investments and enact limitations on physician investment in limited service hospitals[24] if it is going to continue to allow physician-owned limited service hospitals to use the whole hospital exception. FAH stated that payment reform should not be viewed as a solution to the broader issue of physician ownership of and self-referral to limited service hospitals. According to FAH, the refinements to the inpatient PPS would not address, and would do little to mitigate, the underlying concerns about conflict of interest inherent in physician-owned limited service facilities. FAH believes the solution to this problem

[24] The commenters variously used the terms "limited service hospital," "limited service facility," and "specialty hospital." For purposes of this section III.B, we consider the terms "limited service facility" and "limited service hospital" to be synonymous with the term "specialty hospital."

lies in CMS's interpretation and enforcement of the whole hospital exception to the physician self-referral law.[25] OHA stated that the Interim Report ignored the fundamental issue of conflict of interest. OHA asserted that the issue underlying Congress's study of physician investment in specialty hospitals is the harmful effects of the resulting conflicts of interest and physician self-referral.

4. Administrative Action Plan and Timeline for Implementation

FAH stated that the final report should contain an administrative action plan and a timeline for implementation. It interpreted the Interim Report to mean that CMS will provide recommendations to Congress for legislative action as it deems appropriate, and was concerned about the lack of focus in the Interim Report regarding administrative action items. FAH believes the DRA is clear that Congress expects administrative action items and a timeline for implementation.

5. Transparency of Investment

FAH stated that HHS should increase the information required for public disclosure by physician-owned limited service facilities to include the terms of physician-owners' initial investment in the facility and a report on annual distributions or other returns on their investments. For example, the actual dollar amount of a physician's investment and the income distribution received each year since the year of the initial investment should be disclosed. FAH suggested that physician-owners should also be required to disclose whether their investment is through a debt instrument and, if so, who the guarantors are on the debt instrument. According to FAH, physician-owners of limited service facilities should be required annually to provide distribution information.

6. Charity Care and Medicaid Patients

All three commenters addressed the Interim Report's discussion of charity care. AHA and OHA highlighted the statement in the Interim Report that HHS might recommend a minimum charity care requirement, and were opposed to such a requirement. AHA asserted that a minimum charity requirement for hospitals does not target what is needed to address what it perceives as the growing problem of self-referral. According to AHA, a lack of charity care provided by physician-owned, limited service hospitals is symptomatic of the broader problem they pose for the community. AHA suggested that any public policy questions about charity care, which is only a part of the contribution hospitals make to their communities, is within the purview of the Internal Revenue Service (IRS), which is actively engaged in examining those issues.

[25] On February 28, 2005, FAH submitted a rulemaking petition requesting that the Secretary revise 42 CFR § 411.356(c)(3) to prohibit specialty hospitals from qualifying for the whole hospital exception. The American Medical Association opposed the petition. On June 9, 2005, the Secretary responded that HHS lacks the statutory authority to amend the whole hospital exception by regulation in the manner suggested by FAH.

OHA stated that any national minimum requirement cannot recognize the local variances and community economics that drive hospital charity care numbers. In addition, tax-exempt hospitals meet a broader community benefit standard that includes much more than charity care alone. Research, teaching, health outreach and public health programs are common contributions of community hospitals, which are not reflected in charity care numbers, but all of which, in OHA's view, are threatened when hospitals lose profitable patients to physician-owned specialty hospitals. OHA also noted that charity care definitions vary, as do charity care policies, based on the local community's economic situations. In addition, a definition of charity care must recognize the realities of health care delivery. According to OHA, more often than not, a hospital does not know the insurance or financial situation of a patient at the time of service, particularly when the service is delivered through the emergency department. Patients themselves may not know their insurance coverage, or may be reluctant to disclose their personal financial information, leaving the hospital in the difficult position of issuing a bill without adequate documentation that the patient may qualify for free or discounted care. According to OHA, any definition of charity care must recognize that a decision as to whether care is "charity care" cannot be made sometimes for many months after the patient's hospital treatment. OHA also objected to the statement in the Interim Report that the definition of charity care for purposes of the final report would not count monies provided by State and local government entities, private foundations and other non-public sources. It questioned the legal authority of HHS to define how funds earmarked by local political jurisdictions and private foundations are used.

FAH stated that the studies performed to date are clear that physician-owned limited service facilities have not served their fair share of charity care and Medicaid patients, with the result that full service community hospitals, whether investor-owned or nonprofit, are assuming a disproportionate share of the financial burden of these patient groups. FAH suggested that HHS should consider requiring physician-owners to treat equal numbers of low income, uninsured and charity patients in their limited service hospitals as they do in community hospitals.

7. Enforcement of the MMA Moratorium

FAH was concerned that appropriate claim edits were not in place to enforce properly the moratorium. It suggested that CMS conduct post-payment reviews on all limited service facilities that were not excepted from the moratorium, and collect any identified overpayments plus interest. FAH suggested that, going forward, CMS should not process claims from physician-owned limited service facilities until an appropriate process is established that identifies and differentiates between owner and non-owner physicians.

OHA stated that HHS should continue to collect data concerning the proportionality of investment and *bona fide* investment, compelling participation if necessary. Until this data is collected accurately and the results tallied, OHA believes HHS should not move forward with recommendations.

8. Role of OIG

FAH stated that OIG should be involved directly in developing the strategic and implementing plan and should not be limited to a consultant's role. According to FAH, given its responsibilities to enforce the fraud and abuse laws, OIG is best suited to address issues related to physician investment in specialty hospitals. FAH asserted that specialty hospitals are no different from other types of providers, suppliers, and practitioners for which OIG routinely uses enforcement tools to protect against fraud and abuse.

9. EMTALA

OHA applauded CMS's proposal to clarify that, under EMTALA, hospitals with specialized capabilities are required to accept appropriate transfers. It also said that, from a practical standpoint, however, physician-owned specialty hospitals often do not have dedicated emergency departments or 24-hour physician coverage, and therefore a transferring hospital will experience difficulties in finding someone at the hospital with specialized capabilities to accept the transfer. OHA noted that, although CMS's proposal is a step in the right direction, CMS and the EMTALA TAG should consider creative reforms that can be effective in their application.

10. Definition of Primarily Engaged

FAH acknowledged that it is challenging to define what is meant by a hospital being "primarily engaged" in inpatient services. FAH stated that, nonetheless, CMS must bring greater clarity to this definition as a means to guard against facilities that seek hospital status merely for payment benefits. This can be achieved in a reasonable manner that protects rural hospitals, which may have a limited inpatient mix. AHA said that the Interim Report reflects the general consensus that it would be unwise to set a numeric proportionality test for inpatient versus outpatient care due to unintended consequences, especially for small rural hospitals.

11. Enrollment Procedures

AHA recommended that CMS adopt several changes to the Medicare conditions of participation for hospitals and the procedures for enrolling physician-owned limited service hospitals. For example, every hospital should have on the premises "24/7" staff that are proficient in resuscitation and the maintenance of respiration. According to AHA, hospitals should be required to disclose to patients at the time of admission scheduling the service limitations of the facility and the likelihood of transfer to another hospital in the event of complications. AHA suggested that physician-owned limited service hospitals should be required to have agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient. Specifically, the agreements should be required to address: procedures for an appropriate transfer from a limited service hospital for patients not covered under EMTALA; continuity of care (for example, telephone consultation with the receiving

hospital and physician); and support for maintaining full-time emergency capacity at the community hospital, including on-call coverage. AHA also asserted that CMS should collect individual physician ownership information as part of the enrollment process, and that CMS should analyze routinely the claims data from physician-owned hospitals during the first several years of their operation to determine if they are limited service or full service hospitals.

12. Suspension on Enrollment of Specialty Hospitals

FAH stated that the survey instrument seeks comprehensive data from hospitals, and CMS will need substantial time to analyze the responses and to do any necessary follow-up with responding hospitals in order to clarify or explain submitted data. Because of the importance of these issues, HHS should not make finishing the report by August 8, 2006 a top priority, but rather should take as much time as necessary to review and consider all responses before developing a complete and comprehensive strategic and implementing plan. Therefore, CMS should take steps to implement an administrative suspension on the enrollment of new specialty hospitals should HHS decide that there are significant issues that continue to need further review and consideration after August 8, 2006. This action would be similar to action taken by CMS in June 2005 and is clearly within the agency's authority.

IV. Survey Results and Related Information

A. Introduction

In the Interim Report we stated that it was necessary to secure additional information on each component of the Strategic Plan based upon the analysis of information available to CMS at the time.[26] We explored possible ways to obtain this information, including the development of a survey to supplement the data we already had. Our goal in collecting and analyzing data was to bring transparency to the investments of physician-owners in specialty hospitals and to present a picture of the Medicaid population served by, and the charity care practices of, specialty hospitals within the context of their primary competitors, community hospitals.

The Interim Report included a section entitled "Review of Existing Data" in which we described our preliminary efforts to review both the MedPAC and HHS MMA Studies, as well as information gleaned from the applications of over 40 specialty hospitals seeking advisory opinions concerning whether they were "under development" or "in operation" within the meaning of section 507(a) of the MMA. We have completed our final review of the HHS and MedPAC MMA Studies and their findings concerning physician financial incentives, rates of return on investments, the provision of care to Medicaid patients, and uncompensated care. Both studies (and the GAO reports) helped us design

[26] For purposes of this section IV, we refer to HHS and CMS interchangeably as "we."

the survey and determine which elements would be critical to our analysis. These reports and studies had caveats about the validity of some of the data given the small number of hospitals that were involved. Given the larger number of specialty hospitals in our survey, we hoped that this would afford a different picture of various aspects of the operations of specialty hospitals.

We also have completed our review of the information submitted by hospitals in connection with their requests for advisory opinions as to whether they were excepted from the MMA moratorium because they were "under development" as of November 18, 2003. One of the four factors that CMS was required by section 507 of the MMA to consider in determining whether a hospital was under development as of November 18, 2003 was the hospital's "receipt of funding." In that regard, some requestors furnished information describing the funding of the hospital and its physician-investors, the entities that were part of the venture, and the projected rates of return. Some requestors supplied copies of the initial prospectus given to potential investors in the hospital and copies of confidential offering memorandums. We used that information, in conjunction with the information we received from the respondents to the survey, to analyze both proportionality of physician investment return and *bona fide* investment.

Our review of the specialty hospital advisory opinion requests led us to conclude that the funding and investment information supplied varied greatly, and, that in order to obtain a more accurate depiction of the proportionality of physician investment return and *bona fide* investment in specialty hospitals, we needed to supplement this information with additional data. The data in the HHS and GAO studies did not shed sufficient light on this topic. The MedPAC study contained only a conceptual analysis of physicians' economic incentives to form specialty hospitals. Partly for these reasons, we elected to create a survey to be sent by CMS to both specialty and competitor acute care hospitals.[27] The survey solicited information on the issues that specifically were identified in section 5006 of the DRA as well as on related issues that we believe may be of interest to the Congress.

CMS sent the survey to all 130 physician-owned specialty hospitals it had identified.[28] Figure 1 shows the location of specialty hospitals by State. We note specialty hospitals remain concentrated in seven States: California, Kansas, Louisiana, Ohio, Oklahoma, South Dakota and Texas. Specialty hospitals tend to be located in States without CON requirements, in urban markets and primarily in more affluent, high population growth markets, for instance, Austin, Dallas-Fort Worth, Houston, and San Antonio.

[27] A complete copy of the survey and its accompanying instructions is found at Appendix III.

[28] Subsequent to our transmission of the survey, we received information that suggests that a few hospitals are not physician-owned or may have changed the scope of the services they provide. CMS will continue to investigate the characteristics of these hospitals and will publish an updated list of physician-owned specialty hospitals on its website upon completion of its investigation.

Figure 1
Specialty Hospitals by State

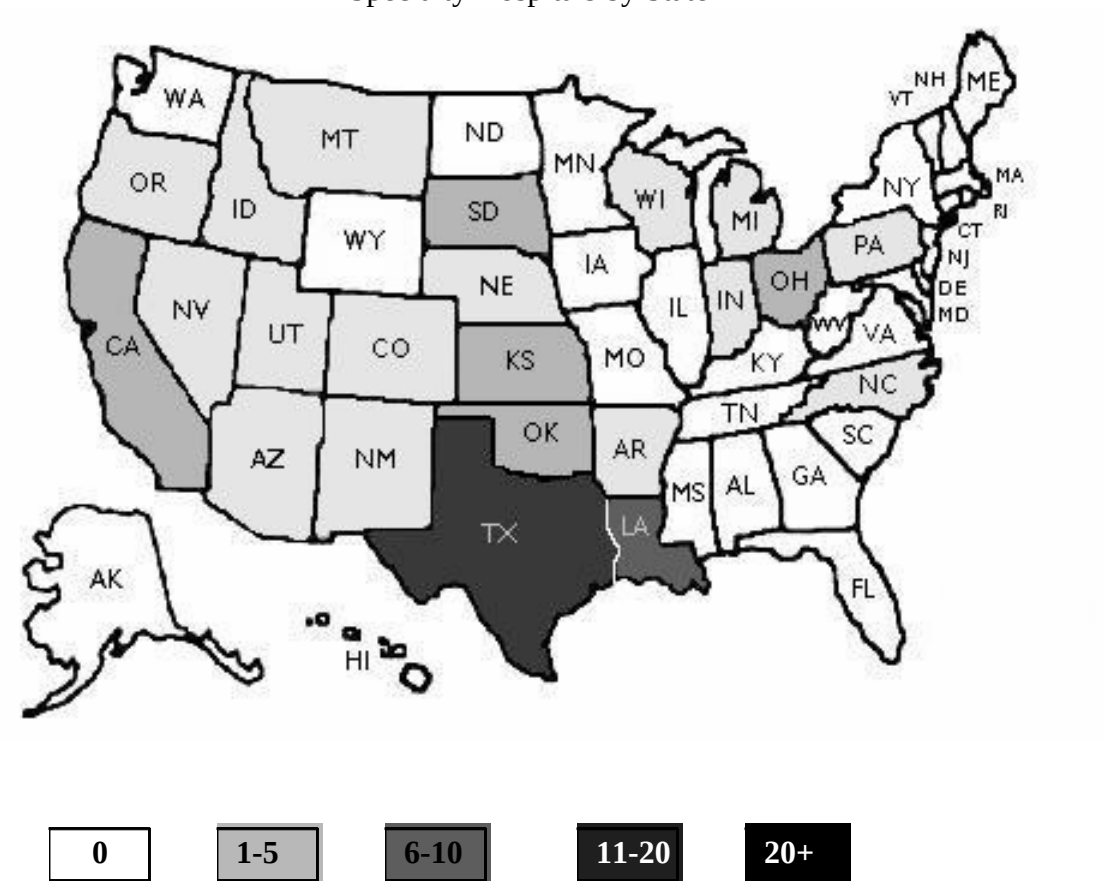


Figure 2 shows the number of specialty hospitals, by category (that is, cardiac, surgical and orthopedic). These figures are current as of May 2006, and are an updated version of the graphic that is found in MedPAC's March 2005 report.

Figure 2
Specialty Hospitals by Category

The survey was also sent to 320 competitor acute care hospitals.[29] Additionally, we received two unsolicited responses from competitor acute care hospitals and, due to the low response rate from this type of hospital and the fact that the two hospitals were not clearly inappropriate candidates for competitor hospitals, we incorporated the data from the two unsolicited survey respondents into our analysis. Due to the short deadline for submission of the final report, CMS chose to send the surveys via electronic mail, beginning May 8, 2006. For purposes of this report, survey data received from hospitals by July 14, 2006 was incorporated and analyzed.

In summary, the data we received on physician investment have not revealed, on their face, any disproportionate or non-*bona fide* arrangements that require CMS to institute a drastic shift in our enforcement approach. However, the extent that hospitals did not respond to our survey questions on investment interests and compensation arrangements (or did not respond completely), gives us sufficient concerns about potential tainted relationships or basis for their non-response that CMS will begin an initiative seeking financial disclosure with those hospitals and will implement a regular disclosure process.

[29] As explained in greater detail at Appendix I, a competitor hospital is one located within the same health referral region (HRR) or hospital service area (HSA) as a specialty hospital. We employed the same methodology that GAO used for its April 6, 2006 report. An HRR or HSA can comprise more than one State, including a state that has a CON requirement. Therefore, a hospital may be a competitor of a specialty hospital even if the two hospitals are located in different states, and irrespective of whether one or both of the States has a CON requirement.

As part of this data collection and analysis initiative, we will analyze survey data received after July 14, 2006 as well. (*See* Strategic and Implementing Plan, Section V.1, below.) Failure to disclose timely the information sought in this effort can result in civil monetary penalties of up to $10,000 for each day beyond the deadline established for disclosure (which in all cases must be at least 30 days).

In addition, we obtained substantial data with respect to Medicaid and charity care patient populations and on the relative characteristics of specialty and competitor hospitals. This data has confirmed our determination to continue making improvements to payment systems and to issue further guidance regarding what we expect of hospitals with emergency departments (*See* Strategic and Implementing Plan, Section V.A-C, below.). This data adds to and enhances the information that the Congress is already considering on issues relating to care provided in these settings.

We note that the survey data had limitations. First, the response to the survey was voluntary. Therefore, many hospitals did not return a survey, and some respondents completed some portions of the survey but left other portions incomplete. In addition, there were tight time constraints for both the collection of data and its analysis. As a result, we could not validate all respondent data. When possible, we did attempt to contact providers that supplied facially implausible data or that supplied incomplete data. If we were unable to verify the data in this manner, we were at times required to exclude the provider from analysis of particular issues. Finally, to increase further the validity of the data we used, we also judgmentally eliminated providers whose responses fell outside an established norm. All of these exclusions required us to vary our data sample sizes depending upon the issue analyzed. Where applicable, the number of respondents to each question is noted. For purposes of the charts on the following pages, the master key is found below.

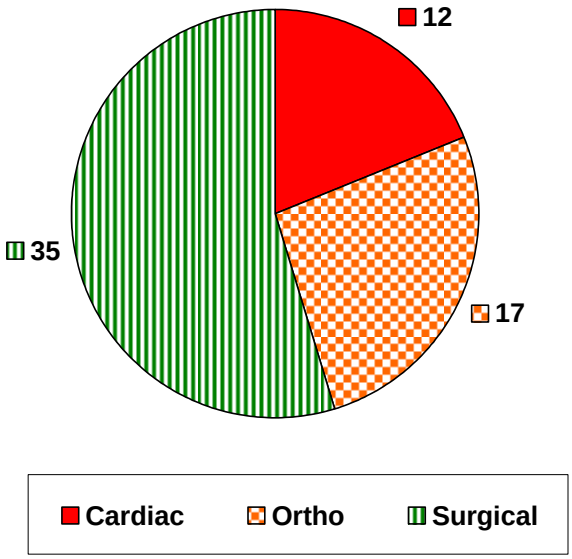
Master Key

- Cardiac
- Ortho
- Surgical
- Competitor Acute
- Medicare
- Medicaid
- Commercial, Self Pay & Other

B. Results of Completed Surveys

As stated above, the survey was sent to 130 physician-owned specialty hospitals and 320 competitor hospitals. We received completed surveys from 64 specialty hospitals and 76 competitor general acute care hospitals, for a total of 140 responses. Although competitor hospitals (23.8 percent response rate) represented the majority of the hospitals to which the survey was directed, proportionally more specialty hospitals (49.2 percent response rate) responded to the survey. Chart 1 provides a breakdown of the respondent specialty hospitals by type.

Chart 1
Specialty Hospital Survey Respondents by Type



C. Characteristics of Respondent Hospitals

Although not specifically required by the DRA, the survey requested information on the broader characteristics of specialty and competitor acute care hospitals**.** Table 1 highlights some of these characteristics.

Table1
Characteristics of Respondent Specialty and Competitor Hospitals[30]

Characteristic	Competitor	Cardiac	Orthopedic	Surgical
Average Number of Staffed Beds	243 (74/76)	54 (12/12)	24 (17/17)	14 (34/35)
Average Daily Census	161 (74/76)	35 (12/12)	8 (17/17)	4 (33/35)
Average Length of Stay (in days)	4.2 (65/76)	3.5 (12/12)	2.6 (17/17)	2.3 (31/35)
Average Operating Margin	10.9% (63/76)	-3.8% (10/12)	20.1% (14/17)	16.9% (23/35)
Average Number of Current Physician-Investors	0 (76/76)	31 (12/12)	25 (15/17)	39 (33/35)
Average Ownership Share Per Physician	0	2.1% (3/12)	2.6% (6/17)	2.2% (8/35)

In its October 2003 report, GAO found that 74 percent of specialty hospitals were for-profit, and that only 20 percent of acute care hospitals were for-profit.[31] Data from our survey indicated that all of the responding specialty hospitals were for-profit, and 38.2 percent of responding competitor acute care hospitals were for-profit. The higher percentage of competitor acute care hospitals with for-profit status in our survey compared to the GAO survey may be attributable, at least in part, to several factors, including the fact that the competitor hospitals we surveyed are located in States where specialty hospitals concentrate. In fact, it is possible that specialty hospitals locate in areas where a higher percentage of for-profit hospitals already exist due to demographic conditions. In addition, GAO data reflects all acute care hospitals and our survey included only those acute care hospitals that are competitors of specialty hospitals.[32] Finally, the higher percentage of for-profit competitor hospitals indicated by our survey (38.2 percent) may be inaccurate due to the low survey response rate (23.8 percent) to our survey by these hospitals.

[30] The numbers in parentheses represent the number of survey respondents that provided complete information for the question over the total number of respondents in that category. For example, we received 74 complete responses from competitor hospitals denoting their average number of staffed beds, out of 76 competitor hospital survey respondents.

[31] *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance,* GAO Report, GAO-04-167 (October 2003) at 8.

[32] *General Hospitals: Operational and Clinical Changes Largely Unaffected by Presence of Competing Specialty Hospitals,* GAO Report, GAO-06-520 (April 2006) at 24.

In its MMA Study, MedPAC found that, with respect to physician-owned specialty hospitals, the aggregate physician investment averaged 35 percent in cardiac hospitals, 67 percent in orthopedic hospitals, and 73 percent in surgical hospitals. For the median specialty hospital, the largest share owned by a single physician was 4 percent.[33] In approximately one-third of specialty hospitals, the largest share owned by a single physician was 2 percent or less, and in approximately one-fifth of specialty hospitals, the largest share was at least 15 percent. The HHS MMA Study concluded that the size of the ownership share appears to be a significant contributing factor in referral of patients.

D. Investment in Specialty Hospitals

1. *Bona Fide* Investment

The Secretary was required by the DRA to examine issues related to whether physician investments are *bona fide*. For purposes of this report, we considered a *bona fide* investment to be one in which the capital contributed by a physician does, in fact, represent an investment for which the physician is at risk. For example, we would not consider an investment to be *bona fide* if, for example, a physician made a 5 percent capital contribution, but some or all of that contribution was funded by another person or entity that did not expect repayment.

In addition, we considered the proportionality of returns in relation to the capital invested, limits on physician risk of loss, whether the physician borrowed funds from the specialty hospital (or a related entity) to invest in the hospital, and whether the physician's investment was guaranteed by the specialty hospital (or other related party).

It is important to note that the structure and nature of a joint venture[34] can be compliant with the whole hospital exception of the physician self-referral statute (*see* section II.A above) but the arrangement can still run afoul of the Federal anti-kickback statute, depending on the facts and circumstances.[35] Some of the areas that OIG focuses on when considering whether a joint venture, including a specialty hospital, is suspect include: (1) investor selection and retention, (2) structure of the enterprise, and (3) initial investment and subsequent distributions. Our survey attempted to probe each of these areas.

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[33] MedPAC MMA Study at 5.

[34] A "joint venture" has been defined as an association of two or more persons to carry out a *single* business transaction, or a few related transactions, for-profit or commercial gain, for which purpose they combine their property, money, efforts, skills, and knowledge. Many jurisdictions require the presence of several specific elements to establish a joint venture, the most common being (1) a contract, (2) a common purpose, (3) a community of interest, (4) an equal right of control, and (5) participation in both profits and losses. Cox, Hazen, ONeal, Corporations, Sec. 1.8.

[35] As explained in more detail in section V.E.1., below, the anti-kickback statute set forth at section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b), is a criminal prohibition against payments (in any form and whether direct or indirect) made purposefully to induce or reward the generation of Federal health care program business.

CMS examined several types of data from respondent hospitals concerning physician investment. The data included information concerning the nature of physician investment, if any, and, where applicable, how the terms offered to physicians compared to those offered to non-physician investors. CMS requested a listing of payments made to physician-investors and asked whether such payments were proportional to the physicians' investments. Additionally, we sought data concerning whether there were limitations on liability for the physicians' investments, and if so, the nature of such limitations.

a. Types of Limits on Physician Risk of Loss or Liability

We inquired as to whether there was any limitation on liability on a physician-investor's investment, such as a stop/loss agreement. In addition, we asked, with respect to each individual physician-investor, whether the physician-investor's risk of loss or liability was limited by agreement or understanding with any other third party. Of the 45 hospitals that responded to the question regarding limitations on physician liability or risk of loss, 41 reported that there were no limitations on investor liability other than that generally applicable to limited liability companies or partnerships. (Under most State laws, investors in such entities are only liable to the extent of any capital invested, unless they actively participate in management, in which case, they may have unlimited liability.)

Four hospitals (two surgical, one orthopedic, and one cardiac) reported some type of limitation on liability. One surgical hospital respondent indicated that a local, unrelated bank had extended non-recourse loans to investing physicians. The response of one surgical hospital was unclear in that it indicated a limitation on physician-investors' liability in response to question 24 on worksheet 2, but the hospital indicated that there were no such limitations for any individual physician-investors in its response to question 10 on worksheet 3. The other two specialty hospitals provided no description of the reported limitation.

We also requested a listing of all payments made by physician-owners/investors based on or related to their investment interest in order to determine the amounts and types of payments that are being made relevant to the hospital. (*See* Table 2.)

Table 2
Type of Payments Made by Physicians[36]

	Average Initial Investment	**Average Capital Calls**	**Average Loan Guarantee Fees**
Cardiac	$85,043 (10/12)	$0 (0/12)	$5,414 (1/12)
Orthopedic	$111,522 (4/17)	$0 (0/17)	$0 (0/17)
Surgical	$85,327 (22/35)	$16,741 (1/35)	$0 (0/35)

Although respondents provided us with a listing, we are unable to ascertain the extent to which investments or capital calls were paid for with cash versus borrowed funds, and we note a significant number of payments for which the respondents (especially the orthopedic hospitals) did not provide details. The HHS MMA Study captured the price paid for ownership shares and noted that it varied widely. The average purchase price of an ownership share of 0.9 percent for a cardiac hospital ranged between $28,000 and $72,000, and, for an orthopedic/surgical hospital, where the average ownership share was 2.2 percent, the range was between $30,000 and $120,000.[37]

b. Loans to Physicians

Related to the issue of whether investments of physician-investors of specialty hospitals are *bona fide* is the concern that some physician-investors may not invest significant personal capital into these ventures, but instead assume debt that is guaranteed by the specialty hospital or a joint venturer. Other allegations have involved loans provided to the physician-investors at favorable terms (lower than fair market value) or loans that are simply forgiven. Under such arrangements, the physician-investor has little or no personal risk underlying his or her investment in the specialty hospital.

In order to determine whether this practice was occurring, CMS requested information concerning loans or loan guarantees made by the hospital to each applicable physician investor. Specific information was requested concerning each lender, the amount of principal, the interest rate and term of the loan, and the status of the borrower's compliance with the loan terms.

[36] The numbers in parentheses represent the number of survey respondents that provided complete information for the question over the total number of respondents in that category. For example, we received 10 responses from cardiac hospitals on the average initial investment of physician-investors out of 12 cardiac hospital survey respondents. Competitor acute care hospitals are not included in this table as none of the 76 reported physician-investors.

[37] HHS MMA Study at 12.

We analyzed the responses to assess the degree to which physicians at competitor acute care hospitals and specialty hospitals were receiving loans and loan guarantees. We received 84 responses from hospitals on this topic. Of this amount, 41 were from competitor acute care hospitals and 43 were from specialty hospitals. We found that only 18 responding hospitals reported loans or loan guarantees to physicians. Only three physician-owned specialty hospitals had such loans or loan guarantees, while 15 competitor acute care hospitals did.

We have reviewed the three specialty hospitals referenced above. One of the hospitals made a loan to 2 investors for terms ranging from 12 months to 60 months. Both were at a rate of interest of prime plus 1 percent. We are unable to conclude that these two loans were at less than market rates. The other two specialty hospitals identified loans from commercial lenders in response to the survey. However, the hospitals did not provide information as to the terms or recipients of any guarantees for these loans.

In addition to the above, MedCath, the owner and operator of multiple cardiac hospitals, including 10 of the 12 cardiac survey respondents, stated that it does not provide loans directly to physicians. However, MedCath does guarantee loans for individual physician investors where a third party lender to a hospital has required MedCath to do so. In this case, according to MedCath, the individual physician investors are charged a fair market value guarantee fee by MedCath based upon their pro rata portion of the guaranteed hospital debt.

c. Capital Assets

We believe that an issue closely related to whether physicians choose to invest in specialty hospitals involves the capital assets required to operate the facility. Capital assets have been defined as assets that have an expected life of more than one year, cannot be turned into cash quickly, and include things such as land, buildings, and other fixed equipment. The size of a hospital, the working capital needed for operations, and the capital needs determine the amount of investment required in a specialty hospital. Importantly, ownership mix can affect the ability of a hospital to borrow funds. Without institutional investors, physicians may have to personally guarantee loans, interest rates may be higher, and access to capital can be more limited.

We carefully reviewed the documentation submitted by specialty hospitals that were seeking a determination that the specialty hospital was "under development" and, thus, not subject to the moratorium. When describing the funding that was received for the project and the arrangement to create the hospital, many requestors stated that physicians contributed money only for an ownership interest in the entity that was to be licensed as a hospital. The physician-investors would not have any ownership interest in the land or the building where the hospital was to be located or the capital equipment that would be used in the hospital. We saw this pattern most often with orthopedic and surgical hospitals (but not with cardiac hospitals) that were set up by a syndicator that purchased the land, contracted to build the hospital and other structures (which the syndicator will then own alone or with a limited number of partners, including, perhaps, some

physicians), and that also purchased the capital equipment. We note that, in arrangements structured in this manner, typically, the land, building, and capital equipment are rented to the operating entity, which incurs costs for them over time. We recognize that this structure of a hospital and its operation could bear significantly on the physician's risk of loss or liability. The amount of physician investment needed in the operating entity could be significantly lower under these types of scenarios, and could bear on the amount of a physician's rate of return on his or her investment.

For both specialty and competitor acute care hospitals, we asked whether the hospital is the sole owner of the land on which the hospital operations are conducted, and, if not, we inquired as to the terms of the lease agreement for the land. We also asked these questions concerning ownership of the hospital buildings and the capital equipment.

Table 3
Capital Asset Ownership by Hospital[38]

	LAND	**BUILDING**	**EQUIPMENT**
Cardiac	83.3% (10/12)	100.0% (11/11)	72.7% (8/11)
Orthopedic	25.0% (4/16)	18.8% (3/16)	50.0% (8/16)
Surgical	15.6% (5/32)	21.4% (6/28)	65.4% (17/26)
Competitor Acute	85.3% (58/68)	75.4% (46/61)	83.0% (49/59)

Business structures that relieve investors of up-front capital costs, such as land, building and equipment costs, raise particular concerns regarding whether investors are assuming *bona fide* business risk and whether they may be benefiting inappropriately in connection with their referrals. Moreover, a relevant factor in assessing *bona fide* business risk is whether an investment interest is comparable to a typical investment in a *bona fide* new business enterprise. These and other factors relating to the venture would be relevant to any inquiry under the Federal fraud and abuse laws.

[38] The numbers in parentheses represent the number of survey respondents answering in the affirmative over the total number of respondents in that category minus those that did not answer the question or provided incomplete information. For example, we received 8 affirmative responses from cardiac hospitals on whether the hospital is the sole owner of the capital equipment out of 11 cardiac hospital survey respondents that provided complete responses to the question (although 12 cardiac hospitals responded to our survey).

d. Investor Selection and Retention

In determining whether a joint venture is *bona fide*, one should closely review how investors are selected and retained. The July 3, 2003 white paper prepared on behalf of FAH by O'Melveny & Myers LLP, concluded that investment interests are most frequently being offered only to those who were in a position to refer.[39] Our survey requested information as to whether non-physicians were given an opportunity to invest in the surveyed hospitals under the same terms as the physician investors.

Table 4
Offering of Investment Interests[40]

	Investment Interest Offered to Non-Physicians For Similar Terms
Cardiac Hospital	100.0% (12/12)
Orthopedic Hospital	70.6% (12/17)
Surgical Hospital	80.0% (28/35)

There are several limitations to our findings. For instance, we did not request data concerning whether there was any type of cap on the number of non-physician investors or the shares they could purchase. Additionally, we must emphasize that the survey was voluntary, the data was self-reported, and, given the time constraints for completing the report, we were unable to validate the data. Nevertheless, we note that each of the subscription agreements that CMS reviewed as part of the Advisory opinion process left to the discretion of the specialty hospital's founding members whether to accept a physician who was interested in purchasing an ownership share. Most of the subscription agreements made inquiry as to the amount of revenue the physician generated in the previous two years, the names of the hospitals to whom he or she referred patients, and the volume of patients referred. Although not explicitly given as a criterion for selecting investors, it appears that the volume of referrals and/or revenue generated may have been a significant factor for some hospitals in determining which physicians were permitted to invest.

[39] *See also*, MedPAC MMA Study at 9.

[40] The numbers in parentheses represent the number of survey respondents that answering in the affirmative over the total number of respondents in that category. For example, we received 12 affirmative responses from orthopedic hospitals on whether non-physicians were given an opportunity to invest for terms similar to physicians out of 17 orthopedic hospital survey respondents. Because our analysis focused on investment in specialty hospitals, we did not include competitor hospitals in Table 4.

We requested information concerning both the total percentage of physician ownership compared to non-physician ownership and the amount of revenue generated by the physician-owners and non-owner physicians. We believe this information can be of assistance when reviewing whether investment interests are related to the value or volume of referrals. There is a similarity between the aggregate percentage of physician ownership in the hospital and the percentage of revenue generated by physician-owners, as shown below.

Table 5
Physician Ownership and Hospital Revenues[41]

	Average Aggregate Percentage of Physician Ownership in Hospital	**Average Revenue Generated by Physician-Owners**	**Average Revenue Generated By Non-Owner Physicians**
Cardiac	37.2% (12/12)	47.6% (12/12)	52.4% (12/12)
Orthopedic	67.5% (13/17)	86.2% (12/17)	13.8% (12/17)
Surgical	66.3% (26/35)	78.7% (25/35)	21.3% (25/35)

Based on an analysis of Medicare claims data, the HHS MMA Study found that physician-owners of specialty hospitals refer or admit the majority of their patients to their specialty hospital. In our survey, we did not inquire specifically about the number of patients referred by physician-owners but rather focused on the revenue generated by the physician-owners.

Our findings with respect to the total average aggregate percentage of physician ownership of specialty hospitals are consistent with the findings from MedPAC in the MedPAC MMA Study. In that report, MedPAC found that, on average, the aggregate percentage of physician ownership equals 60 percent.[42] MedPAC also found that physicians at cardiac hospitals have the smallest average aggregate ownership percentage

[41] The numbers in parentheses represent the number of survey respondents that provided complete information for the question over the total number of respondents in that category. For example, we received 26 responses from surgical hospitals on the aggregate percentage of physician ownership out of 35 surgical hospital survey respondents. Competitor acute care hospitals are not included in this table as none of the 76 reported physician investors.

[42] MedPAC MMA Study at 5.

(35 percent), whereas those at surgical hospitals have the largest average aggregate ownership percentage (73 percent).[43] About one-third of orthopedic and surgical hospitals were owned almost entirely by their physicians, whereas no cardiac hospital was. At half of all physician-owned specialty hospitals, the largest individual physician shareholder owned at least a 4 percent interest in the hospital. The largest share owned by any individual physician varies considerably across the specialty hospitals.

e. Initial Investment and Subsequent Distributions

As stated above, another factor in determining whether an investment is *bona fide* is to review the initial investments and any subsequent distributions to physicians. In order to evaluate this, CMS requested information related to initial physician investment, classes of stock (if any), whether there had been any independent valuation of the stock, and subsequent distributions.

Opponents of specialty hospitals have contended that often specialty hospitals have multiple classes of stock and that the stock sold to physician-investors has been under-priced. We believed that those assertions warranted further scrutiny. As a result, we analyzed the range of classes of stock to determine if most hospitals had one class of stock, or if there was variation among the competitor and specialty hospitals. Of the 21 specialty hospitals that responded to our question, 11 hospitals had one class of stock, and 10 had two or more.

Literature and studies have focused upon the large rates of return to physicians associated with investment in specialty hospitals.[44] For example, in a briefing paper presented to CMS in September 2004, the Hospital Corporation of America (HCA), a corporate competitor of specialty hospitals, argued that, based upon its review of publicly available information, physician-investors were getting extraordinary financial returns with only minimal risk. HCA also contended that "capital sponsors sell physician investments at a price far below market value and the quid pro quo is a below-market investment [with] above-market returns in exchange for referrals."

FAH, which counts HCA among its constituent members, in its July 3, 2003 white paper on MedCath cardiac hospitals, also reviewed aspects of specialty hospital financing. FAH concluded that capital structures, which are sponsored and guaranteed by private equity or hospital partners, are highly-leveraged (in many cases 90 percent versus 50 percent for competitor hospitals). FAH buttressed this conclusion by emphasizing the fact that investment interests in these hospitals were offered almost exclusively to

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[43] *Id.*

[44] *The Impact of Physician-owned Limited-service Hospitals: A Summary of Four Case Studies,* McManis Consulting (February 16, 2005); Boulton, G., "Orthopedic hospital posts remarkable profits," Milwaukee Journal Sentinal (online), June 26, 2006.

physicians in a position to refer, the interests were offered at prices heavily discounted below fair market value, and the risk to physician-investors was minimal.

Physician-investors realize increased income from profit distributions based on their own and others' work at specialty hospitals. Increased productivity may also result in more professional fees. Annual distributions at some specialty hospitals often exceed 20 percent of the physician's initial investment, although some specialty hospitals have not made distributions.[45]

2. Proportionality of Investment

We requested information in our survey regarding physician-investors' capital contributions and the returns on their investments. Specifically, we wanted to determine whether the return on investment was proportional to the capital contributed. In other words, we wanted to ascertain whether physicians make capital investments of a certain percentage and receive returns on invested capital as if they made a higher capital investment.

Thirty specialty hospital respondents reported proportionate returns compared to physician investment. We note, however, that 34 out of 64 specialty hospitals (53.1 percent) did not complete this portion of the survey (or did not complete it in time for us to analyze the responses) and, thus, we are unable to determine at this point whether the physician-investors in such hospitals received proportionate returns on their investments or had *bona fide* investments.

3. Reporting of Physician Investment Information

Of the 22 States that have existing specialty hospitals, only Texas requires physicians with ownership interests in specialty hospitals to disclose such ownership interests to the State. Section 162.052(b) of the Texas Occupations Code, effective September 1, 2005, states as follows:

> "(b) A physician shall notify the Department of State Health Services of any ownership interest held by the physician in a niche hospital."[46]

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[45] *Report to the Congress: Physician-Owned Specialty Hospitals*, MedPAC (March 2005) at 8.

[46] The term "niche hospital" is defined at § 105.002 of the Texas Occupations Code as a hospital that classifies at least two-thirds of its Medicare patients (or if data is not available, all of its patients) in not more than two "major DRGs," or in "surgical DRGs." A niche hospital must also specialize in one or more of the following areas: (1) cardiac, (2) orthopedics, (3) surgery, or (4) women's health. Excluded from the definition are, among others, public hospitals and hospitals with fewer than 10 claims per bed per year. Section 162.052(c) of the Occupations Code provides that an ownership interest in a niche hospital does not include ownership in publicly traded shares of a registered investment company, such as a mutual fund, that owns publicly traded shares or debt obligations issued by a niche hospital or an entity that owns the niche hospital. Section 162.052(d) of the Occupations Code provides that the governing board, in consultation

Sixteen States require physicians to disclose ownership interests in specialty hospitals to the patients they refer to the hospital.[47] These statutes are not aimed at specialty hospitals in particular; rather they permit physicians with an investment interest in a hospital or other facility to refer a patient to the hospital or other facility, provided that the physician discloses the interest to the patient.[48]

The effectiveness of patient disclosure laws has been questioned. In a report addressing the issue of financial arrangements between physicians and health care businesses, OIG stated in 1989, that:

> While this option is perhaps the least onerous of all those described in this section, it may also be the least likely to influence actual patterns of use of services. Patients have little basis with which to judge the efficiency, quality, or even pricing of one facility versus another. Patient choice in this environment may have little meaning.[49]

As one commentator noted, "[m]ost statutes do not require specific language, creating the possibility that the disclosure form is actually being used as an advertisement.[50]

We surveyed hospitals concerning their willingness to submit investment information. We asked whether the hospitals would voluntarily agree to provide ownership or investment information to the Secretary on an annual basis, such as names and identifying numbers of physician-investors, percent of ownership, amount of investment, and rate of return on investment. We further asked, if the answer was a qualified yes, what reasons for collection and uses of the data would be permissible. Finally, we asked

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with the Department of State Health Services, shall adopt rules for the form and content of the notice required by § 162.052(b).

[47] Choudry, et. al., *Specialty versus Community Hospitals: What Role for the Law?*, Health Affairs (August 9, 2005) at W5-365.

[48] Comment, *The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures*, 73 N.C.L. Rev. 293, 313-17 (1994); *Financial Arrangements Between Physicians and Health Care Businesses: State Laws and Regulations*, OIG Report, No. OAI-12-88-01412 (April 1989); Mitchell and Scott, *Evidence on Complex Structures of Physician Joint Ventures*, 9 Yale J. on Reg. 489, 501 (Summer 1992).

[49] *Financial Arrangements Between Physicians and Health Care Businesses*, OIG Report, No. OAI-12-88-01410 (May 1989) at 30.

[50] Comment, *The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures*, 73 N.C.L. Rev. 293, 317 (1994). Based on interviews with patients who were treated at specialty hospitals, the HHS MMA Study found that patients did not view physician ownership as problematic, but rather as potentially enhancing the quality of care by increasing the physician's attentiveness to the quality of his or her staff and the quality of care provided by the hospital. HHS MMA Study at 55.

what information should be captured if the Congress or the Secretary were to impose an annual reporting requirement.

Thirteen specialty hospitals and 11 competitor hospitals responded to some or all of our questions on disclosure of physician investment information. Fourteen hospitals (nine specialty and five competitor) hospitals responded that they would be willing to submit physician-investor information. Four of these 14 hospitals (all four being specialty hospitals) stated that they would be willing to disclose such information provided that all hospitals were required to disclose ownership or compensation arrangements.

With respect to our question regarding what type of information should be provided if there were a mandatory reporting requirement, nine specialty and nine competitor hospitals gave suggestions as to the type of information that should be captured via a mandatory reporting requirement. Two hospitals (one specialty and one competitor) believed that the requested information on the survey appeared reasonable as a basis for an annual reporting requirement. Several of the respondent competitor and specialty hospitals believed that information concerning the mix of the hospital's patients (for example, Medicare, Medicaid, indigent, managed care, etc.) should be captured.

4. Structure of the Business Enterprise

One important component of making the determination as to whether a joint venture appears to be compliant with applicable law is analyzing the structure of the enterprise. Therefore, we requested information concerning the hospital's business structure. Our survey requested organizational charts for each specialty hospital and competitor acute care hospital. We received responses from 70 hospitals providing such organizational information, of which 34 are specialty hospitals and 36 are competitor acute care hospitals. We found that 31 specialty hospitals reported joint ventures between an entity or entities and physicians, and one specialty hospital reported a joint venture between physicians only.

For those specialty hospitals that responded to our survey, the typical business model reflected that physicians from the local community enter into a joint venture with a for-profit entity, which has solicited local investors in the specialty hospital. In many cases, the for-profit entity is a syndicator, or developer, such as a highly-capitalized surgical facility company.

5. Previous Affiliation as an Ambulatory Surgical Center

Another relevant aspect of the business enterprise is the form of its previous existence, if any. Both the HHS and the MedPAC MMA Studies concluded that a portion of specialty hospitals have resulted from the conversion from another type of facility, especially an ASC. This is often attributed to the fact that Medicare does not pay facility fees for procedures in ASCs that require overnight stays. Physician-owners of ASCs converting to hospitals might also benefit from higher hospital outpatient rates as compared to ASC rates, fewer restrictions on allowable procedures, and the ability to refer patients, and

charge Medicare, for ancillary services such as labs and imaging.[51] Therefore, we chose to request information concerning whether the specialty hospitals may have previously operated as another type of provider, and if so, what type. Of the 64 reporting specialty hospitals, 14 were previously organized as another type of entity.[52] All but two of the 14 were organized as ASCs. Our findings are consistent with the MedPAC MMA Study that indicated that ASCs were most likely to be converted to surgical or orthopedic hospitals, rather than to cardiac hospitals, given the nature of the services provided and the smaller amount of capital and equipment needed.

E. Compensation Arrangements

Our survey requested information concerning compensation arrangements between hospitals and physician-investors.[53] Hospitals were asked whether the physician-investor has or had any management contract or other compensation arrangement (including a loan) with the hospital or an entity related by common ownership or control. We received responses from 64 specialty hospitals. Thirty-four of these respondents reported a total of 135 compensation arrangements with physicians (not including payments to entities such as real estate companies, equipment leasing entities, and management companies, which were reported separately on Worksheet 5 of the survey). The services for which compensation was paid were largely for medical directors, on-call coverage, administrative (non-Board) services, and clinical services such as diagnostic test interpretations.

All 12 of the responding cardiac hospitals reported having at least one compensation arrangement, and, in the aggregate, they had a total of 66 arrangements: 11 for medical directors; seven for on-call coverage; 25 for hospital administrative duties; one for board of director duties; seven for readings or interpretations; three for provider-based physician services; and 12 for unspecified services.

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[51] Most services furnished by ASCs are not subject to the physician self-referral law because they are not DHS. *See* 42 CFR § 411.351, which expressly exempts from the definition of DHS items and services for which payment is included in the ASC composite rate. In addition, there is an exception at 42 CFR § 411.355(f) for prosthetics, prosthetic devices, and durable medical equipment implanted during a procedure performed in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice, even when the Medicare payment for these items is not bundled into the ASC payment rate.

[52] In reality, cardiac hospitals would not be included in the universe of specialty hospitals when reviewing previous affiliation as an ASC because it is unlikely that a cardiac hospital would have converted from an ASC.

[53] None of the 76 responding competitor hospitals reported having physician investors; however, of the 47 responding nonprofit competitor hospitals, several noted in their responses that nonprofit hospitals sometimes sell participating bonds to affiliated or referring physicians. Participating bonds are tax-exempt offerings that are sold at least partly to physicians to allow them to participate in the success or failure of a section 501(c)(3) (of the Internal Revenue Code) hospital. The interest rate paid on the bonds may be much higher (for example, between 10 and 12 percent) and the issues may be much smaller.

Of the 17 orthopedic hospitals, eight reported a total of 18 compensation arrangements: four for medical directors; four for board service; three for provider-based physician services; and one each for on-call coverage, interpretations, and hospital administrative duties. Four arrangements were not specified.

Of the 35 surgical hospitals, 14 reported a total of 51 compensation arrangements. (One hospital reported compensation arrangements with 28 physicians). There were five arrangements for medical director services; two for management services; two for on-call coverage services; two for administrative services; two for provider-based physician services; one for board services; and 37 for unspecified services.

The information on aggregate compensation and the method of compensation is insufficient to draw conclusions about the compensation arrangements because most respondents provided incomplete information. However, of those hospitals that did respond, most described the method of compensation as per-service or time-based with per-unit amounts.

F. Medicaid/Section 1115 Waivers

The DRA required the Secretary to examine issues related to the provision of care to patients who are eligible for medical assistance under a State plan approved under title XIX of the Act, including patients who receive benefits under a demonstration project approved under Title XI of the Act (commonly referred to as a "section 1115 waiver"). Through the survey, we have examined two types of data from responding hospitals: patient revenues generated for services provided to Medicaid beneficiaries, and Medicaid patient admissions or visits as a percentage of total admissions or visits. We provide, as a preliminary matter, a brief description of the Medicaid program and its significance to acute care hospitals, and then discuss the specific results of our survey.

1. Overview

a. Medicaid (Title XIX)

Title XIX of the Social Security Act is a Federal/State entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources. This program, known as Medicaid, became law in 1965 as a cooperative venture jointly funded by the Federal and State governments (including the District of Columbia and the Territories) to assist States in furnishing medical assistance to eligible needy persons. Medicaid is the largest source of funding for medical and health-related services for America's poorest people.

Within broad national guidelines established by Federal statutes, regulations, and policies, each State (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program. Medicaid policies for eligibility, services, and payment are complex and vary considerably, even among States of similar size or geographic

proximity. Thus, a person who is eligible for Medicaid in one State may not be eligible in another State, and the services covered by one State may differ considerably in amount, duration, or scope from services covered in a similar or neighboring State. In addition, State legislatures may change Medicaid eligibility, services, and/or reimbursement during the year.

States generally have broad discretion in determining which groups their Medicaid programs will cover and the financial criteria for Medicaid eligibility. To be eligible for Federal funds, however, States are required to provide Medicaid coverage for certain individuals who receive Federally-assisted income maintenance payments, as well as for related groups not receiving cash payments. The mandatory Medicaid eligibility groups include the following: children under age 6 and pregnant women whose family income is at or below 133 percent of the Federal poverty level (FPL); Supplemental Security Income (SSI) recipients in most States; recipients of adoption or foster care assistance under Title IV of the Social Security Act; special protected groups (typically individuals who lose their cash assistance due to earnings from work or from increased Social Security benefits, but who may keep Medicaid for a period of time); children who are under age 19 in families with incomes at or below the FPL; and certain Medicare beneficiaries (described later). States also have the option of providing Medicaid coverage for other groups. These optional groups share characteristics of the mandatory groups (that is, they fall within defined categories), but the eligibility criteria are somewhat more liberally defined.

The medically needy option allows States to extend Medicaid eligibility to additional persons. These persons could be made eligible for Medicaid under one of the mandatory or optional groups. Persons may qualify immediately or may "spend down" by incurring medical expenses that reduce their income to or below their State's medically needy income level.

Medicaid eligibility and benefit provisions for the medically needy can be more restrictive than for the categorically needy. If a State elects to have a medically needy program, there are Federal requirements that certain groups and certain services must be included. As of August 2002, 35 States plus the District of Columbia have elected to have a medically needy program and are providing at least some medically needy services to medically needy recipients. All remaining States utilize the "special income level" option to extend Medicaid to the "near poor" in medical institutional settings.

b. Section 1115 Waivers

Section 1115 of the Act provides the Secretary broad authority to authorize experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid statute. Section 1115 projects are intended to test and evaluate a policy or approach that has not been demonstrated on a widespread basis. Some States use section 1115 waivers to expand eligibility to individuals not otherwise eligible under the Medicaid program, provide services that are not typically covered, or use innovative service delivery systems.

Projects are generally approved to operate for a five-year period, and States may submit renewal requests to continue the project for additional periods of time. These projects must be "budget neutral" over the life of the project, meaning that they cannot be expected to cost the Federal government more than it would cost without the waiver. Currently, about 80 projects are operating under section 1115 waiver authority.

2. Challenges Facing Hospitals Serving Medicaid Beneficiaries

The Medicaid program is a safety net for much of our nation's vulnerable, low-income or uninsured populations. Medicaid enrollment and expenditures have both been increasing substantially and are anticipated to continue to increase in the future.[54] At the same time, providers have complained that Medicaid reimbursement is below cost, adversely affecting hospital margins.

3. Medicaid/Section 1115 Waiver Inpatient Discharges and Outpatient Visit Data

Both MedPAC and GAO noted that specialty hospitals tend to have lower Medicaid patient censuses than competitor hospitals.[55] However, both MedPAC and GAO attributed this differential to a variety of factors, including the location of the hospital, its mission, Medicaid managed care contracts, the existence of an emergency room at the hospital, and Medicaid patients' choice of hospitals. MedPAC's data compared specialty hospitals to peer hospitals and community hospitals in the same market. MedPAC reported that Medicaid inpatient discharges at these hospitals comprised 15 percent of their total discharges, whereas specialty hospitals tended to have substantially lower rates (4 percent for cardiac hospitals and one percent for orthopedic hospitals).[56] GAO similarly found that specialty hospitals tend to treat a lower percentage of Medicaid inpatients among all patients with the same types of conditions.[57]

The results of our survey show Medicaid inpatient discharge rates averaging 18.4 percent of total inpatient discharges for the competitor hospitals responding to our survey

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[54] The Medicaid Commission chaired by the Secretary has reported that, in the five-year period from 1998 to 2003, total enrollment in the program increased by 30 percent. Enrollment is expected to continue to increase substantially. At the same time, Medicaid expenditures increased at a faster rate than other insurance coverage types, with overall Medicaid expenditures increasing by 62 percent between 1998 and 2003. *Medicaid Commission Report to the Secretary and the Congress*, (September 1, 2005) at 7-8.

[55] *See* MedPAC MMA Study at 17.

[56] MedPAC MMA Study at 18.

[57] *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, GAO Report, GAO-04-167 (October 2003) at 20.

compared to only 3.6 percent for the respondent specialty hospitals.[58] The differential between competitor hospitals and specialty hospitals is even greater when surgical and orthopedic hospitals are considered in isolation from cardiac hospitals. Cardiac hospitals had percentages of total inpatient discharges attributable to Medicaid patients of 4.6 percent, the rates were 2.4 percent for surgical hospitals and 2.5 percent for orthopedic hospitals.

Our survey accumulated data not only on inpatient discharges, but also for outpatient visits. We found the differential between competitor and specialty hospitals was less pronounced on the outpatient side. For the competitor hospitals responding to our survey, Medicaid outpatient visits averaged 12.3 percent of total outpatient visits. For the respondent specialty hospitals, Medicaid outpatient visits averaged 6.7 percent of total outpatient visits for cardiac hospitals, 4.3 percent for orthopedic hospitals, and 7.7 percent for surgical hospitals, or 6.1 percent overall.[59]

Table 6
Medicaid Patient Case Mix of Responding Hospitals[60]
(as a percentage of Total Inpatient Discharges or Total Outpatient Visits)

	Medicaid Inpatient Discharges	**Medicaid Outpatient Visits**
Competitor Acute	18.4%	12.3%
Cardiac	4.6%	6.7%
Orthopedic	2.5%	4.3%
Surgical	2.4%	7.7%
Specialty (All)	3.6%	6.1%

[58] The Medicaid inpatient discharge figures are based on information provided by 64 of 76 total competitor hospital respondents and 61 of 64 total specialty hospital respondents.

[59] The Medicaid outpatient visit figures are based on information provided by 57 of 76 total competitor hospital respondents and 59 of 64 total specialty hospital respondents.

[60] The inpatient figures are based on information provided by 64 of 76 competitor hospital respondents and 61of 64 specialty hospital respondents. The outpatient figures are based on information provided by 57 of 76 competitor hospital respondents and 59 of 64 specialty hospital respondents. The differential is due to survey responses that were excluded either because no data was provided or the data provided could not be validated.

4. Medicaid/Section 1115 Waiver Revenue Data

MedPAC reviewed specialty hospitals on the basis of their percentage of Medicaid revenues, finding that cardiac hospitals had patient revenues from Medicaid patients of between 2 and 3 percent (depending on whether they had an emergency department) and orthopedic and surgical hospitals had revenues from Medicaid patients of 5 percent.[61] MedPAC compared these figures to those of peer hospitals and community hospitals in the same market, finding that peer and community hospitals had 8 percent and 9 percent Medicaid patient revenues, respectively.

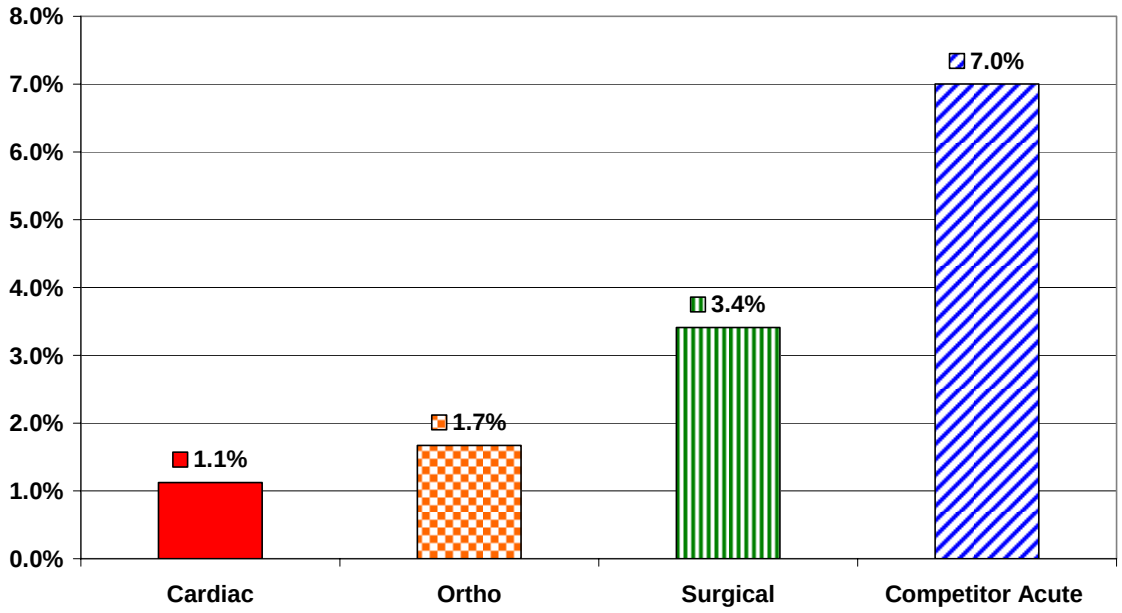
We also analyzed reported revenue data for the responding hospitals.[62] For competitor hospitals responding to our survey, we found that Medicaid revenues averaged 7.0 percent of total net patient revenues, whereas the specialty hospitals averaged only 2.3 percent. The distinction is even greater for cardiac hospitals: only 1.1 percent of revenues were generated from services provided to Medicaid patients. Orthopedic and surgical hospitals had Medicaid revenues of only 1.7 percent and 3.4 percent, respectively.[63]

[61] MedPAC MMA Study at 19.

[62] Our survey obtained revenue data for FY 2004 and FY 2005. In our analysis, we combined data for both years, eliminating from consideration hospitals that provided incomplete data for one or both years. This resulted in a total sample size of 63 responding competitor hospitals and 47 responding specialty hospitals.

[63] Among the factors that may impact Medicaid rates at specialty hospitals are the availability of Medicaid managed care contracts, high incidence of OB/GYN services in Medicaid populations, and the patient census of referring physicians. *See* MedPAC MMA Study at 10, 18.

Chart 2
Medicaid Revenues of Responding Hospitals
(as a % of Total Net Patient Revenue)



G. Charity Care

In section 507 of the MMA, the Congress required the Secretary to assess the differences in "uncompensated care" between specialty hospitals and local full-service community hospitals, and the relative value of any tax exemption available to the latter class of hospitals.[64] In section 5006 of the DRA, the Congress required the Secretary to address the provision by specialty hospitals of care to charity patients and to Medicaid patients and patients receiving medical assistance under an 1115 waiver demonstration project. For purposes of this survey, we consider care to charity patients (for purposes of this report, referred to as "charity care") to be medical treatment furnished to hospital patients

[64] For the HHS MMA Study required under section 507 of the MMA, we considered net community benefit to equal uncompensated costs and tax payments as percentages of a hospital's 2003 aggregate total operating revenue. We then assumed that the 21 competitor hospitals in the six market areas we studied experienced the national average of Medicaid shortfall, 1.4 percent, and that the specialty hospitals in these market areas experienced no Medicaid shortfall because of their very small number of Medicaid patients, to arrive at the following results:

Net community benefit

Cardiac hospitals:	3.74 percent of total operating revenue
Orthopedic/Surgical hospitals:	7.23 percent of total operating revenue
Competitor hospitals:	2.2 percent of total operating revenue

The HHS MMS Study at 59.

with no expectation of receiving payment for all or a portion of the care provided (that is, a discount or other allowance may constitute charity care).[65]

1. History of and Current Interest in Tax Exemptions for Charity Care

In 1894, Congress exempted charities from the first Federal income tax, and State law followed. At that time, nonprofit hospitals provided care mainly to the poor, as the non-poor received their care at home. In 1913, in the first Internal Revenue Code, "charitable" was defined to include relief of the poor, the distressed, or the underprivileged. By the 1920s, hospitals began using technology that was not available to patients in their homes, so paying patients began receiving their care in hospitals. Hospital insurance began before World War II and, after 1945, expanded rapidly. The housing boom after World War II was accompanied by a boom in hospital construction, partly fueled by the Hospital Survey and Construction Act of 1946. This Act, popularly known as "Hill-Burton," extended Federal funds in exchange for providing charity care.[66] As of July 7, 2006, 64 general acute care hospitals still have Hill-Burton obligations.[67]

In 1956, the first IRS guidance on tax-exempt hospitals required such entities to "be operated to the extent of its financial ability for those who cannot pay for the services rendered." These hospitals could not "refuse to accept patients in need of hospital care who [could] pay for the services rendered." A charitable hospital could not be considered to be dispensing charity if it operated "with the expectation of full payment" and incurred bad debt from those who did not pay for the services.[68]

Medicare and Medicaid began to provide health insurance benefits for the elderly and poor nationwide in 1965. In 1969, the IRS eliminated the requirement for a threshold level of care to qualify for Federal tax exemption because Medicaid guaranteed hospitals payment for treating many categories of indigent patients. Instead, the IRS ruled that a hospital was entitled to a tax exemption if it provided "care for all those persons in the community able to pay the cost thereof either directly or through third party reimbursement," because "it was promoting the health of a class of persons that is broad enough to benefit the community."[69] For the past 36 years, nonprofit hospitals have been

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[65] Charity care is just one of the two components of uncompensated care, the other being bad debt. In turn, uncompensated care is only part of the broader concept of community benefit. Community benefit encompasses such activities as research, community health fairs and other educational activities, preventive care programs, and more.

[66] *See* Bloche, M. Gregg, *Tax Preferences for Nonprofits: From Per Se Exemption to Pay-For-Performance*, Health Affairs (June 2006) at 304-307; Hyman, David A., and Sage, William M., *Subsidizing Health Care Providers Through the Health Code: Status or Conduct?*, Health Affairs (June 2006) at 312-315.

[67] *See* http://www.hrsa.gov/hillburton/hillburtonfacilities.htm.

[68] Rev. Rul. 56-185, 1956-1 CB 202.

[69] Rev. Rul. 69-545, 1969-2 CB 117.

able to qualify for exemption from Federal taxation on the basis of this overall community benefit standard. Some State and local governments require a threshold level of free care or below-cost care to qualify for exemption from their taxes.

In return for Federal tax exemption, a nonprofit entity has to be organized and operated exclusively to promote one of a number of specific purposes, including charitable, religious, education, and scientific ends. To qualify for nonprofit status, an organization must retain its net earnings and use them to promote the purposes for which the nonprofit was created. It may not distribute net earnings to those who control it, whether officers, directors, trustees, or key employees.

Recently, the Congress has expressed concern, through hearings chaired by Senator Grassley and Representative Thomas, that nonprofit hospitals may not deserve the significant tax advantages that they receive. On March 8, 2006, the Senate Committee on Finance held a hearing entitled "Taking a Checkup on the Nation's Health Care Tax Policy: A Prognosis." Chairman Grassley stated that the goal of the hearing was to look at existing tax incentives and ask the question: "Are we getting our money's worth?" Senator Grassley also pointed out that the tax issue must be examined through both the health policy lens and the tax policy lens.[70] On May 26, 2005, Representative Thomas convened a hearing for the House Committee on Ways and Means on the tax exempt hospital sector specifically for the purpose of "examining the legal history of tax exemption for hospitals; IRS oversight of tax-exempt hospitals; the need for congressional oversight of the standards for hospital tax-exemption; and Federal policies that subsidize treatment of the indigent by hospitals." Also, on May 25, 2005, Senator Grassley sent a letter to 10 nonprofit hospitals and hospital systems, asking them 46 specific questions on a variety of issues, designed to elicit information concerning whether the hospitals' charitable activities justified, in Senator Grassley's view, the tax advantages that they enjoy.

In May 2006, the IRS sent a compliance questionnaire to more than 550 tax-exempt hospitals to determine whether their activities are consistent with their tax-exempt status. The questionnaire sought detailed information about the operations and billing practices of these hospitals and also about the compensation of top hospital executives.[71] The Director of the Exempt Organizations Division of the IRS stated that the responses to the questionnaire could be used in deciding whether standards for nonprofit hospitals should be changed or clarified.[72]

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[70] Senator Grassley pointed out at the hearing that, in 2005, the value of the health care tax expenditure equaled $177.6 billion.

[71] GAO recently reviewed executive compensation issues at selected private, nonprofit hospitals. *See Nonprofit Hospital Systems: Survey on Executive Compensation Policies and Practices*, GAO Report, GAO-06-907R (June 30, 2006).

[72] Pear, Robert, "I.R.S. Checking Compliance by Tax-Exempt Hospitals," New York Times (June 19, 2006).

2. Challenges in Measuring Charity Care

The overwhelming majority of charity care is provided by nonprofit and government hospitals.[73] Just how much charity care is being provided is difficult to determine, however.[74] A PricewaterhouseCoopers 2005 survey of hospitals showed that hospitals provide an average of 5 percent of net operating income in charity care, although some provided a substantially higher amount. The survey also found that 76 percent of hospitals calculate their charity care based on charges instead of costs, and that an additional 9 percent of hospitals base their calculation on a combination of charges and costs.[75] Because hospital charges are typically significantly higher than hospital costs, and because hospitals may employ different charge structures for different payers,[76] the amount of charity care reported by hospitals may be overstated in this regard.

Charity care may also be understated to some extent. Although charity care and bad debts are mutually exclusive concepts, in practice they overlap. Charity care is viewed typically as care for which the hospital never expected to receive payment. If a patient states that he or she has insurance or an ability to pay out–of-pocket at the time of admission (for example, out of fear that he or she will not receive treatment) but, in fact, has no insurance or ability to pay, or if the patient simply refuses or is unable to provide information to the hospital to allow it to make a determination of whether the patient qualifies for charity care under its policies, the hospital may classify the patient as a private pay patient. If the patient subsequently refuses or is unable to pay, the hospital will treat the case as a bad debt, but had it received accurate information from the beginning, the patient may have qualified for charity care under the hospital's policies.

MedPAC suggested to the Congress that CMS develop a worksheet to collect data on the costs incurred by hospitals for providing inpatient and outpatient services for which they are not compensated. Pursuant to the Congress's instructions in the Balanced Budget Refinement Act of 1999,[77] CMS developed worksheet S-10 to the Medicare cost report,

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[73] *Acts of Charity: Charity Care Strategies for Hospitals in a Changing Landscape*, PricewaterhouseCoopers Health Research Institute (2005) at 1, available at http://healthcare.pwc.com/pubcharitycare.html (last accessed on August 3, 2006).

[74] Tax-exempt hospitals, like other tax-exempt organizations, generally must submit a Form 990 each year to the IRS. This form tracks charitable activities and expenses.

[75] *See* note 84 at 2.

[76] In the past several years, multiple class action lawsuits have been filed on behalf of uninsured patients who do not meet indigence guidelines and are billed by nonprofit hospitals at full charges. USA*Today* reported in 2005 that there were approximately 50 such suits brought in the Federal courts, and that, whereas most had either been dismissed or were being dismissed, the battleground was about to shift to the State courts. *See* http://www.medicalnewstoday.com/medicalnews.php?newsid=23424.

[77] Pub. L. No. 106-113, section 112.

which was effective for cost reporting periods beginning on or after April 30, 2002. Currently, worksheet S-10 has no reimbursement impacts. Disproportionate share hospital (DSH) payments are settled on worksheet E-Part A of the cost report. Eventually, the data from worksheet S-10 may be used to adjust DSH payments. Concerns were raised from GAO, MedPAC, and others on the usefulness of the data. MedPAC suggested changes to worksheet S-10.[78]

CMS is currently evaluating potential changes to the existing worksheet S-10 based on numerous factors, including MedPAC recommendations. These changes will provide clarification to the existing definitions that should help hospitals provide more uniform submissions.

3. Charity Care Data

Our survey solicited data on charity care provided to Medicare, Medicaid, and other patients for FY 2004 and FY 2005. We found that competitor hospitals provided a substantially higher amount of charity care to patients than did specialty hospitals.[79]

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[78] MedPAC's suggested data collection instrument provides definitions and detailed guidance for what might be included and excluded in reporting uncompensated care, including charity care and bad debt, as well as data on Medicaid, State Children's Health Insurance Programs, and other State and local indigent care programs.

[79] Our survey data revealed a large disparity between the provision of charity care to patients covered by public payers as compared to all other payers at specialty hospitals. Whereas the competitor acute care hospitals tend to allocate charity care broadly across all payers, it appears that specialty hospitals concentrate their charity care dollars on non-Medicare and non-Medicaid patients. Again the low Medicare and Medicaid population rates at specialty hospitals may also account for this disparity.

Table 7
Charity Care[80]

	Charity Care as a Percent of Net Patient Revenue
Cardiac	3.9% (9/10)
Orthopedic	1.0% (12/14)
Surgical	0.2% (16/23)
Competitor Acute	7.9% (60/63)

H. Other Related Data

1. Bad Debt

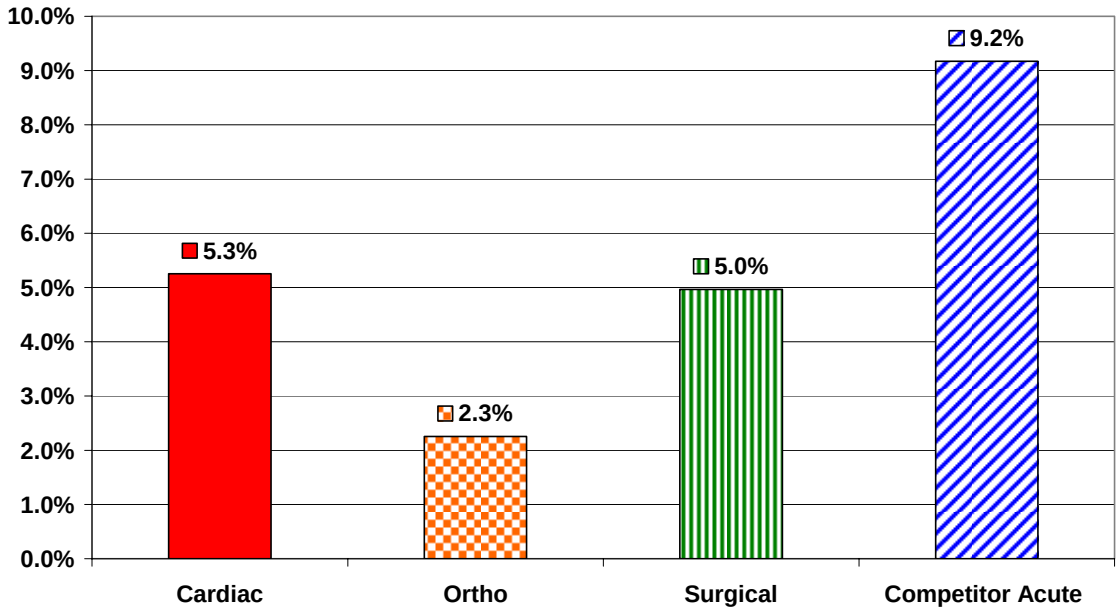
Bad debt consists of services for which hospitals expected to, but did not, receive payment.[81] Our survey solicited data on hospital bad debt expenses for FY 2004 and FY 2005.[82] We found that competitor hospitals are bearing a higher burden of bad debt expenses than specialty hospitals. Specifically, competitor hospitals responding to our survey reported bad debt averaging 9.2 percent of net patient revenues. In contrast, specialty hospitals carry a bad debt burden that is 3.8 percent of net patient revenues.

[80] The figures cited in Table 7 are based upon information provided by 10 cardiac hospitals, 14 orthopedic hospitals, 23 surgical hospitals, and 63 competitor acute care hospitals. The numbers in parentheses represent the number of survey respondents answering in the affirmative over the total number of respondents in that category..

[81] Medicare partially reimburses acute care hospitals for bad debts for Medicare beneficiaries. 42 CFR §§ 413.89(e) and (f). Such bad debt arises out of the nonpayment of deductibles and copayments after providers have made reasonable efforts to collect unpaid amounts. Medicare Provider Reimbursement Manual, Part I, CMS Pub. 15-1, § 310. For purposes of Medicare, the amount of bad debt reimbursed by the program is not included as uncompensated care.

[82] GAO defined uncompensated care as the sum of charity care and bad debt costs of hospitals in its study, *Nonprofit, For-Profit and Government Hospitals: Uncompensated Care and Other Community Benefits*, GAO Report, GAO-05-743T (May 26, 2005) at 21. Because our survey collected bad debt *costs*, but charity care *charges*, the data collected from these fields are not comparable and, therefore, we do not derive a calculation of uncompensated care costs.

Chart 3
Bad Debt at Responding Hospitals
(as a % of Total Net Patient Revenue)



2. Disproportionate Share Hospital Payments

Hospitals may receive direct payments from government sources to help them cover unreimbursed costs. Such payments may include Medicare and Medicaid payments known as DSH payments.

Medicare DSH payments are adjustments to payments to hospitals that serve a disproportionate share of low-income patients. The Congress mandated this adjustment due to its belief that hospitals serving such patients have higher Medicare costs per case. Hospitals qualify for the Medicare DSH adjustments based on the volume of low-income patients they service.[83]

Medicaid DSH payments are funded jointly by the States and the Federal government. Medicaid DSH was first authorized under the Omnibus Budget Reconciliation Act of 1987, which permitted States considerable flexibility in identifying DSH hospitals and determining DSH payment levels. To address abuses related to DSH payments, in the Omnibus Budget Reconciliation Act of 1993,[84] DSH payments to each hospital generally

[83] To qualify for Medicare DSH payments, a hospital must serve a disproportionate share of low-income patients. *See* 42 CFR § 412.106.

[84] Pub. L. No. 103-66.

were limited to the uncompensated care costs associated with hospital services furnished to Medicaid and uninsured patients (other than through the DSH payments themselves).[85] Typically, Medicaid DSH payments to hospitals are based on the volume of a hospital's charity care or general assistance days.

Although DSH payments constitute revenue to providers, and therefore are not a measure of charity care, they are, to a degree, a reflection of the patient mix seen by the hospitals and a measure of the volume of poor, uninsured, and underinsured patients treated by the hospital. Indeed, MedPAC's finding that specialty hospitals are less likely to treat low-income patients was premised in part on the measure of DSH payments received by hospitals under Medicare.[86]

In our survey, we solicited information on DSH payments made by Medicare and Medicaid for FY 2004 and FY 2005. We found that 40 of the 63 competitor hospitals responding to our survey (or 63.5 percent) received either Medicaid or Medicare DSH payments. In contrast, five out of the 47 responding specialty hospitals (or 10.6 percent) received such payments.

Table 8
Disproportionate Share Hospitals[87]

	Percent of Responding Hospitals that receive DSH Payments
Cardiac	30.0% (3/10)
Orthopedic	0.0% (0/14)
Surgical	8.7% (2/23)
Competitor acute care	63.5% (40/63)

[85] Social Security Act, section 1923(g)(1).

[86] *See* MedPAC MMA Study at 4.

[87] The figures cited in Table 8 are based upon information provided by 10 cardiac hospitals, 14 orthopedic hospitals, 23 surgical hospitals, and 63 competitor hospitals. This differs from the total number of survey respondents because of exclusions due to data validation or incompleteness. For example, three cardiac hospitals out of 10 responding cardiac hospitals indicated that they received DSH payments.

3. Overall Hospital Payer Mix

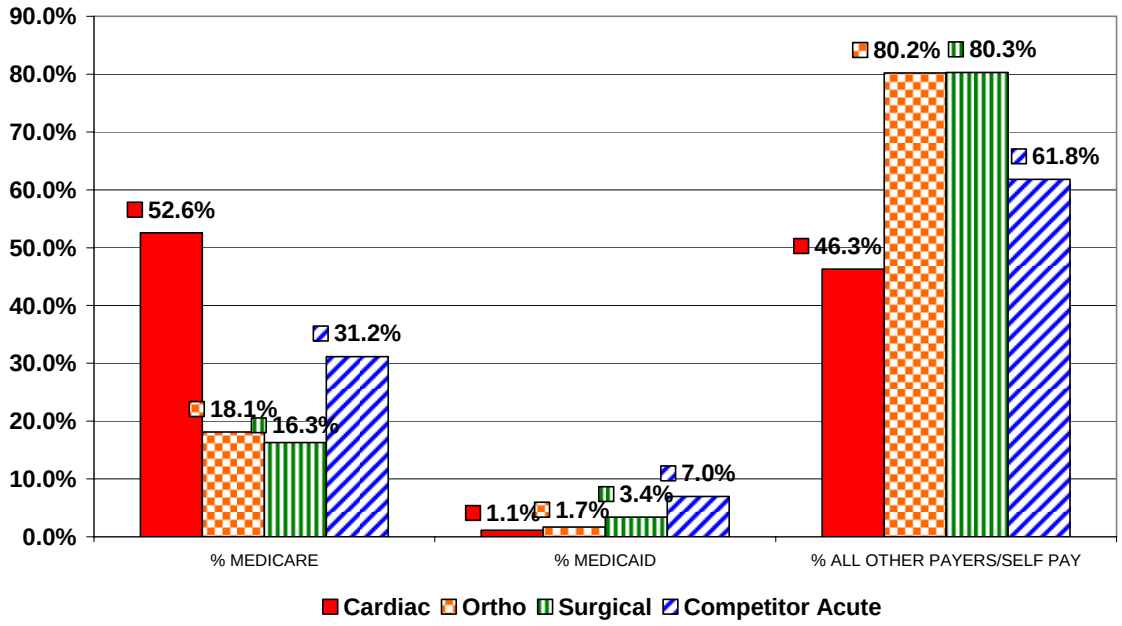
Although payer mix was not identified in the DRA specifically as an issue for report by HHS, our survey was designed to solicit information on both the patient and the payer mix of specialty hospitals and their competitors.

We have analyzed the payer mix of specialty and competitor hospitals, both in terms of patient discharges or visits, and in terms of revenues generated therefrom.

First, we analyzed reported revenue data for the responding hospitals. Our survey found that competitor hospitals had Medicaid revenue of 7.0 percent, Medicare revenue of 31.2 percent, and other sources of revenue of 61.8 percent of total net patient revenue, for combined FY 2004 and FY 2005. In contrast, physician-owned specialty hospitals had Medicaid revenue of 2.3 percent, Medicare revenue of 22.5 percent, and other sources of revenue of 75.2 percent of total net patient revenue in the same time period.

We broke down the data for specialty hospitals to further understand the payer mix of cardiac, orthopedic, and surgical hospitals. For responding cardiac hospitals, Medicaid revenue was 1.1 percent, Medicare revenue averaged approximately 52.6 percent, and other sources constituted 46.3 percent of total net patient revenue for combined FY 2004 and FY 2005. Responses of orthopedic hospitals reflected Medicaid revenue of 1.7 percent, Medicare revenue of 18.1 percent, and revenue from other sources of 80.2 percent of total net patient revenue for combined FY 2004 and FY 2005. For responding surgical hospitals, Medicaid revenue averaged 3.4 percent, Medicare revenue averaged 16.3 percent, and other sources constituted 80.3 percent of total net patient revenue for combined FY 2004 and FY 2005.

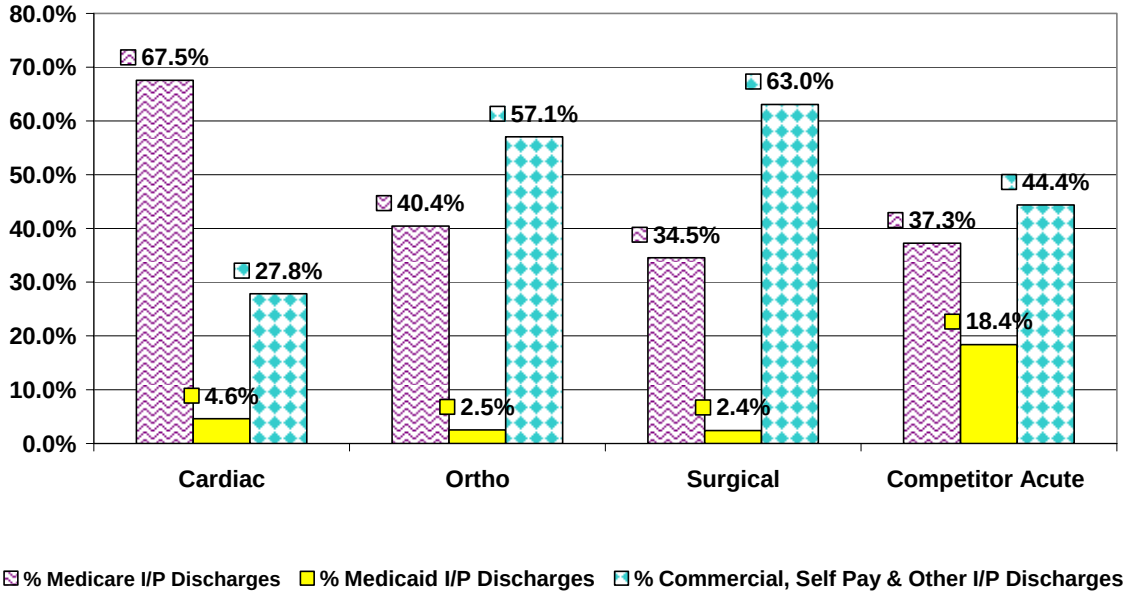
Chart 4
Payer Mix for Responding Hospitals
(as a % of Total Net Patient Revenue)



We also analyzed the percentages of each hospital's inpatient discharges, outpatient visits, and emergency department visits attributable to each payer. Our survey found that, for respondent competitor hospitals, Medicaid patients accounted for 18.4 percent of all inpatient discharges, Medicare patients accounted for 37.3 percent of inpatient discharges, and other sources constituted 44.4 percent of total inpatient discharges. In contrast, for all specialty hospitals responding to our survey, Medicaid patients accounted for 3.6 percent of all inpatient discharges, Medicare patients averaged 53.8 percent of inpatient discharges, and other sources constituted 42.6 percent of total inpatient discharges.[88]

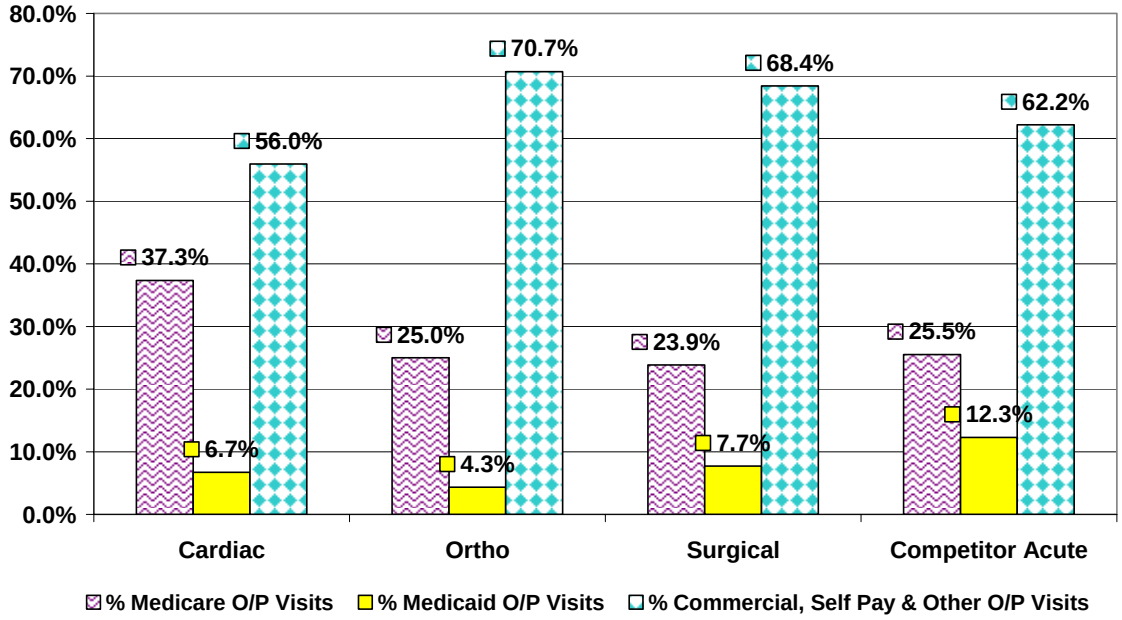
[88] We note that cardiac hospitals account for the bulk of the Medicare inpatient rate for all specialty hospitals. Our analysis reveals that, when cardiac hospitals are considered separately, they account for close to 68 percent of all Medicare inpatient discharges at specialty hospitals. In contrast, orthopedic and surgical hospitals averaged only 17 percent and 15 percent Medicare inpatient discharge rates, respectively.

Chart 5
Inpatient Discharges by Payer at Responding Hospitals
(as a % of Total Inpatient Discharges)



We also analyzed the percentages of each hospital's outpatient visits attributable to each payer. For competitor hospitals responding to our survey, Medicaid averaged 12.3 percent of all outpatient visits, Medicare averaged 25.5 percent of outpatient visits, and other sources constituted 62.2 percent of total outpatient visits. In contrast, for specialty hospitals, Medicaid patients accounted for 6.1 percent of all outpatient visits, Medicare patients averaged 26.2 percent of outpatient visits, and other sources constituted 67.7 percent of total outpatient visits.

Chart 6
Outpatient Visits by Payer at Responding Hospitals
(as a % of Total Outpatient Visits)



I. Level of Inpatient Versus Outpatient Services

In the FY 2006 inpatient PPS final rule, we noted that section 1861(e) of the Act defines a hospital for Medicare purposes.[89] To be considered a hospital, an institution must, among other requirements, be primarily engaged in furnishing services to inpatients.

In the Interim Report, we noted that cardiac specialty hospitals resemble full-service competitor hospitals in many ways. We also stated that even 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 competitor hospitals, including some small rural hospitals. We are concerned that adoption of a fixed definition of "primarily engaged in furnishing services to inpatients" may have deleterious effects on some rural and competitor hospitals. At the same time, we stated that some specialty hospitals and, in particular, orthopedic and surgical hospitals, more closely resemble ASCs than other hospitals because their business relies heavily on outpatient services.

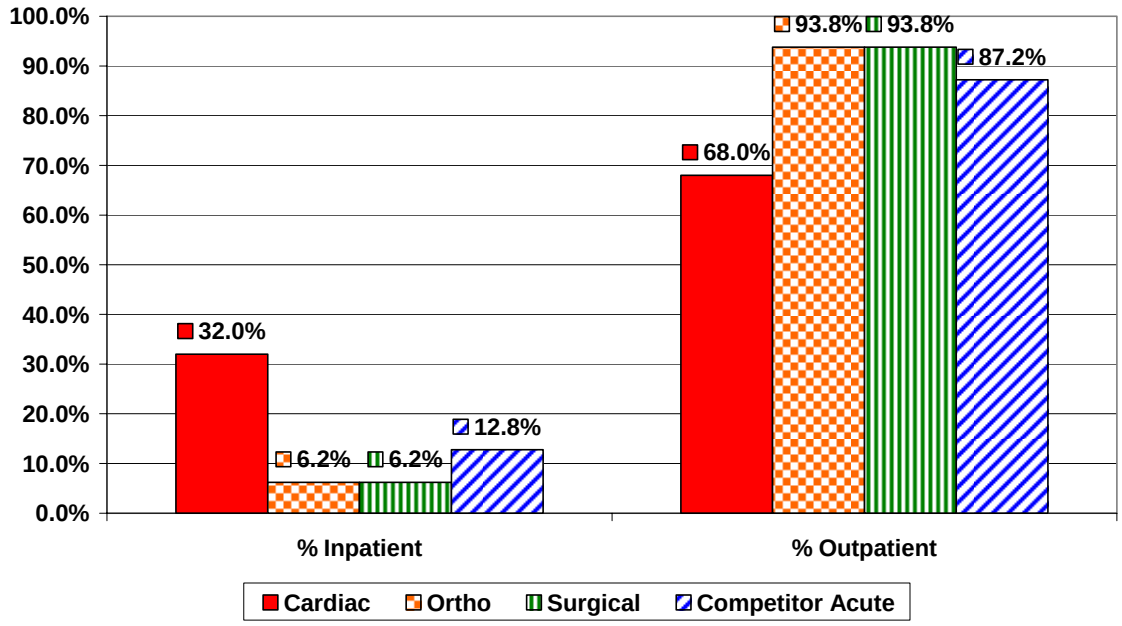
GAO also noted dissimilarities between specialty and general acute care hospitals in terms of the mix of inpatient and outpatient revenues. GAO found that specialty

[89] *See* 70 FR at 47462-47463.

hospitals reported inpatient revenues of 46 percent of total revenues, compared to 57 percent of total revenues for general hospitals.[90] GAO also noted substantially higher inpatient revenues at cardiac than at surgical and orthopedic specialty hospitals.[91]

We designed our survey to allow us to examine the relative characteristics of specialty hospitals and their competitors in terms of the volume of inpatient and outpatient services. Our survey indicates that (1) cardiac hospitals provide substantially higher numbers of services to inpatients than other hospitals reporting to us; and (2) orthopedic and surgical hospitals focus slightly more on the provision of outpatient services than do competitor acute care hospitals and much more on the provision of outpatient services than do cardiac hospitals.

Chart 7
Inpatient versus Outpatient Volume at Responding Hospitals
(as a % of Total Patient Volume)



J. Emergency Departments

Opponents of specialty hospitals claim that they are much less likely than competitor acute care hospitals to operate a dedicated emergency department, which, in turn, may impact disproportionately Medicaid and uninsured patients, and which may serve to

[90] *Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance*, GAO Report, GAO-04-167 (October 2003) at 22.

[91] *Id.*

direct such patients to competitor hospitals. Emergency departments have high operating costs because patients tend to be more critically ill and the departments must be staffed and prepared on a full-time basis, among other things. GAO found in a prior study that only 45 percent of specialty hospitals maintained dedicated emergency departments, whereas 92 percent of general hospitals have such facilities.[92] Of the specialty hospitals studied by GAO, the frequency of emergency rooms spanned a high of 72 percent in cardiac hospitals and a low of 33 percent in orthopedic hospitals.[93]

Accordingly, we designed our survey to allow us to examine the relative characteristics of specialty hospitals and their competitors in terms of emergency departments. Our survey results are consistent with previous studies showing that: (1) competitor acute care and cardiac hospitals are much more likely to have emergency departments than are orthopedic and surgical hospitals; and (2) orthopedic and surgical hospitals have smaller emergency departments, if they have them at all.

[92] *Specialty Hospitals: Geographic Location, Services Provider and Financial Performance*, GAO Report, GAO-04-167 (October 2003) at 18. We note that the 45 percent figure includes cardiac, orthopedic, surgical, and women's hospitals. *See also* Iglehart, *The Emergence of Physician-Owned Specialty Hospitals*, New England Journal of Medicine (January 6, 2005) at 79.

[93] *Specialty Hospitals: Geographic Location, Services Provider and Financial Performance*, GAO Report, GAO-04-167 (October 2003) at 18.

Table 9
Emergency Departments

	Percent of Respondents Reporting Emergency Departments[94]	**Average No. of Emergency Department Beds (for those hospitals reporting EDs) [95]**
Cardiac	100.0% (12/12)	7.8 (11/12)
Orthopedic	41.2% (7/17)	1.7 (7/7)
Surgical	46.9% (15/32)	1.7 (15/15)
Competitor acute care	98.5% (66/67)	23.6 (57/66)

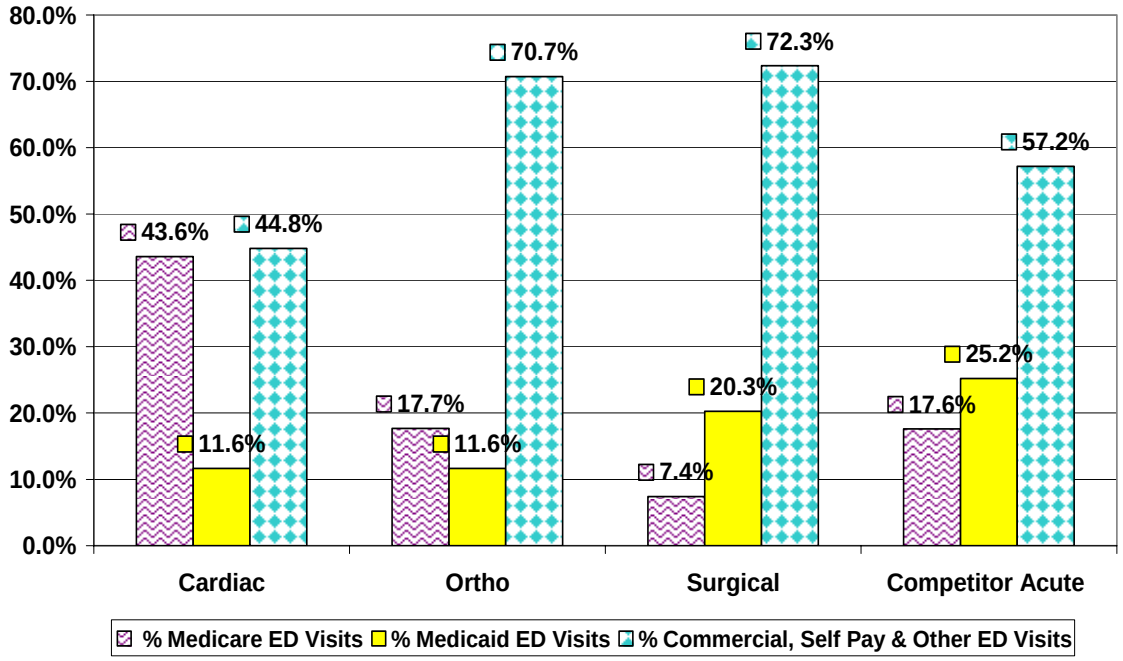
We have also found that orthopedic and surgical hospitals have lower admission rates through the emergency department than do competitor and cardiac hospitals. (Rates for competitor hospitals were 17.0 percent; cardiac hospitals, 28.4 percent; orthopedic hospitals, 1.1 percent; and surgical hospitals, 3.0 percent.)

Finally, we analyzed the percentages of each hospital's emergency room visits attributable to each payer. Our survey indicated that, for competitor hospitals responding to our survey, 25.2 percent of all emergency room visits were by Medicaid patients, 17.6 percent of visits were by Medicare patients, and 57.2 percent were by commercial, self pay or other patients. In contrast, for all specialty hospitals responding to our survey, Medicaid patients accounted for 14.5 percent of all emergency department visits, Medicare patients accounted for 29.0 percent of such visits, and commercial, self pay and other patients represented 56.5 percent of emergency department visits.

[94] The figures cited in Table 9 are based upon information provided by 12 cardiac hospitals, 17 orthopedic hospitals, 32 surgical hospitals, and 67 competitor hospitals. This differs from the total number of survey respondents because of exclusions due to data validation or incompleteness. For example, 7 out of 17 orthopedic hospitals reported having an emergency department.

[95] The parenthetical reference displays the number of hospitals with an emergency department that also provided us with data on their number of emergency department beds as compared to the total number of survey respondents who answered "yes" to the question regarding whether they have an emergency department. We excluded those hospitals that reported having emergency departments, but that failed to disclose the number of beds.

Chart 8
Emergency Department Visits by Payer at Responding Hospitals
(as a % of Total ED Visits)



V. Strategic and Implementing Plan

We set forth below our plan for addressing issues related to specialty hospitals, including the specific issues identified in section 5006 of the DRA. This plan identifies administrative actions that we have undertaken or intend to undertake. We are not recommending legislative action at this time. We arrived at our plan after considering the factual findings made by us and others such as MedPAC and GAO, soliciting public input on our Interim Report, and reviewing the relevant literature on specialty hospitals and issues related to charity care.

A. Continue Making Improvements in the DRG and ASC Payment Systems

Following the HHS Report to Congress on specialty hospitals mandated under section 507 of the MMA, CMS announced four key recommendations, including among them, reforming payment rates for inpatient hospital services through DRG refinements, and reforming payment rates for ASCs. The Interim Report noted the actions CMS has taken thus far to make improvements in these payment systems. Like MedPAC, we continue to believe that the most effective way to deal with perceived unfair competition by specialty hospitals in the form of selecting more profitable DRGs and more profitable patients (that is, less severely ill) within those DRGs, is to make the DRG payment system more accurate. This would reduce or remove the incentive for cherry-picking cardiac cases by

specialty hospitals[96] by providing equitable and accurate payment across all cases, consistent with MedPAC's recommendation for addressing the issue of physician-owned specialty hospitals and improvements to the inpatient hospital PPS.

In the inpatient PPS final rule for FY 2007, we created 20 new DRGs, and modified 32 others across 13 different clinical areas involving 1,666,476 cases, in order to improve the DRG system's recognition of severity of illness. In addition, we will begin adoption of a system of cost weights over a 3-year transition period, beginning in FY 2007, that will significantly improve the accuracy of Medicare's payments. We estimate that, once these new cost weights are fully adopted, there will be an aggregate reduction of over 5 percent in the relative weights for cardiac specialty hospitals. As indicated in the FY 2007 inpatient PPS final rule, CMS intends to study further adjustments to both the DRG and weighting systems, and may make further changes to the inpatient PPS for FY 2008.

Similarly, community hospitals have complained that orthopedic and surgical specialty hospitals unfairly take advantage of higher outpatient PPS rates for procedures that can be performed in ASCs. In the Interim Report, we noted that the existing ASC fee schedule is crude compared to the outpatient PPS, especially given the recent changes in outpatient medical practice, and that the basic structure of the payment rates has not been updated since 1990. As a result, we noted that payment rates for particular services in ASCs differ significantly from those performed in hospital outpatient departments and paid under the outpatient PPS. We continue to believe that reforms to the ASC fee schedule are necessary to better reflect the resources required to perform specific surgical procedures, and to bring them in line with payments made under other payment systems to the extent that similar procedures and utilization of resources are involved. We further believe that these reforms may discourage physicians and other investors from forming orthopedic and surgical specialty hospitals simply to take advantage of the typically higher payments made under the payment systems for inpatient and outpatient hospital services.

B. Align Physician and Hospital Incentives

We believe that closer alignment of physician and hospital incentives has the potential to reduce physicians' motivation for creating specialty hospitals and to improve patient outcomes and the efficiency of care delivery. Current Medicare payment systems often put physicians and hospitals at cross purposes. For example, under the physician fee schedule, a physician has an incentive to provide a large quantity of services to maximize revenue while, under the DRG prospective payment system, a hospital is incented to conserve resources to maximize its profit.

Physician proponents of specialty hospitals claim that a physician ownership interest allows the physician to exercise total control over the hospital's capital and human

[96] The issue of whether physician-owned specialty hospitals take advantage of the current DRG payment system by selecting cases in profitable DRGs pertains mostly to cardiac hospitals, because orthopedic and surgical specialty hospitals have relatively few inpatient cases.

resources, which represents maximum alignment of physician and hospital incentives. Physicians claim that the control inherent in specialty hospital ownership enables them to configure the hospital to provide higher quality of care and better service to patients at a lower cost, as compared to the levels of quality, service, and costs of competitor hospitals. Physicians are also able to benefit personally from having an ownership interest in the hospital. Physician-owners can configure the facilities to be more convenient and productive for their individual practices. By sharing in the profits of the hospital, they are able to benefit financially from managing their facilities more efficiently. Competitor community hospital executives assert, however, that physician control is not limited to specialty hospitals. These leaders claim that physicians exercise a large measure of control over the resources used and quality of outcomes for the patients treated in the community facilities as well. In addition, community hospital executives complain that physicians do not actively participate in their hospitals' quality improvement activities.

We believe that there are other mechanisms besides direct physician ownership of specialty hospitals that would align more closely physician and hospital incentives. First, we intend to pursue demonstration projects under the authority of section 5007 of the DRA to explore ways for physicians to participate meaningfully in the governance and management of hospitals, as well as to benefit financially from operating the clinical enterprise more efficiently. In addition, CMS continues to move its payment systems toward value-based purchasing. Alignment of physician and hospital quality and cost measures and payment methodologies under a value-based purchasing program has the potential to increase the incentives for physicians and hospitals to collaborate. Under a value-based purchasing program, both physicians and hospitals benefit financially from improvements in quality, services, and costs of care for their shared patients. Finally, we are also using our authority under section 646 of the MMA to develop health care quality demonstration programs that create the opportunity for hospitals and physicians to implement quality improvement strategies through better-aligned incentives. All three initiatives – the DRA gainsharing projects, value-based purchasing, and the health care quality demonstration programs – comprise the second prong of our strategic and implementing plan. The following paragraphs briefly discuss these CMS efforts to implement this component of the plan.

1. Gainsharing

As noted by MedPAC in its Report to Congress required under section 507 of the MMA, gainsharing offers an opportunity to align physician and hospital incentives, while limiting the potentially undesirable incentives inherent in physician ownership of hospitals. Initiatives such as gainsharing allow physicians and hospitals to share the savings from agreed-upon efficiency measures, such as standardizing products, substituting generic drugs, or re-engineering clinical practice protocols. These initiatives provide physicians with incentives to conserve resources in alignment with the hospitals' incentives to maximize efficiency of care. It is very important, of course, that patients be protected from breaches in quality resulting from inappropriate underutilization of services or from inappropriate referrals to generate financial gain. In the DRA, the

Congress authorized CMS to test various gainsharing arrangements, with appropriate patient protections. The patient protections specified by statute include a process for patient notification of the arrangement, continuous monitoring of quality and efficiency of care, and assurances that the participating physicians are not being rewarded on the basis of volume or value of referrals. CMS is currently preparing to solicit proposals for participation in the 3-year Gainsharing Demonstration.

2. Value-Based Purchasing

Value-based purchasing has the potential to promote alignment of physician and hospital incentives, and is another tool that CMS is implementing as part of payment system reforms. The current "siloed" Medicare payment systems are based on resource consumption, rather than achieving quality outcomes or avoiding unnecessary costs. In addition, the different payment systems often offer different financial incentives. For our physician and hospital value-based purchasing programs, we are considering aligned measures, as well as aligned payment incentives for a hospital stay or episode of care. The aligned measures could cover clinical quality (for example, risk adjusted outcomes measures), patient safety (for example, surgical infection rates), preventive services (for example, immunization rates), care coordination and transitions (for example, discharge planning), or cost of care (for example, adjusted actual to expected resource use during hospitalization). Alignment of value-based purchasing incentives will allow physicians and hospitals to work together to share in rewards that reflect their joint activities in improving care.

3. Hospital-Physician Quality Demonstration Programs

Finally, the MMA also authorized a demonstration project that allows us to test ways to better align physician and hospital incentives. Under the authority granted us in section 646 of the MMA, the Medicare Health Care Quality Demonstration Programs, we will be examining over 5 years how quality improvement strategies, such as implementation of aligned financial and non-financial incentives, in an integrated health system or regional health coalition can significantly improve quality of care while increasing efficiency across an entire health care system. Alignment of incentives is only one example of the many major and multi-faceted improvements that will be tested in "bundles" in this demonstration. These proposed payment models must be budget-neutral.

C. Issue Guidance on Patient Safety Measures

1. Medicare Conditions of Participation for Hospitals

The Medicare hospital conditions of participation regulations at 42 CFR Part 482, impose requirements on hospitals that have emergency departments, as well as requirements on hospitals without emergency departments. Specifically, 42 CFR § 482.12(f)(1) provides that, if emergency services are provided at the hospital, the hospital must comply with the emergency services condition of participation at 42 CFR § 482.55; and 42 CFR § 482.12(f)(2) addresses those hospitals that do not have emergency departments. Section

482.12(f)(2) requires hospitals without emergency departments to have "written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate." Also, 42 CFR § 482.13(c)(2), which applies to all hospitals, provides that the patient has the right to receive care in a safe setting.

Due to the large percentage of physician-owned specialty hospitals without emergency departments, we believe it is appropriate to issue further guidance on what we expect of hospitals without emergency departments with respect to the appraisal, initial treatment, and, when appropriate, referral of patients with medical emergencies. For example, we intend to consider the specific requirements for appraising a patient's medical condition and for providing initial treatment to that patient. We will consider whether personnel trained in proper patient revival techniques (such as Advanced Cardiac Life Support-trained nurses) must be on the premises at all times or whether it will be sufficient for such personnel to be available immediately to the hospital. Although all hospital patients are deserving of the same level of patient protections, we will consider whether the specific needs of surgical patients warrant different or additional written policies for the appraisal, initial treatment, and referral, when appropriate, of patients with medical emergencies.

Many patients with a medical emergency may not require referral to another hospital because the first hospital is able to provide the needed interventions to treat appropriately the patient. We are considering issuing further guidance to ensure that where it is necessary for a hospital to refer a patient to another hospital, the referring hospital must have appropriate procedures and qualified staff for appraisal of the patient and the provision of initial treatment until the patient can be transferred. In addition, the referring hospital would be required to provide the receiving hospital with information that it possesses and that is necessary for the appraisal and continued treatment of the patient.

2. EMTALA Requirements

In the Interim Report, we focused on the need for a specialty hospital to receive emergency patients who are within the treatment capability of the specialty hospitals. As noted in the Interim Report, we proposed to clarify in the FY 2007 inpatient PPS rule that hospitals with specialized capabilities (including hospitals without emergency departments) are required under EMTALA to accept appropriate transfers of unstable patients. We have finalized that proposal in the FY 2007 inpatient PPS final rule.

3. OIG Patient Care and Safety Study

Finally, we note that OIG is currently studying patient care and safety issues in physician-owned specialty hospitals. OIG will focus on whether physician-owned specialty hospitals have minimum standards in place to ensure patient safety, and the extent to which there are any documented concerns about patient care and safety at these hospitals. It will not examine any clinical measures assessing quality of care at these hospitals. We will take into consideration OIG's findings and discuss with OIG its specific recommendations.

D. Promote Transparency of Investment

1. Required Disclosure of Investment and Ownership Information

Section 5006 of the DRA requires us to consider the issue of annual disclosure of investment information. Accordingly, we first considered whether we have existing authority to require specialty or other hospitals to provide us with investment information on a routine basis. Such information could include the names of investors, the percentage of their shares, and the returns on their investments, as well as other information that would pertain to whether the return was proportional to the capital invested or whether the investments were *bona fide*.

Section 1877(f) of the Act allows the Secretary to collect, in such form, manner, and at such times as the Secretary shall specify, "information concerning [an] entity's ownership, investment and compensation arrangements, including" (1) the covered items and services furnished by the provider or supplier; and (2) the names and unique physician identification numbers (UPINs) of all physicians (or their immediate family members) with an ownership or investment interest, or compensation arrangement. The implementing regulation, 42 CFR § 411.361, states that CMS and OIG may require entities to submit information concerning their financial arrangements (ownership, investment, or compensation) with a physician (or his or her immediate family member), including the name and UPIN of each physician-owner or investor, and the extent and/or value of the ownership or investment interest or compensation arrangement. Therefore, we believe the statute and the regulation provide the necessary authority for requiring hospitals to disclose the names of physician-owners or investors, the nature and extent of their interests, and information concerning any possible compensation arrangements such as loans, or profit distributions, dividends, or other payments made by the hospital to the physicians. We note that failure to disclose timely the information sought can result in civil monetary penalties of up to $10,000 for each day beyond the deadline established for disclosure (which in all cases must be at least 30 days).[97]

We also decided to query hospitals concerning their willingness to submit investment information. Specifically, our survey of specialty hospitals and competitor hospitals asked whether the hospital or any of its physician-investors currently submit investment information to the State and, if not, would the hospital voluntarily agree to provide such information to the Secretary on an annual basis. Finally, we asked if the Congress or the Secretary were to impose an annual reporting requirement, what information should be captured. As noted in section IV.D.3 above, we received relatively few responses to our inquiry. Through the responses and our research, we determined that, of the States in which specialty hospitals are currently located, Texas is the only State in which specialty hospitals are required to submit information on physician-investors. Although only a few

[97] Section 1877(g)(5) of the Act, 42 U.S.C. § 1395nn(g)(5); 42 CFR § 411.361(f).

specialty hospitals responded to the survey, most were not opposed to a reporting requirement generally. However, some stated that, if a reporting requirement were imposed, it should apply to all hospitals.

We will require hospitals to provide us information on a periodic basis concerning their investment and compensation relationships with physicians. We are not limiting our requirement to information concerning physician investments in specialty hospitals for three reasons. First, all physician ownership in hospitals potentially implicates the physician self-referral statute (although some arrangements will fit within one or more of the whole hospital, rural provider, or Puerto Rican hospital exceptions). Second, physician investment in any type of hospital raises potential issues concerning compensation arrangements that can be associated with the investment. As explained in more detail below in section V.E.1, a disproportionate return on investment or non-*bona fide* investment (for example, through a sham loan), creates a prohibited compensation arrangement under the physician self-referral law and raises the possibility of an illegal kickback scheme. Third, other types of compensation arrangements, that is, those that do not arise from an investment interest per se, implicate the physician self-referral statute (and, depending on the circumstances, potentially the anti-kickback statute). For example, we note that some hospitals enter into contractual relationships, such as medical directorships, with referring physicians. Also, hospitals and physicians may have joint ventures for the purposes of providing services under arrangements, including services that formerly were provided directly by the hospital.

Because we are unable to determine at this point whether the hospitals that did not respond to our survey questions on investment interests and compensation arrangements (or did not respond completely) had tainted relationships or whether their non-response was for other reasons, we will begin our required disclosure initiative with those hospitals. We will also implement a regular disclosure process. We have not yet designed the process, but will consider such issues as whether we should (1) survey all hospitals annually, (2) stagger our survey so that all hospitals are queried but not all in the same year, and/or (3) focus our inquiry on certain types of relationships or certain hospitals. We will also consider whether, having once provided information, hospitals need submit only updated information on a yearly or other periodic basis.

2. Disclosure to Patients of Physician Ownership in Hospital

Some commenters, including competitor community hospitals, have complained that patients may be steered toward a specialty hospital by their physician if the physician has an investment interest in the hospital. As noted in section IV of this final report, the evidence thus far is inconclusive as to whether ownership of specialty hospitals leads to a significant increase in utilization. We also recognize that requiring disclosure to patients will not be entirely effective in preventing unnecessary or inappropriate self-referrals. Nevertheless, we believe that a well-crafted disclosure requirement, which, at a minimum, would require hospitals to disclose to patients whether they are physician-owned and, if so, the names of the physician-owners, is consistent with our approach that hospitals should be transparent as to their pricing and their quality outcomes. A well-

educated consumer is essential to improving the quality and efficiency of our healthcare system. Accordingly, we are exploring a change to our regulations, either on hospital conditions of participation or on provider agreement requirements, to require hospitals to disclose to patients investment interests, and possibly certain compensation arrangements as well, with physicians who refer to the hospital.

3. Changes to Enrollment Form to Capture Type of Hospital

Currently the provider enrollment form, the CMS-855A, does not distinguish between specialty hospitals and other types of hospitals. We will propose changing the CMS-855A to capture whether the applicant hospital is, or is projected to be, a specialty hospital. We will need to define specialty hospital (for example, the definition could be limited to cardiac, orthopedic and surgical hospitals or could include other types of specialty hospitals, such as women's hospitals) and establish criteria for determining the area of focus (for example, a certain percentage of discharges occurring or projected to occur within certain MDCs). In advance of any change to the CMS-855A, we will instruct our contractors to begin capturing data by contacting those hospitals that check the hospital box on the CMS-855A, and inquiring whether they are, or plan to be, a specialty hospital.

E. Enforcement

1. Enforcement Against Entities that are Party to Arrangements Involving Disproportionate Returns or Non-*Bona Fide* Investments

Section 5006 of the DRA tasked us with considering the issues of disproportionate returns on investment and non-*bona fide* investments in specialty hospitals. We consider a disproportionate return on investment to encompass a situation in which a physician-investor makes a capital contribution of, say, 2 percent but receives a profit distribution in excess of 2 percent. As described elsewhere in this report, investments may not be *bona fide* for a number of reasons. For example, a non-*bona fide* investment would include one in which the physician-investor has received a loan at less than fair market value rates from the hospital or from an entity or person with a financial interest in the hospital. Although our survey results did not reveal, on their face, any disproportionate or non-*bona fide* arrangements, we will take appropriate action against the parties involved in any such arrangements that we discover, including through our planned required disclosure of investment interests and compensation arrangements, as announced in section V.D.1 of this report.

a. The Physician Self-Referral Statute

The physician self-referral law and regulations require that each financial relationship that exists between a physician (or his or her immediate family member) and an entity furnishing DHS must be protected by an exception in order for the entity to submit claims for Medicare services referred to it by the physician. Therefore, if a physician has both an investment interest in, and a compensation arrangement with, a hospital, the physician

would need to have both an exception covering the investment interest as well as an exception covering the compensation arrangement.[98] We believe that we can reasonably interpret our regulations as meaning that only *true* profit distributions and dividends paid to a physician-investor in a specialty hospital are excused from having to meet a compensation arrangement exception. As we have stated previously, "an excepted ownership or investment interest may not be used to shield payments that are not legitimately related to the ownership or investment interest (such as funneling additional remuneration to physicians as ostensible 'returns' from an investment entity)."[99]

To the extent that a referring physician-investor has, for example, a 2 percent ownership interest in a specialty hospital and receives a 10 percent share of the profit distributions, the excess 8 percent is compensation that is not a true profit distribution. That is, a hospital would not be able to shield compensation from needing an exception by characterizing it as a profit distribution if, in fact, it is not a true profit distribution. Because there is no compensation exception that would apply to the excess 8 percent distribution given in this hypothetical situation, a violation of the physician self-referral statute would result.[100] Likewise, a referring physician-investor in a specialty hospital who received a no-interest loan from the hospital to purchase his or her interest in the hospital, would have a compensation arrangement for which no exception would exist.

Penalties under the physician self-referral statute can be quite severe. Any claims submitted by a hospital for services rendered to Medicare patients who were referred to the hospital by a physician with a non-protected compensation arrangement would be denied. If such claims were paid prior to the discovery of the non-protected compensation arrangement, the claims would be subject to reopening and recoupment. In addition, any person that presents, or causes to be presented, a claim for services that the person knows or should know is for a service for which payment cannot be made under the physician self-referral law is liable for a civil monetary penalty of up to $15,000 per service, an assessment of up to three times the amount claimed, and exclusion from Federal and State health care programs. Liability may also arise under the False Claims Act.

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[98] In this regard, we note that 42 CFR §411.356 states that "the following ownership or investment interests do not constitute a financial relationship. . . ." Thus worded, the regulation simply disregards, among whatever financial relationships a physician or an immediate family member may have with an entity, certain ownership or investment interests, such as an ownership or investment interest in a hospital. The regulation does not say that, if one of the enumerated ownership or investment interests exists, all other financial relationships are also disregarded. This reading is also supported by 42 CFR § 411.354(b)4), which states that a protected ownership or investment interest "need not also meet an exception for compensation arrangements . . . with respect to profit distributions, dividends, or interest payments on secured obligations," thus implying that other types of remuneration would need to meet a compensation exception.

[99] 69 FR at 16062 (March 26, 2004).

[100] This hypothetical assumes referrals for fee-for-service Medicare services between the hospital and the physician-investor.

The denial of payment provisions of the physician self-referral statute are administered by CMS, and the civil monetary penalty and exclusion provisions for knowing violations are administered by OIG. Consistent with current practice, if CMS learns of a credible allegation of a knowing violation of the physician self-referral statute (including, but not limited to, one involving disproportionate returns or non-*bona fide* investment), it will forward such information to OIG for appropriate action. CMS will work with OIG and other law enforcement agencies to support the investigation and prosecution of fraud and abuse cases, including without limitation, cases involving violations of the physician self-referral statute and the False Claims Act.

b. The Anti-Kickback Statute

Consistent with current practice, CMS also will refer credible allegations of improper referral payments to OIG for potential investigation under the Federal anti-kickback statute. The anti-kickback statute makes it a criminal offense knowingly and willingly to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid.

OIG shares enforcement responsibility under the anti-kickback statute with the United States Department of Justice (DOJ), which prosecutes criminal cases on behalf of the United States. OIG investigates allegations of illegal kickbacks and works with DOJ and the United States Attorneys to prosecute criminal cases. In addition, OIG supports DOJ's civil prosecutions under the False Claims Act of certain cases involving kickback allegations. In addition, where a party commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act and may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act. OIG pursues these administrative remedies in coordination with DOJ.

Hospitals should also be mindful that compliance with the anti-kickback statute is a condition of payment under Medicare and other Federal health care programs. As such, liability may arise under the False Claims Act where the anti-kickback statute violation results in the submission of a claim for payment under a Federal health care program. As noted above, CMS will work with OIG and other law enforcement agencies to support

the investigation and prosecution of fraud and abuse cases involving Medicare, Medicaid, and other Federal health care programs.

The government has long-standing concerns about joint venture arrangements between those in a position to refer or generate Federal health care program business and those in a position to benefit from those referrals or business. These concerns are set forth in detail in guidance issued by OIG.[101]

A chief concern is that remuneration from a joint venture might be a disguised payment for past or future referrals from an investor to the venture or from one investor to a co-investor. Such remuneration may take a variety of forms, including dividends, profit distributions, or, with respect to contractual joint ventures, the economic benefit received under the terms of the operative contracts.

With respect to joint ventures, OIG has identified three areas of special concern: (1) the manner in which joint venture participants are selected and retained; (2) the manner in which the joint venture is structured; and (3) the manner in which the investments are financed and profits distributed. Within each area, OIG has identified particularly suspect features.

(i) The Manner in which Joint Venture Participants are Selected and Retained

Examples of suspect features related to the selection of joint venture participants include, without limitation:

- A substantial number of participants are in a position to make or influence referrals to the venture, other participants, or both;

- Participants that are expected to make a large number of referrals are offered a greater or more favorable investment or business opportunity in the joint venture than those anticipated to make fewer referrals;

- Participants are actively encouraged or required to make referrals to the joint venture;

- Participants are encouraged or required to divest their ownership interest if they fail to sustain an "acceptable" level of referrals;

[101] *OIG Supplemental Compliance Program Guidance for Hospitals*, 70 FR 4858 (Jan. 31, 2005). *See also, 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in* 59 FR 65372 *(*December 19, 1994); *OIG Special Advisory Bulletin on Contractual Joint Ventures*, 68 FR 23148 (April 30, 2003). These documents may be found on OIG's website at http://oig.hhs.gov/authorities.html.

- The venture (or its participants) tracks its sources of referrals and distributes this information to the participants; and

- The investment interests are nontransferable or subject to transfer restrictions related to referrals.

(ii) The Manner in which the Joint Venture is Structured

A venture may be suspect if one of its participants is already engaged in the line of business to be conducted by the joint venture, and that participant will own all or most of the equipment, provide or perform all or most of the items or services, or take responsibility for all or most of the day-to-day operations, while other participants primarily contribute a captive referral base.

(iii) The Manner in which the Investments are Financed and Profits are Distributed

Examples of suspect features in this area include, without limitation:

- Participants are offered investment shares for a nominal or no capital contribution;

- The amount of capital that participants invest is disproportionately small, and the returns on the investment are disproportionately large, when compared to a typical investment in a new business enterprise;

- Participants are permitted to borrow their capital investments from another participant or from the joint venture, and to pay back the loan through deductions from profit distributions, thus eliminating even the need to contribute cash;

- Participants are paid extraordinary returns on the investment in comparison with the risk involved; and

- A substantial portion of the gross revenues of the venture are derived from participant-driven referrals.[102]

Because of the risks inherent with joint ventures involving parties in actual or potential referral relationships, OIG has advised that, whenever possible, hospitals and physicians should structure their ventures to fit squarely in one of the safe harbors for investment

[102] *OIG Supplemental Compliance Program Guidance for Hospitals*, 70 FR at 4865. *See also 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted at* 59 FR at 65372 (December 19, 1994). These documents are available on OIG's website at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html*.

interests, such as the "small entity" investment safe harbor, the safe harbor for investment interests in an entity located in an underserved area, or the hospital-physician ASC safe harbor.[103] These safe harbors include conditions addressing the three areas noted above. These include, without limitation, conditions (1) requiring returns on investment that are directly proportional to the investor's capital investment; (2) ensuring *bona fide* investment and business risk; and (3) prohibiting investment terms that take into account in any manner the volume or value of referrals.

We believe our planned initiative to collect and review data on hospital ownership and compensation arrangements with physicians (as described in section V.D.1 above) will significantly enhance the ability of the government to detect and prevent fraud and abuse, to take appropriate enforcement actions, and to promote voluntary compliance with the Federal fraud and abuse statutes. We further believe that collection of this data will significantly enhance the government's understanding of the evolving financial relationships in the hospital industry, particularly in the area of specialty services, and will facilitate informed policymaking in the future to protect the Federal health care programs and their beneficiaries while at the same time ensuring the delivery of cost-effective, medically necessary, high quality care.

2. Continued Enforcement of the MMA Moratorium

As noted in the Interim Report, CMS investigated and determined that two hospitals that did not seek advisory opinions as to whether they were exempted from the MMA moratorium were, in fact, specialty hospitals, and were subject to the moratorium.

Based on the information one of the hospitals submitted with its request for an advisory opinion, CMS preliminarily determined that the hospital increased the number of its physician-investors past the time allowed by the MMA. After requesting and receiving additional information from the hospital, CMS confirmed its preliminary determination. Based on a data run from its contractor, CMS further determined that the hospital billed Medicare for claims totaling approximately $118,000 for services rendered to patients who were referred to the hospital by physician-investors during the period of the MMA moratorium. Under section 1877(g) of the Act, no payment can be made for designated health services rendered to a Medicare beneficiary as a result of a prohibited referral. Accordingly, an initial determination of overpayment notice for this amount was sent to the hospital on May 4, 2006. The Hospital has submitted rebuttal information to the notice and likely will appeal the overpayment. CMS will continue to defend its determination.

CMS investigated a second hospital after being requested to do so by the Senate Committee on Finance, which had received information indicating that the hospital was a

[103] These safe harbors are codified at 42 CFR §§ 1001.952(a)(2), 1001.952(a)(3) and 1001.952(r)(4), respectively.

physician-owned specialty hospital. CMS requested and received information from the hospital that indicated that the hospital was a physician-owned orthopedic specialty that was not under development as of November 18, 2003. Based on a data run from its contractor, CMS determined that the hospital billed Medicare for claims totaling approximately $542,000 for services rendered to patients who were referred to the hospital by physician-investors during the period of the MMA moratorium. An overpayment notice was issued in May 2006 for this amount.

CMS also attempted to ascertain whether there were other hospitals that did not seek an advisory opinion as to whether they were subject to the MMA moratorium but which, in fact, were specialty hospitals and which may have violated the moratorium. CMS first compiled a list of short term acute care hospitals that received Medicare provider agreements on or after November 17, 2003 and which had a bed capacity of less than 75 beds.[104] From the resulting list of 78 hospitals, CMS disregarded those hospitals that had requested an advisory opinion or of which it was already aware, as well as those few hospitals that received provider agreements after the expiration of the MMA moratorium. CMS also disregarded hospitals that received their provider agreements prior to April 1, 2004, because it was confident that any specialty hospital that received its provider agreement prior to that date would have been "under development" as of November 18, 2003 and, thus, would have been excepted from the MMA moratorium.

To determine preliminarily whether any of the hospitals identified through the steps noted above were primarily engaged in the care and treatment of patients with a cardiac or orthopedic condition, or those receiving a surgical procedure, CMS conducted a review of inpatient claims data. That is, CMS examined MedPAR data to capture the percentage of the hospitals' total discharges that fell within MDC 5, MDC 8, and the type of DRG within the MDCs (that is, medical or surgical). Consistent with its earlier actions and the criteria used by MedPAC and GAO, CMS established a threshold whereby, if 45 percent or greater of the hospital's total discharges fell within MDC 5 or MDC 8, or 45 percent of its total discharges were surgical in nature, CMS considered the hospital to be a specialty hospital. After performing the claims analysis CMS arrived at a final list of 10 hospitals.

On April 20, 2006, CMS sent a letter to each of the 10 hospitals, requiring information concerning the ownership of the hospital and the nature of the services performed.[105] Based on the information CMS received in response to the letter, CMS determined that

[104] These limitations in the search criteria were necessary because the number of all hospitals that received a Medicare provider agreement after November 17, 2003 (which would include change of ownership circumstances) was approximately 550, an unmanageable number.

[105] Specifically, the letter required: the names and UPIN of each physician who had (or whose immediate family member had) an ownership or investment interest in the hospital between December 8, 2003 and June 8, 2005; a list of MDCs, and the DRGs within those MDCs, by type (medical or surgical) for all inpatient discharges since the beginning of the hospital's operation through June 8, 2005; and a pie chart (by percentages) of the MDC/DRG (by type – medical or surgical) data for all inpatients discharged since the beginning of the hospital's operation through June 8, 2005.

two hospitals were likely to have been under development, and thus excepted from the MMA moratorium. The responses also indicated that two hospitals did not have physician-owners and two hospitals had not submitted bills to Medicare for the period during the moratorium. Information submitted by four hospitals indicates that they were subject to the MMA moratorium. Initial determination of overpayment letters were sent in July 2006 to the four hospitals, demanding repayment of approximately $12.1 million in the aggregate. As of this writing, all four hospitals have submitted rebuttal statements, which CMS has not yet reviewed.

F. Charity Care and Care to Medicaid/Section 1115 Waiver Patients

In the HHS MMA Study, pursuant to the statutory mandate, we gathered information about the provision of community benefit by specialty hospitals. In that study we concluded that the proportion of net revenue that specialty hospitals devote to both uncompensated care and taxes significantly exceeds the proportion of net revenues that competitor hospitals devote to uncompensated care. Section 5006 of the DRA, however, tasked us with gathering information on the provision by specialty hospitals of charity care and care to Medicaid and section 1115 waiver patients. Our findings from the survey with respect to Medicaid patients are consistent with those of MedPAC and GAO. We found that the reporting specialty hospitals provided proportionally less care to Medicaid patients than did the reporting competitor hospitals. This was true for both inpatient and outpatient services. The reporting specialty hospitals also incurred much less bad debt proportionally than did the reporting competitor hospitals. Finally, the reporting specialty hospitals also provided substantially less charity care than the reporting competitor hospitals. As noted in sections IV.F and IV.G, however, the reasons why specialty hospitals appear to be providing much less care proportionally to Medicaid and charity care patients may be due to a variety of factors, including the fact that fewer specialty hospitals have dedicated emergency departments which are often the point of entry for patients who are sicker and poorer.

We are not making a recommendation at this time for Congress to require specialty hospitals or other hospitals to furnish minimum levels of charity care or care to Medicaid or section 1115 waiver patients. Rather, we hope that the findings from our survey as to the amount of care provided to these patient populations by specialty hospitals and competitor hospitals will assist Congress in addressing questions about the responsibilities for-profit and nonprofit hospitals should bear with respect to serving the indigent, the uninsured and the undersinsured. We also note that our planned revisions to worksheet S-10 on the Medicare cost report may provide for better tracking of the amount of charity care and uncompensated care delivered by hospitals. In addition to the difficulties in determining how much charity care is provided at a hospital and the reasons why specialty hospitals provide less care proportionally to these vulnerable populations, are the thorny tasks of how to value the community benefit provided by hospitals, and how to compare the community benefit rendered by nonprofit hospitals, which receive tax exemptions and government subsidies such as DSH payments and uncompensated care pool arrangements, to that delivered by the for-profit hospitals, which pay taxes and typically do not receive such subsidies.

G. Non-Selected Policy Options

1. Recommend that the Congress Amend the Whole Hospital Exception in the Physician Self-Referral Statute

We are not recommending at this time that the Congress amend the whole hospital exception to prohibit physician ownership of specialty hospitals. Some, including FAH and AHA, contend that allowing physician ownership in specialty hospitals creates an impermissible conflict of interest between the physician's duty to render care and the physician's financial interest, and leads to increased utilization. They also assert that allowing physician ownership of specialty hospitals is contrary to the spirit of the whole hospital exception because ownership in a specialty hospital is more akin to ownership of a department of a full-service hospital, which is prohibited.

We begin with the observation that the Congress is acutely aware of the complaints of FAH, AHA, and others concerning physician ownership of specialty hospitals, but has not chosen to amend the whole hospital exception. Indeed, section 507 of the MMA reflected a deliberate rejection of the attempt by some in the Congress to outlaw physician-owned specialty hospitals, and even the Fair Hospital Competition Act of 2005 would not have amended the whole hospital exception to bar all physician self-referrals to specialty hospitals. Section 5006 of the DRA requires us to address certain specific issues relating to physician investment and the provision of care by physician-owned specialty hospitals to Medicaid and charity care patients, and to develop a strategic and implementing plan related to those issues. Not included among the issues specified in section 5006 is the question of whether the whole hospital exception should be repealed or modified with respect to specialty hospitals. Thus, section 5006 starts with the premise that, at least for the time being, physician ownership of, and self-referral to, specialty hospitals will be permitted, and our task, then, is to devise a plan for dealing with certain issues that pertain to these entities.

Although we are not making a recommendation with respect to the whole hospital exception, through this final report we are providing additional information to the Congress so that it can decide what action, if any, it wishes to take with respect to the whole hospital exception. In this regard, we again note that, although some have argued that physician ownership in specialty hospitals, because of their limited size, is more akin to ownership of a department of a hospital and, thus, is inconsistent with the whole hospital exception, the Congress did not enact an absolute bar to physician ownership of small facilities in order to ensure that there would be no incentive for physicians to self-refer. To the contrary, the physician self-referral statute allows physician ownership of any hospital regardless of its size, including ownership in small community hospitals, and also allows physician ownership of rural facilities (including, but not limited to, hospitals), regardless of their size.

2. Continue the Suspension on Enrollment of New Specialty Hospitals

In commenting on the Interim Report, FAH suggested that CMS should continue administratively the suspension on enrollment of new specialty hospitals should it decide that there are significant issues that need further review and consideration after the due date for the final report. FAH stated that this action would be similar to action taken by CMS in June 2005 and is clearly within the agency's authority. It is not clear to us, however, that we have the authority to continue the suspension on the enrollment of new physician-owned specialty hospitals past August 8, 2006. Section 5006 of the DRA provides that the suspension on enrollment that we instituted on June 9, 2005 is to continue until the earlier of the date that the Secretary submits the final report, or the date that is six months after the date of enactment of the DRA (August 8, 2006), and that, if the final report is not issued by August 8, 2006, the suspension is to be continued for an additional two months. Thus, because the Congress provided for definite end dates for the suspension, including an end date in the event that the final report was not issued by August 8, 2006, we question whether we would have the authority to continue the suspension beyond the time specifically provided for in section 5006 of the DRA. That is, we believe that the end dates specified by the Congress may not be simply an end to the mandate for the suspension, but may be an end to the authorization for the suspension. In any event, we do not believe that a continuation of the suspension is warranted.

3. Define "Primarily Engaged" by Regulation

We stated in the Interim Report that we had not identified a feasible way to define by regulation the statutory requirement in section 1861(e) of the Act that a hospital is an entity that is "primarily engaged" in furnishing services to hospital inpatients. Instead, we said, CMS will continue to interpret "primarily engaged" on a case-by-case basis as it continues to explore other options for addressing this issue. FAH states that CMS must bring greater clarity to this definition, whereas AHA stated that the Interim Report reflects the general consensus that it would be unwise to define "hospital" in terms of the proportion of inpatient to outpatient procedures, due to unintended consequences, especially for small rural hospitals. We are in no better position now than we were at the time the Interim Report was issued to define "primarily engaged" by regulation and, thus, are not committing at this time to engage in rulemaking.

VI. CONCLUSION

This final report is the culmination of our study of the issues tasked to us by the Congress in section 5006 of the DRA, and reflects our analysis of findings made by us and by others, such as MedPAC and GAO, and our review of the relevant literature. We believe our strategic and implementing plan represents a reasoned approach to the present controversy surrounding the competition between specialty hospitals and community hospitals. Specifically, our continued improvements in the inpatient hospital and ambulatory surgical center payment systems will make our payments more accurate and will reduce incentives for those who seek to form specialty hospitals simply to take

advantage of imprecision in our payment systems. Our gainsharing demonstrations will provide us with valuable information on how physician and hospital incentives might be aligned appropriately. Our additional guidance for hospitals that do not have emergency departments will further ensure patient safety. Our transparency of investment initiatives, and the continued cooperative efforts of CMS and OIG, will allow us to discover more easily and take appropriate action against disproportionate returns and non-*bona fide* investments and other noncompliant compensation arrangements. Finally, our findings with respect to Medicaid and charity care patient populations will add to the information that the Congress is already considering on issues relating to uncompensated care.