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VIA ELECTRONIC MAIL (Donald.Romano@cms.hhs.gov) &
OVERNIGHT DELIVERY

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Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mailstop: C4-25-01
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Re: Request for Public Comment on Specialty Hospital Strategic and Implementing Plan

Dear Mr. Romano:

This letter provides the comments and recommendations of MedCath Corporation ("MedCath") in response to your request for public comment regarding the methodology to be utilized by the Centers for Medicare & Medicaid Services ("CMS") in developing the specialty hospital strategic and implementing plan (the "Plan") as required by the Deficit Reduction Act of 2005 (the "DRA"). We appreciate the opportunity to provide these comments and recommendations..

MedCath is a national provider of cardiovascular services. MedCath develops, builds, and operates fully-licensed general acute care hospitals (among other facilities) focusing on the delivery of high-quality cardiovascular care. All of our twelve hospitals are owned in partnership with physicians and, in certain instances, with local community hospitals. Further, all of our hospitals comply with (and in some instances exceed) the requirements of the several existing laws regulating physician investment in specialty hospitals.

Pursuant to the DRA and as described by CMS during its March 8, 2006 special open door forum, CMS is required to analyze three general areas regarding physician-owned specialty hospitals: (1) physician investment; (2) care to certain categories of patients; and (3) enforcement. Specifically, the DRA requires the Secretary of the Department of Health and Human Services ("HHS") to develop the Plan to address the following issues regarding physician investment in specialty hospitals: (1) proportionality of investment return; (2) *bona fide* investment; (3) annual disclosure of investment information; (4) provision of (a) care to patients receiving benefits under Medicaid or a demonstration project and (b) charity care; and (5) appropriate enforcement. By August 8, 2006, the Secretary is to submit a final report to Congress on the Plan, including any recommendations for appropriate legislative and/or administrative actions.

CMS is seeking public comment regarding such substantive matters as:

- What is meant by "proportionality of investment return?"
- What is meant by "*bona fide* investment?"
- Should annual disclosure of investment information be required and, if so, what type of information should be included?

- What definition of "charity care" should be utilized in the Plan?

Given that the final report on the Plan must be submitted by August 8, 2006, CMS also is seeking public comment on how best to evaluate these substantive areas.

As discussed in detail below, we believe that these substantive areas have already been addressed by existing law, regulation, and guidance issued by federal agencies. In particular, the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)), the federal physician self-referral law (commonly referred to as the "Stark Law") (42 U.S.C. § 1395nn), a civil monetary penalty ("CMP") provision (42 U.S.C. § 1320a-7a(b)), and their implementing regulations and supplemental guidance, control and regulate physician investment in specialty hospitals. These laws dictate the structure and operation of physician-owned specialty hospitals including such matters as physician investment and patient care requirements.

To the extent that legislators and/or federal agencies are concerned with, for example, the "proportionality of investment return" or a "*bona fide* investment," these statutes provide authority for enforcement agencies to examine and sanction inappropriate practices. As an example, under the anti-kickback statute, the small entity safe harbor addresses such factors as the percentage of a physician's investment interest and investment returns. Given that compliance with a safe harbor is not mandatory, supplemental guidance from the HHS Office of Inspector General ("OIG") discusses such matters as financing and profit distributions. In terms of enforcement, the United States Department of Justice ("DOJ") has independent jurisdiction over the anti-kickback statute and the OIG maintains limited jurisdiction.

We do not believe that the DRA envisions new interpretations of or amendments to these statutes. Nor do we believe that the DRA mandates any revision to the Stark Law and its whole hospital exception. We believe that in enacting the DRA, Congress has simply directed CMS to review the noted substantive areas and assess whether existing law is being appropriately applied.

It is important to note that the statutes discussed above generally do not provide express or mandatory definitions of key terms or concepts given the inherent complexity of the underlying issues. Instead, the statutes rely upon certain "factors for consideration" such that case-by-case determinations can be made. As such, we believe that any refinement of key terms or concepts is unnecessary and potentially counter-productive as it may inappropriately hinder the enforcement activities of DOJ and OIG. Should CMS nonetheless determine to further clarify the substantive areas discussed above, the agency must be cognizant of and account for these inherent complexities.

For example, any analysis of the care specialty hospitals provide to Medicaid beneficiaries must examine <u>both</u> the composition of patients served at specialty hospitals <u>and</u> the competitors of those specialty hospitals in that market. Moreover, any analysis must account for such factors as: (1) specific market dynamics which may limit the ability of specialty hospitals to provide care to Medicaid beneficiaries (<u>e.g.</u>, specialty hospital exclusion from certain managed care plans) and (2) the nature of certain services which may impact the patients receiving those services (<u>e.g.</u>, specialty heart hospitals provide care to fewer Medicaid beneficiaries because this population – younger women and children – typically does not suffer from coronary artery disease in the same proportion as members of the general population).

As another example, "charity care" for purposes of the Plan should not be defined so narrowly as to exclude other categories of care provided to the medically indigent and underinsured (<u>e.g.</u>, bad debt). As discussed in Part III.B.2 <u>infra</u> and as recognized by the American Hospital Association ("AHA"), "hospitals have difficulty in distinguishing bad debt from charity care" and "[c]are delivered to a patient may be classified as charity care by one hospital, but bad debt by another."[1] Additionally, hospitals may receive payment from other sources to help cover their unreimbursed costs including subsidies, county allowances, uncompensated care pools, Hurricane Katrina uncompensated care funds, tobacco settlement funds, among other sources.

From a procedural standpoint, we believe that existing CMS data, in conjunction with several comprehensive reports, provide CMS with sufficient information to examine the applicable substantive areas without necessitating the compilation of additional information. Such existing CMS data includes:

- Information contained in certain specialty hospital advisory opinion requests;
- Medicaid data; and
- Disproportionate share hospital information.

Such comprehensive reports include:

- Medicare Payment Advisory Commission's ("MedPAC's") "Report to the Congress, Physician-Owned Specialty Hospitals" (Mar. 2005);
- CMS's "Study of Physician-Owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (May 2005);
- Government Accountability Office's ("GAO's") "Nonprofit, For-Profit, and Government Hospitals – Uncompensated Care and Other Community Benefits" (May 2005); and
- Research Triangle Institute's ("RTI's") "Specialty Hospital Evaluation Final Report" prepared for CMS (Sept. 2005).

For purposes of these comments and recommendations, we first describe MedCath's specialty hospital operations. We next detail existing law governing specialty hospitals. We then discuss the substantive areas for review pursuant to the DRA and finally outline information presently available to CMS for completion of its Plan.

I. MEDCATH'S SPECIALTY HOSPITAL OPERATIONS

A. Mission

MedCath, a national provider of cardiovascular services, has a focused vision: to redefine the way cardiovascular care is delivered. While all but one of our twelve hospitals (because of unique state licensure requirements) is licensed as a general acute care hospital, the hospitals focus on serving the unique needs of patients suffering from cardiovascular disease. MedCath is an innovative company with an unique approach that is revolutionizing the hospital industry by bridging the gap between the practice of medicine and the business of medicine.

1 AHA, "Uncompensated Hospital Care Cost Fact Sheet" p.2. (Nov. 2005).

B. Physician Partners and Risk to Investment

MedCath partners with local cardiologists and cardiovascular surgeons who have established reputations for clinical excellence. Our physician partners become owners in our hospitals because of dissatisfaction with the quality of care, efficiency, resources, and bureaucracy of their local hospitals, and to have an opportunity to make dramatic improvements in the delivery of health care. With ownership in the facility, and a significant role in the governance and operation of the hospital, physicians are motivated to design and operate highly efficient care delivery systems that have a direct, positive impact on patient care.

We believe this alignment of interest between the physicians and the hospital operator is a primary reason why MedCath hospitals have been able to improve the quality of care, reduce the average length of stay, save money to government payors, and achieve high levels of patient satisfaction.[2] We have found that the economic investment of physicians, under a physician ownership model, is in the best interest of the communities served and has resulted in the provision of a higher level of care and cost efficiencies.

In the case of MedCath's partnerships, all investors must assume substantial financial risk and accountability for the hospital and the care provided. As start-up businesses, all of our hospitals experience significant early stage losses, and there is no assurance they will subsequently be able to turn profitable. For some of our physician partners, this has led to a financial return on their investment. For others, it has led to no financial benefit and in the case of one of our hospitals, which we had to sell due to the anti-competitive tactics of the surrounding general hospitals, a loss of almost all of their investment.

C. Emergency Department Operation

Each of our hospitals operates a staffed emergency department that is open twenty-four hours a day, seven days a week, and is equipped with an average of eight Intensive Care Unit beds in addition to the inpatient beds to which patients can be transferred. As a result, MedCath hospitals are capable of treating nearly every patient regardless of their condition or ability to pay.[3] We are capable of fulfilling this need because each of our hospitals includes a medical staff of 175-300 specialists, sub-specialists, and primary care physicians (most of whom are not owners of the hospital) who are available to care for any patient that walks through our doors, whether they are a patient with a heart problem or not.

In fact, in the twelve-month period ending September 30, 2005, more than 60,000 patients were treated in the emergency departments of MedCath's hospitals. Approximately 63% of those treated were non-cardiac patients. Only approximately 2% of these non-cardiac patients were transferred to another hospital – a common practice among hospitals across the United States as not every acute care hospital (not even the large systems) offers specialized services such as trauma, burn, or psychiatric care. Our hospitals admitted, treated, and/or released the remaining 98% of these patients.[4]

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2 The Lewin Group, A Comparative Study of Patient Severity, Quality of Care and Community Impact at MedCath Heart Hospitals (Feb. 2004).

3 Hospitals with emergency departments must comply with the regulations required by the Emergency Medical Treatment and Labor Act ("EMTALA") and provide services to anyone coming to our hospitals seeking emergency medical care, regardless of their condition and their ability to pay.

4 Trendstar discharge-based data October 1, 2004 – September 30, 2005.

D. Care to Medically Indigent and Underinsured

Given their licensure as general acute care facilities, our hospitals are required by law to treat patients regardless of their ability to pay.[5] While this is the law, MedCath also believes it is a community responsibility to treat anyone who walks in our doors and requires medical care.

In fact, a Lewin Group study found that in all four markets where comparable data was available, MedCath hospitals ranked in the top half of area hospitals for the volume of cardiac care provided to indigent patients.[6] Approximately 75-85% of the self-pay/uninsured care is provided without compensation. Despite this large amount of uncompensated care, our hospitals and their services are available to all patients in need of cardiovascular care. Out payor mix for the twelve-month period ending September 30, 2005 is as follows:

Medicare	48.4 %
Medicaid	4.5 %
Self-pay/Uninsured	6.5 %
Private insurance and other	40.6 %

These percentages, especially the levels of Medicaid and self-insured/uninsured, are very similar to the typical general acute care hospital's cardiovascular services. With respect to Medicaid, certain ancillary factors impact our ability to treat still more Medicaid beneficiaries. First, the volume of Medicaid patients is not uniformly distributed across hospitals (including both general and specialty hospitals). In most communities, only one or two hospitals serve the vast majority of Medicaid patients with the other hospitals in the community serving the remainder. Based upon 2002 Medicare hospital cost report data, only 10% of hospitals provided nearly 60% of inpatient care for Medicaid patients.

Second, Medicaid programs in certain states in which we operate provide care for their beneficiaries through capitated arrangements with managed care plans. Because we are often blocked from participating by our competitors, we do not have contractual arrangements with these managed care plans in some of the areas that we operate. For example, in Arizona we have been involuntarily excluded from participation with these plans and, as such, our Medicaid levels are naturally comparatively lower.

Lastly, heart hospitals are inherently less likely to draw Medicaid patients because these patients, comprised primarily of younger women and children, do not typically require cardiac care. In fact, only about 9% of total Medicaid discharges nationally are for cardiac care while 42% of Medicaid inpatient care is for obstetrics.

E. Integration Into Community Health Care Networks

A growing number of not-for-profit health care systems around the country have embraced the concept of physician ownership as a means to improve the quality of care and cost effectiveness within their own health care systems. In fact, two of MedCath's hospitals are three-way partnerships between a community hospital or health system, MedCath, and local physicians.

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5 See note 3 supra.

6 The Lewin Group, A Comparative Study of Patient Severity, Quality of Care between MedCath Heart Hospitals and Peer Hospitals in The MedCath Market Area (Mar. 2004).

First, Avera McKennan, MedCath, and local physicians in Sioux Falls, South Dakota, built and opened the Avera Heart Hospital of South Dakota in March 2001, which is currently delivering high quality cardiovascular care to the patients of South Dakota and surrounding states. Second, Carondelet Health Network, MedCath, and local physicians in Tucson, Arizona are partners in the Tucson Heart Hospital. Clearly, these community health care networks recognize the value of the MedCath model.

II. EXISTING LAW GOVERNING SPECIALTY HOSPITALS

There are several existing statutes, regulations, and guidance documents issued by federal agencies controlling and regulating physician investment in specialty hospitals. In structuring and operating any physician-owned specialty hospital, hospitals and physicians must thoroughly examine, understand, and comply with these laws. MedCath, for example, works with legal counsel to comply with these laws. As such, we believe that MedCath's hospitals comply with and some respects exceed applicable legal requirements.

A. Federal Anti-Kickback Statute

The federal anti-kickback statute prohibits improper payments in connection with the delivery of items or services covered by certain federal health care programs, including Medicare and Medicaid. Violations of this criminal statute constitute a felony punishable by fines, imprisonment, exclusion from federal health care programs, and imposition of CMPs. Additionally, in certain circumstances, violations of the anti-kickback statute may implicate the civil False Claims Act (31 U.S.C. § 3730). Given its criminal nature, DOJ exercises primary jurisdiction and enforcement of the anti-kickback statute, while the OIG retains limited jurisdiction and provides interpretation of the statute.

The anti-kickback statute is very broad in scope and prohibits not only payments for patient referrals, but also improper investment or business relationships between two or more individuals or organizations. The regulatory exemptions from the anti-kickback statute or "safe harbors" set forth specific threshold requirements that, if fully met, will shield the entities involved from prosecution for an arrangement. With respect to physician investment in specialty hospitals, the most relevant safe harbor concerns small entity investment interests that do not qualify as publicly-traded.[7] This safe harbor addresses such factors as: (1) percentage of physician investment interest; (2) terms and marketing of physician investment interest; (3) loans and guarantees to physician-investors; and (4) investment returns.

Importantly, failure to comply with a safe harbor does not mean that an arrangement is illegal or even suspect.[8] As stated by the OIG, the legality of a particular business arrangement is determined by comparing the specific facts of the transaction to the prohibitions under the statute.

To assist entities in structuring legally compliant arrangements, the OIG has issued several special alerts, bulletins, and advisory opinions. Most relevant to physician investment in specialty hospitals, in 1989, the OIG issued a Special Fraud Alert on joint ventures and contractual arrangements.[9] The Special Fraud Alert provides examples of potentially unlawful

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7 See 42 C.F.R. § 1001.952(a)(2).

8 See 64 Fed. Reg. 63,521 (Nov. 19, 1999).

9 See Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), reprinted in Medicare and Medicaid Guide (CCH) [Transfer Binder 1990] ¶ 38,448.

activity in three areas relating to joint ventures: (1) the selection of investors; (2) business structure; and (3) financing and profit distributions. In particular, the guidance warns against "shell" joint ventures.

In 2003, the OIG issued a Special Advisory Bulletin on Contractual Joint Ventures. This Special Advisory Bulletin expands upon the 1989 Special Fraud Alert and further details the criteria the OIG will utilize in identifying questionable arrangements. The Specialty Advisory Bulletin reflects that OIG's concern regarding joint ventures primarily established to service a provider's existing patient base, at minimal risk, and where the provider has little involvement in the financing or operation of the new business.

Finally, the OIG has issued several advisory opinions regarding the propriety of certain proposed joint ventures including: (1) outpatient radiology imaging joint ventures and (2) ambulatory surgical center joint ventures.[10] These advisory opinions evaluate several elements of proposed arrangements including: (1) the structuring of profit distributions to referral sources; (2) investment amounts; and (3) the types and scope of services provided. All of this guidance provides some of the "factors for consideration" when evaluating an arrangement.

B. Stark Law

The Stark Law prohibits physicians from referring Medicare and Medicaid patients to an entity for the furnishing of certain designated health services if the physician (or immediate family member) has a financial relationship with the entity. Additionally, the entity may not submit any claim for payment for services furnished pursuant to a prohibited referral. Violations of the Stark Law may result in non-payment of services, recoupment of improperly paid services, exclusion from the Medicare and Medicaid programs, and CMPs. Additionally, knowing violations of the Stark Law may also give rise to liability under the civil False Claims Act. Primary jurisdiction for interpretation and enforcement of the Stark Law rests with CMS, although DOJ and OIG may exert jurisdiction based upon False Claims Act violations, among other instances.

Unlike the federal anti-kickback statute, a Stark Law exception must be satisfied in order to permit arrangements that otherwise are prohibited by the statute. With respect to physician investment in specialty hospitals, the most relevant exception is for physician ownership in a hospital.[11] The "whole hospital" exception requires that: (1) the physician be authorized to perform services at the hospital; and (2) the ownership or investment interest is in the hospital itself and not in a subdivision of the hospital. In addition, the hospital must qualify as a "hospital" under the Medicare conditions of participation.[12]

C. Civil Monetary Penalty Statute

A CMP provision prohibits hospitals from knowingly making payments to physicians as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries. In 1999, the OIG issued a Special Advisory Bulletin regarding gainsharing which suggests that ownership distributions to physician investors in specialty hospitals could implicate this CMP provision. Additionally, the Special Advisory Bulletin notes that these arrangements also may implicate the federal anti-kickback statute and the Stark Law. The OIG recognizes, however,

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[10] See, e.g., OIG Adv. Op. Nos. 97-5 (Oct. 6, 1997), 98-12 (Sept. 16, 1998).

[11] See 42 U.S.C. § 1395nn(d)(3); 42 C.F.R. § 411.356(c)(3).

[12] See 63 Fed. Reg. 1659, 1698-99 (Jan. 9, 1998).

that properly structured gainsharing arrangements can serve legitimate business and medical purposes. Responsibility for enforcement of the CMP provision primarily resides with the OIG.

D. Analysis of Existing Law

When viewed together and given their scope, it is clear that the federal anti-kickback statute, Stark Law, and CMP provision, control and regulate all aspects of physician investment in specialty hospitals. Specifically, the broad federal anti-kickback statute, small entity investment interest safe harbor, the joint venture guidance from the OIG, the Stark law and whole hospital exception, and the CMP provision effectively dictate the structure and operation of physician-owned specialty hospitals. Indeed, these laws either explicitly or implicitly address the substantive issues to be analyzed by the Plan including: (1) proportionality of investment return; (2) *bona fide* investment; (3) annual disclosure of investment information; and (4) provision of (a) care to patients receiving benefits under Medicaid or a demonstration project and (b) charity care.

Stated differently, the issues under the Plan must necessarily be analyzed and addressed by physician-owned specialty hospitals in order to comply with applicable law. These laws are structured such that the OIG, DOJ, and/or CMS have sufficient authority to examine and sanction inappropriate practices. When viewed in this context, we believe that CMS's mandate under the DRA does not extend to new interpretations of or amendments to these laws, but does require that CMS determine whether these laws are being appropriately applied. To the extent that CMS believes that enforcement agencies should become more vigilant regarding inappropriate arrangements, pre-existing law provides a variety of sanctions that may be employed.

Moreover, we do not believe that any revision to the Stark Law and/or the whole hospital exception is mandated under the DRA. We believe physician-owned specialty hospitals that are licensed as general acute care hospitals, have emergency departments, provide care to the medically indigent and underinsured, and otherwise offer a full-range of services are "whole" hospitals and not subdivisions which should be afforded protection under the Stark Law's whole hospital exception. It is simply a misnomer to describe such specialty hospitals as "limited service," or otherwise not complying with the letter or spirit of the whole hospital exception.

III. AREAS OF SUBSTANTIVE REVIEW

To a large degree, the statutes discussed above have been purposefully enacted without providing express or mandatory definitions of key terms or concepts given the inherent complexity of the underlying issues. Instead, the statutes and enforcement agencies rely upon broad "factors for consideration" in evaluating arrangements such that case-by-case determinations can be made. As such, we believe that any refinement of key terms or concepts is unnecessary and potentially counter-productive as it may inappropriately hinder the enforcement activities of DOJ and OIG.

Should CMS nonetheless determine to further clarify the substantive areas under its Plan, we believe that the agency must be cognizant of and account for certain inherent complexities. As detailed below, we address each substantive area under the Plan and highlight some of these complexities.

A. Physician Investment

The DRA outlines three issues regarding physician investment in specialty hospitals: (1) proportionality of investment return; (2) *bona fide* investment; and (3) annual disclosure of investment information. With respect to the proportionality of investment return and *bona fide* investment, the small entity investment interest safe harbor discusses these concepts. Given that compliance with a safe harbor is not required, additional guidance from the OIG also addresses these issues. While we believe that these concepts must be examined on a case-by-case basis, existing law suggests that "proportionality of investment return" means that any allocations or distributions to physician-investors in a specialty hospital should be pro rata based upon the physician's percentage of investment interest. A "*bona fide* investment" would be one where a physician's investment is substantial and not derived from loans or guarantees.

We believe that under MedCath's model (or similar physician-ownership model) any investment returns physician-investors may receive are appropriate given the substantial capital contributions of physician-investors and the high risks inherent in starting a hospital. Moreover, any such investment returns are justifiable given the benefits of physician involvement in hospital governance and operation which leads to improved clinical outcomes, reductions in length of stays, cost savings, and high levels of patient satisfaction.

With respect to any disclosure of investment information, we believe that pre-existing federal and state law contemplates this issue. While not necessarily required by these laws, it is MedCath's policy to encourage all partner physicians to disclose to patients that they have an investment in the hospital. This disclosure allows patients and other third-parties to make informed health care decisions.

We do believe, however, that disclosure of any other type of investment information to patients or other third parties (e.g., returns on investment) is not required by law, and would involve confidential and proprietary business information. In fact, under the Stark Law, while CMS and the OIG may obtain such information from hospitals, any public disclosure of this information is subject to Freedom of Information Act and other requirements.[13] In this way, there is a recognition of the sensitivity of such information. Moreover, any such disclosure would involve complexities purposefully unaddressed by existing law (e.g., when should investment returns be calculated and how should they be calculated?). Given these considerations, we do not recommend that under the Plan CMS require these types of disclosures to patients or other third parties.

B. Patient Care

The DRA outlines two issues regarding patient care and specialty hospitals: the provision of care to patients receiving benefits under Medicaid or a demonstration project; and charity care. We believe that any attempt by CMS to further clarify these areas would necessarily involve complexities that would not be easily addressed in the context of the Plan.

1. Care to Medicaid or Demonstration Project Patients

With respect to provision of services to Medicaid (or demonstration project) patients, any analysis must be sure to compare "apples-to-apples." First, analysis of the care specialty hospitals provide to Medicaid beneficiaries must examine both the composition of patients served at specialty hospitals and the competitors of those specialty hospitals in that market. By making this comparison, low Medicaid admission data at a specialty hospital may properly be viewed as a reflection of the individual market, rather than any action by the specialty hospital.

Second, any analysis must recognize and account for the fact that the volume of Medicaid patients is not uniformly distributed across hospitals. In most markets, only one or two hospitals

13 See 42 C.F.R. § 411.361.

serve the vast majority of Medicaid patients, while the other hospitals in the market provide services to the remainder of patients.

Third, specific market dynamics may limit the ability of specialty hospitals to provide care to Medicaid beneficiaries. For example, many state Medicaid programs provide care for their beneficiaries through capitated arrangements with managed care plans. MedCath hospitals, like many specialty hospitals, often are blocked by competitors from participating in such managed care plans. As such, we do not have contractual agreements with these plans and are effectively precluded from providing services to the Medicaid beneficiaries enrolled in these plans.

Finally, any analysis of the services provided to Medicaid (or demonstration project) patients must be performed on a service-by-service basis. For example, heart hospitals inherently are less likely to provide services to Medicaid patients because these patients are comprised primarily of younger women and children – a patient population that typically does not require cardiac care.

2. Charity Care

With respect to analysis of the charity care provided by specialty hospitals, inherent complexities make any meaningful analysis in the context of the Plan difficult. Any definition of charity care utilized by CMS must recognize the distinctions between hospital charges and hospital costs, and then be broad enough to account for all care to the medically indigent and underinsured.

As recognized by GAO, specific definitions of charity care vary.[14] In its report, GAO defined charity care as "charges for patients deemed unable to pay all or part of their bill, less any payments made by, or on behalf of, that specific patient." On the other hand, in its annual publication on the level of uncompensated care delivered in the United States, AHA defines charity care as consisting of "services for which hospitals neither received, nor expected to receive, payment because they had determined the patient's inability to pay."[15] In its fact sheet and because "hospital charge data can be misleading," AHA reports its data on uncompensated care in terms of costs.

The various definitions of charity care also attempt to distinguish bad debt. While definitions of "bad debt" also vary, bad debt is typically thought to consists of the uncollectible payment that a patient is expected to, but does not pay. In any event, and as expressly recognized by AHA, "hospitals have difficulty in distinguishing bad debt from charity care." Moreover, "[c]are delivered to a patient may be classified as charity care by one hospital, but bad debt by another."

Additionally, hospitals may receive payment from other sources to help cover their unreimbursed costs. These sources include subsidies, county allowances, uncompensated care pools, Hurricane Katrina uncompensated care funds, tobacco settlement funds, among other sources. The variety of these sources and the different methodologies utilized by hospitals in accounting for these payments would make review of these sources exceedingly difficult.

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[14] See GAO, Nonprofit, For-Profit, and Government Hospitals – Uncompensated Care and other Community Benefits, GAO-05-743T (May 26, 2005).

[15] AHA, "Uncompensated Hospital Care Cost Fact Sheet" p.2. (Nov. 2005).

C. Appropriate Enforcement

The DRA requires the Plan to address "appropriate enforcement." As discussed in detail above, we believe that existing law controls and regulates physician investment in specialty hospitals. We do not believe that the DRA contemplates that CMS suggest new interpretations or amendments to these laws, but that CMS evaluate whether these laws are appropriately applied.

Further, we do not believe that with the DRA Congress has suggested that physician-owned specialty hospitals be eliminated. As such, we do not believe that any revision to the Stark Law and/or the whole hospital exception is mandated under the DRA. Indeed, specialty hospitals, such as MedCath's hospitals which are licensed as general acute care hospitals, have emergency departments, and provide care to the medically indigent and underinsured are "whole" hospitals and not subdivisions which should be afforded protection under the Stark Law's whole hospital exception. Such specialty hospitals are not "limited service," but hospitals which comply with both the express terms and underlying intent of the whole hospital exception.

IV. INFORMATION AVAILABLE TO COMPLETE THE PLAN

Pursuant to the DRA, the final report on the Plan must be submitted by August 8, 2006. Given the DRA's tight deadlines and the ability of CMS to collect and analyze voluminous new data, we believe that existing CMS data, in connection with several comprehensive reports, provide the agency with sufficient data to develop the Plan. Such existing CMS data includes:

- In connection with the specialty hospital moratorium mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), CMS has received information relating to approximately forty specialty hospital advisory opinion requests. These advisory opinion requests concerned whether certain specialty hospitals were "under development" for purposes of the moratorium and likely contain substantial supporting materials;

- Medicaid data that CMS collects on a routine and consistent basis; and

- Disproportionate share hospital information that CMS collects on a routine and consistent basis.

The MMA also directed MedPAC and HHS to report to the Congress on certain issues concerning physician-owned specialty hospitals. Specifically, MedPAC considered: (1) the cost of care at physician-owned specialty and full-service community hospitals; (2) the financial impact of physician-owned specialty hospitals on local full-service community hospitals; (3) differences in the payer mix between specialty and full-service community hospitals; (4) patient selection within categories of cases, comparing specialty and full-service community hospitals; and (5) improvements to Medicare's hospital inpatient prospective payment system that should be made to better reflect the cost of care in a hospital setting. In March 2005, MedPAC provided its "Report to the Congress, Physician-Owned Specialty Hospitals."

On the other hand, HHS considered: (1) the referral patterns of physician-owners; (2) the quality of care furnished in physician-owned specialty hospitals; and (3) the extent to which special hospitals furnish uncompensated care. In May 2005, HHS provided its "Study of Physician-Owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003."

While the MedPAC and HHS reports are not directed squarely on all the issues raised by the DRA, when taken together and with the comprehensive research utilized to prepare these reports, all the substantive matters for review under the DRA are addressed. Additionally, these reports may be supplemented by: (1) RTI's "Specialty Hospital Evaluation Final Report" which was produced under the direction and funding of CMS and (2) GAO's "Nonprofit, For-Profit, and Government Hospitals – Uncompensated Care and other Community Benefits."

MedCath appreciates the opportunity to submit these comments and recommendations. We are available and would be pleased to discuss these issues further with CMS.

Sincerely,

James E. Harris
Executive Vice President and Chief Financial Officer