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Charles N. Kahn III
President

June 12, 2006

VIA ELECTRONIC MAIL

Mr. Donald Romano
Director, Division of Technical Payment Policy
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C5-02-23
Baltimore, MD 21244

Re: DRA Interim Report on Specialty Hospitals

Dear Mr. Romano:

The Federation of American Hospitals appreciates the opportunity to comment on the Interim Report on the Strategic Plan Regarding Physician Investment in Specialty Hospitals: Section 5006 of the Deficit Reduction Act ("DRA") ("Interim Report"). The DRA has identified critical issues for the Department of Health and Human Services ("HHS") to analyze and address in its strategic and implementing plan ("the Plan"). As you know, the Federation long has been concerned with the conflict of interest inherent in physician ownership and self referral to their limited service facilities. We welcome the opportunity to comment on the Department's work to date on this important issue.

I. The Office of Inspector General Should Play a Direct Role in Developing the Plan

As addressed by the Interim Report, DRA section 5006 directs the Secretary of HHS to develop a strategic and implementing plan concerning, among other things, whether physician investments in specialty hospitals are proportional to investment returns; whether the investments are bona fide investments; whether HHS should require annual disclosure of investment information; and, what are appropriate enforcement mechanisms to address these issues. In directing this mandate to the HHS Secretary, Congress clearly expects all appropriate components of HHS to participate directly in implementing this mandate. Therefore, the HHS Office of Inspector General ("OIG") should be directly involved in developing the Plan.

Given its daily responsibilities to enforce the anti-kickback and civil monetary penalties laws, the Federation strongly believes the OIG is best suited to address these particular issues. However, the Interim Report states that the OIG only may be a consultant to the Centers for Medicare & Medicaid Services ("CMS") in developing the Plan. The rationale given for this conclusion is that section 9 of the Inspector General Act prohibits inspectors general from assuming "program operating responsibilities" so as to insulate them from "any responsibility for developing or running the very programs that they might be asked to review." (Interim Report, p. 10.)

However, this argument is neither compelling nor logical. A main purpose of inspectors general is "to provide leadership and coordination and recommend policies for activities designed . . . to prevent and detect fraud and abuse in such programs and operations." (Inspector General Act § 2(2).) It is hard to comprehend how any of the OIG action items we recommended in our March 31, 2006 comment letter (which is attached) regarding the implementation of DRA section 5006 constitute engaging in program operations. Our recommendations clearly are based on the enforcement statutes within the OIG's jurisdiction and represent actions that the OIG takes routinely in other enforcement contexts.

Therefore, we cannot understand how HHS reached the conclusion that the OIG may not participate directly in the Plan's development. The logic (or illogic) of this conclusion draws a clear distinction between physician-owned limited service facilities and every other type of provider, supplier and practitioner for which the OIG routinely uses these enforcement tools to protect against fraud and abuse.

Moreover, this conclusion seems to be in stark contrast with other public statements by CMS about the impact of the DRA provision on the OIG. During his recent testimony before the Senate Finance Committee, CMS Administrator Mark McClellan indicated clearly that the issues the DRA identifies implicate the anti-kickback statute, and that CMS will need to consult with the OIG as well as relevant state authorities to address these issues.

The Federation believes it is obviously more efficient, effective, and above all appropriate for the OIG to participate directly in the development of the Plan and to make its views and recommendations known directly. The process is poorly served by having CMS report about what the OIG should address. Clearly, CMS cannot bind the OIG to any particular action items within the meaning of a "strategic and implementing" administrative plan.

II. The Final Report Should Contain An Administrative Action Plan and a Time Line for Implementation

The Interim Report indicates that the final report will be completed on or before August 8, 2006 and will set forth "any specific recommendations with respect to the issues we have been tasked to analyze under section 5006 of the DRA." (Interim Report, pp. 10-11.) We interpret this to mean that CMS will provide recommendations to

Congress for legislative action as it deems appropriate. However, this section is silent about whether the final report to Congress will include administrative action items and a time line for implementation.

Because the DRA language clearly contemplates that HHS's Plan will be "strategic and implementing," we are concerned about the lack of focus in the Interim Report regarding administrative action items. While we understand that the Plan may include legislative recommendations, Congressional intent is clear that HHS is expected to identify steps it will take under existing authority to address the DRA's concerns. As a result, the lack of reference to administrative action items and a time line in the Interim Report is a real concern.

We are not alone in expressing this concern. This same issue was a focus of the Senate Finance Committee's questioning of Administrator McClellan during the recent hearing. While Congress can act on its own or upon recommendations from HHS, the DRA is clear that Congress expects administrative action items and a time line for implementation, and the Senate Finance Committee expressed clearly the same view.

In the Interim Report, CMS presents a detailed review of items that it undertook to review during its administrative enrollment suspension which began in 2005. While these items are relevant, they are not the specific issues identified by the DRA. Clearly, Congress expects more focus and action on the DRA-specified items.

Because CMS addresses the issues that were reviewed as part of the 2005 enrollment suspension, we comment on those issues here. First and foremost, the payment refinements that CMS is considering to the inpatient prospective payment system do not address, and actually do very little to mitigate, the underlying concerns about conflict of interest inherent in physician-owned limited service facilities.

While the payment reform discussion is one worth having, it should not be viewed as a solution to the broader issue of physician ownership and self-referral of limited service hospitals. For CMS purposes, the solution to this problem lies in the agency's interpretation and enforcement of the whole hospital exception to the physician self-referral law. As stated in our 2005 rulemaking petition on this topic, revisiting the whole hospital exception regulation is the only way to address this problem in a truly meaningful and direct way.

CMS is also considering proposing a more specific definition of "hospital" for Medicare certification purposes. Specifically, CMS is analyzing what is meant by being "primarily engaged" in inpatient services. While this inquiry is challenging, CMS must bring greater clarity to this definition as a means to guard against facilities that seek hospital status for its payment benefits. We continue to believe this can be achieved in a reasonable manner that protects rural hospitals which may have a limited inpatient mix. Unless this definition is clarified by CMS, the public's perception of a hospital will be altered forever by the emergence of physician-owned limited service facilities which fail

to provide a comprehensive mix of services and the levels of care that are expected commonly of a hospital.

III. Significantly More Work Needs to be Done on the DRA-Identified Issues

As stated above, the bulk of the Interim Report provides an update about CMS's work regarding issues that it analyzed during the 2005 administrative suspension. While the Interim Report indicates a need for additional information to fully respond to the DRA issues, CMS indicates that the advisory opinion process related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003's ("MMA") moratorium provided the agency with useful information. However, the Interim Report does not address the DRA issues in the context of the available information and sheds very little light on the agency's current thinking on the issues. For this reason, it is difficult to respond with substantive comments on the Interim Report.

The DRA-identified issues implicate complex financing arrangements that are closely held secrets by those parties that enter into them. The Federation has already provided to you information to help shed light upon examples of these arrangements. Moreover, the Federation supports CMS's decision to seek additional information from hospitals, both limited service and general acute care, for purposes of developing the Plan. We appreciate the opportunity to comment on the survey instrument and were glad to help facilitate participation by general acute care hospitals in the survey process. We are optimistic that this information will greatly assist HHS's efforts to respond to this mandate.

With regard to particular DRA issues under consideration, we express the following views. In keeping with its current focus on transparency, HHS should increase the information required for public disclosure by physician-owned limited service facilities to include the terms of a physician-owner's initial investment in the facility and to report on annual distributions or other returns on their investment. For example, the actual dollar amount of a physician's investment and the income distribution received each year since the year of investment should be disclosed. Physician-owners should also be transparent about, and disclose on, whether their investment is through a debt instrument and, if so, who the guarantors are on that debt instrument. Going forward, physician-owners should be required annually to provide distribution information.

The issues of charity care and Medicaid patient mix are also being considered. The studies performed to date are clear that physician-owned limited service facilities have not served their fair share of these patient groups, with the resulting impact being that full service community hospitals, whether investor-owned or non-profit, are assuming a disproportionate share of the financial burden of these patient groups in those communities.

While our members will continue to serve these patients as part of their mission as community hospital providers, physician-owned limited service hospitals should be required also to provide care to these patient groups, which is consistent with what the

American public expects of its hospitals. To this end, we recommend that HHS consider requiring physician-owners to treat equal numbers of low income, uninsured, and charity patients in their limited service hospitals as they do in their community hospitals.

Finally, the issue of appropriate enforcement is of significant importance. As we indicated in earlier correspondence, the OIG should be enforcing current law to review whether existing physician-owned limited service hospital arrangements comply with the anti-kickback statute.

CMS also should be doing additional enforcement work in this regard. In his recent testimony, Administrator McClellan described the scope of the MMA's moratorium. In his view, the moratorium did not require CMS to refrain from approving new limited service facilities, nor did it prohibit CMS from paying claims for services furnished by physicians who are not owners of the limited service facility. Instead, the moratorium only prohibited CMS from paying claims related to physician-owners.

Based on this statement, we conclude that CMS's policy intent was to pay claims for physician non-owners practicing in limited service facilities, but not for other physician-owners. However, it is unclear how CMS's contractors could have known whether the physician who provided services related to the hospital claim was an owner or not an owner, because the Medicare claim form would not provide necessary information to draw this distinction. Therefore, it seems that CMS failed to put in place the necessary and proper safeguards to effectuate the moratorium's policy intent and to prevent false claims from being filed.

Because we are concerned that appropriate claim edits were not in place to enforce properly the moratorium, CMS should conduct post-payment reviews on all non-grandfathered limited service facilities. The scope of these audits should be to determine where overpayments were made during the moratorium, and CMS should collect any identified overpayments plus interest. Going forward, CMS should not process claims from physician-owned limited service facilities until an appropriate process is established which identifies and differentiates between owning and non-owning physicians.

In summary, at this point in time, there clearly is much work to be done by HHS to properly implement DRA section 5006. We stand ready to provide further explanation of any of the materials that we provided previously to you. While we understand the short time frame for issuing the final Plan, it is critical that the Department work diligently to analyze the investment information and to complete the significant work that is necessary to assess the fraud and abuse implications of these arrangements. To do otherwise would be to ignore the intent of Congress in enacting DRA section 5006.

IV. The Suspension on Enrollment Should Be Extended if CMS Does Not Complete Its Work by the August 8th Deadline

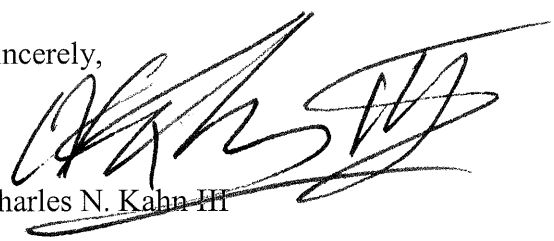
The survey instrument seeks comprehensive data from hospitals. For many, responding to the survey will require a significant time commitment. Once all responses

are submitted, CMS will need substantial time to review thoroughly the hospital responses, analyze the data, and at the very least, confer with the OIG about the findings. We also can envision the need for follow up contacts with responding hospitals to clarify or explain submitted data. Because of the importance of these issues, we urge HHS not to make finishing the report by August 8, 2006 the top priority, as the Interim Report implies. Instead, HHS should take as much time as is necessary to properly review and consider all responses before developing a complete and comprehensive Plan.

CMS should take steps to implement an administrative suspension on the enrollment of new specialty hospitals should HHS decide there are significant issues that continue to need further review and consideration after August 8th. This action would be similar to action taken by CMS in June 2005 and is clearly within the agency's authority. Notably, the Senate Finance Committee expressed this same conclusion during its recent hearing. We encourage HHS to reconsider the contrary position stated by Dr. McClellan in his testimony at that hearing when assessing its authority in this area. The most important purpose for HHS must be to develop policies that address these critical issues in a meaningful way. Time should not constrain the Department's work in this regard; proper policy is the ultimate objective.

Should you have any questions about our letter or need additional assistance, please contact Jeff Micklos of my staff at (202) 624-1521.

Sincerely,



Charles N. Kahn III

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FEDERATION OF AMERICAN HOSPITALS
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Charles N. Kahn III
President

March 31, 2006

The Honorable Michael O. Leavitt
Secretary, Department of Health and Human Services
200 Independence Ave, S.W.
Secretary's Office
Washington, DC 20001

Re: DRA § 5006: Strategic and Implementing Plan for Specialty Hospitals

Dear Secretary Leavitt:

Section 5006 of the Deficit Reduction Act of 2005 ("DRA") requires the Secretary of the Department of Health and Human Services ("HHS") to develop a "strategic and implementing plan" to address physician ownership of "specialty hospitals," as defined under the physician self-referral law (the "Plan"). The Federation of American Hospitals ("FAH") submits to HHS the following ideas and recommendations for how the Plan should address physician ownership of, and self referral to, specialty hospitals.

First and foremost, physician ownership of, and referrals to, specialty hospitals implicate multiple statutes under HHS' authority. For fraud and abuse purposes, significant attention focused upon the whole hospital exception to the physician self referral law ("Stark Law"). However, physician ownership and self referral arrangements also implicate the anti-kickback statute ("AKS") and the civil monetary penalties law ("CMPL").

Moreover, the presence of specialty hospitals in the marketplace highlights a need for modifications to existing Medicare operational policies for other purposes, including Medicare enrollment, cost reporting, and Hospital Conditions of Participation ("CoPs"). Therefore, the Plan required by the DRA should be a comprehensive product developed through the collaboration of the Centers for Medicare & Medicaid Services ("CMS"), which is responsible for enforcing the Stark Law and operational Medicare requirements, and the Office of Inspector General ("OIG"), which is responsible for enforcing the AKS and CMPL.

In our view, the CMS and the OIG each should be involved directly in developing and implementing the Plan to satisfy fully the DRA's mandate. Both the CMS and the OIG have unique expertise on issues that are critical to the operations of physician-owned specialty hospitals. Your leadership is necessary to ensure that each HHS component plays an appropriate role in responding to Congress.

The Plan, like most effective strategic plans, should encompass both short term and long term actions. Necessary steps can be taken in the short term to review enforcement priorities and improve HHS' oversight under current law. However, long range policy development also is critical to a comprehensive solution that adequately addresses specialty hospitals' adverse effect on our nation's health care system.

Some people, including those within HHS, have referred to this statutory directive as requiring a "report" to Congress. The plain language of the statute directs HHS to prepare a "strategic and implementing plan," which we interpret to mean a comprehensive list of regulatory and enforcement initiatives that the Department can and should take under existing statutory authority in addition to any recommendations for possible legislative action.

The DRA contains a list of issues that should be considered when developing the Plan. A report to Congress that only presents HHS' views about the list of DRA's identified issues without related action items does not satisfy the DRA's directive. Simply stated, if Congress desired to receive a report, it would have asked for a report, just like it did under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Clearly, Congress contemplated something more from HHS than a report to address the issues identified by the DRA.

Outlined below are our ideas and suggestions which capture our members' insights into this list of issues.

Bona Fide Investment

Generally, federal fraud and abuse laws are designed to prevent business arrangements that increase patient referrals resulting in financial benefits for the referral source. The laws are very complex and their exceptions have been subject to various interpretations by healthcare lawyers. Given the limited service mix of physician-owned specialty hospitals, the financial impact related to a particular referral source's behavior is greater than in full service community hospitals. This reality warrants a heightened level of regulatory and enforcement scrutiny of physician-owned specialty hospitals.

The DRA's directive to analyze bona fide investments is a critical query into the physician-owned specialty hospital issue. Over the years, FAH has studied various specialty hospitals and common elements are evident: (1) The rates of return on investments by physicians are extraordinary, with physicians making three, four, or five times (if not more) their investments in a short period of time; (2) physician-investors do not invest significant capital into these ventures but instead assume debt investments which are guaranteed by the joint venture hospital partner or specialty hospital sponsor, assuring little personal risk for the physician-investors; (3) the ownership interest is offered to referring physicians at substantially below fair market value (*i.e.* what would be paid on the open market for a low risk, high reward investment); and (4) physician-investors may become and remain investors only if they have and maintain a state medical license and are and remain active members of the specialty hospital's medical staff.

All of these factors taken together raise questions as to whether the physicians have made bona fide investments, which should be an absolute requirement for compliance under fraud and abuse laws. Instead, it seems clear that such arrangements constitute sweetheart deals that result in patient selection and self-referral of the most lucrative lower acuity patients, which is the exact behavior that fraud and abuse statutes were designed to prohibit.

To be a bona fide investment, physician-owners at least should be at risk for the amount of indebtedness they assume when structuring the arrangement. Physician-owners of specialty hospitals should not have their indebtedness guaranteed by the specialty hospital itself or any partner in that venture. Similar requirements apply to entities in the small health care joint venture safe harbor. (*See* 42 C.F.R. § 1001.952(a)(2).)

The Internal Revenue Service has specific rules under which an investor is "at risk" in a particular venture (*See* Internal Revenue Code ["IRC"] § 465.). Specialty hospitals that include a tax exempt hospital-partner already should be complying with these rules. However, similar standards should be considered for all specialty hospital ventures between physicians and other partners as part of the AKS and Stark Law enforcement oversight.

During the last several years and continuing presently, across the country, there has been a proliferation of new physician ancillary service joint ventures in diagnostic imaging services, ambulatory surgery, and cardiology. If HHS fails to seriously address the issue of "bona fide investment" by physicians in specialty hospitals when HHS has been directed expressly to do so by Congress, the industry may interpret such failure as a green light for aggressively structuring these and other ventures on similarly highly favorable terms to physician-investors.

Proportionality of Investment Return

Congress directed HHS to consider proportionality of investment return when developing the Plan. While this term may seem straightforward, it is difficult to reach a precise definition of proportionality of investment return. In many ways, the concept is tied to bona fide investment. One overarching principle should apply: a physician-investor only should be permitted to receive an investment return that reflects the level of ownership for which the physician is "at risk."

Whether the proportionality of a particular investment return is acceptable should depend upon whether the physician-owner has contributed equity or assumed debt as his or her means of investment; and if debt is assumed, whether the physician-investor is a personal guarantor on some or all of the debt. Also, the investment mix of equity and debt for a particular investor should be taken into account. A physician-owner who is not personally at risk for a debt instrument should not be entitled to the same investment return as someone who has contributed cash or other cash-equivalent capital. However, because the investor is a referral source, normal market forces are not likely to ensure this outcome.

HHS should consider whether it is appropriate to impose a cap on the investment return of a physician-owner who has not personally guaranteed completely a debt instrument used to invest in the facility. In our view, physicians who benefit from non-recourse financing receive a disproportionate return on investment. Of course, such favorable investment terms allow specialty hospital sponsors to keep key referral sources happy.

Disclosure of Investment Information

Under current law, the CMS and the OIG have the authority to collect a significant amount of information from entities that wish to participate in federal healthcare programs. This authority allows the CMS and the OIG to request investment information from physician-owned specialty hospitals so there can be a meaningful analysis of the financial arrangement's effect on utilization patterns and patient care. Specialty hospitals studies show that patient selection is prevalent under this business model, and further study must be given to the direct link between financial benefits to referral sources

and the services rendered by these facilities. To this end, existing authority would permit the CMS and the OIG to achieve this purpose easily by requesting greater disclosure of investment information.

Medicaid and Charity Care Patient Mix

Several studies, most notably the Medical Payment Advisory Commission's ("MedPAC") March 2005 Specialty Report to Congress and earlier work by the Government Accountability Office, provide clear and convincing evidence that physician-owned specialty hospitals have a Medicaid/charity care caseload that is substantially less than that of full-service community hospitals. For example, according to MedPAC, physician-owned heart hospitals treat 75 percent fewer Medicaid patients, and orthopedic hospitals treat 95 percent fewer. Arguably, these findings correlate with the observations of both MedPAC and GAO, that physician-owned specialty hospitals are much less likely to operate comprehensive, 24/7 emergency departments, which generally serve as the gateway to health care for low or no-paying Medicaid and uninsured patients, who have the added misfortune of presenting with higher-acuity conditions.

Medicare payment reforms are incapable of addressing this significant, favorable medical and economic selection, which is widely prevalent among physician-owned specialty hospitals, and which severely burdens full-service community hospitals. CMS must develop effective solutions to address this concern, or this patient case-mix disparity between specialty and community hospitals will worsen, especially as specialty hospitals proliferate further.

Appropriate Enforcement

Congress tasked HHS with considering appropriate enforcement to protect against the ills of physician ownership and self referral. In our view, appropriate enforcement should be interpreted broadly. HHS should assess its current administration of federal health care programs and enforcement of related fraud and abuse laws to ensure that the requirements of each applicable statute and policy are being applied appropriately to the emerging physician-owned specialty hospital model.

Recent legislative activity has focused on whether there should be changes to the Stark Law, but HHS should look closely at existing program and fraud and abuse requirements to ascertain specialty hospital compliance. As stated above, there are fraud and abuse statutes beyond the Stark Law that are implicated clearly by specialty hospital arrangements and operations, and these business arrangements should be reviewed accordingly.

Appropriate enforcement also should include HHS' focus upon Medicare operational requirements. Enforcement of program administration rules also is critical to ensure that all physician-owned specialty hospitals are identified properly — that they, in fact, meet the requirements to participate in Medicare as hospitals, and that they are disclosing sufficient information that leads to effective and efficient program administration.

III. Recommended Action Plans

FAH recommends that the CMS and the OIG consider including the following action items in their respective parts of the Plan.

A. Centers for Medicare & Medicaid Services

1. Improved Enforcement and Administrative Oversight by the CMS:

a. ***Modify Medicare Enrollment Form to Identify Physician-Owned Specialty Hospitals.*** CMS must be able to identify physician-owned specialty hospitals for purposes of administering the Medicare program. Thus, such facilities should be required to certify their provider status to the CMS for purposes of Medicare participation. This certification is critical from a compliance perspective to support program administration, and the Medicare enrollment form is a good vehicle to accomplish this goal.

We recommend changing Section 2.A.2.of Form CMS-855A for Medicare enrollment to include a "specialty hospital" selection under the Type of Provider question. The CMS is currently considering modifications to this Medicare enrollment form, and in February 2006, FAH made this same recommendation in that forum to the Office of Management and Budget Desk Officer. This change to Form 855A can be accomplished easily in the next couple of months when the draft form is finalized.

During the MMA's moratorium, the CMS instructed its contractors to follow a three-step process when analyzing enrollment applications from prospective Medicare hospitals. This process includes asking the hospital questions about its anticipated operations and service mix to glean whether it is a "specialty hospital." However, it does not appear that the CMS gave adequate guidance regarding the particular terms used in the contractor's questions, nor was the responding hospital held to a meaningful certification standard regarding its responses such as the certification contained in the Medicare enrollment form.

As a result, the effectiveness of the MMA moratorium has been questioned, resulting in the Senate Finance Committee's current review of the CMS' administration of the moratorium. Going forward, it is important for the CMS to obtain certifications directly from specialty hospitals about their planned operations along with furnishing additional guidance on the applicable terminology.

b. ***Define Parameters for "Hospital" under the Medicare Conditions of Participation ("CoPs").*** The CMS should conclude its ongoing work to define what it means to be "primarily engaged in inpatient services," which is one standard by which a hospital is defined under Medicare CoPs. We recognize the difficulty with developing a "one size fits all" definition based on a bright line standard for percentage of inpatient volume, especially given the impact such a definition can have on rural hospitals. However, the CMS must look for ways to make this standard more meaningful.

c. ***Increase Disclosure of Information for Physician-Owned Specialty Hospitals.*** The Stark Law authorizes the CMS and the OIG to collect significant information regarding a participating entity's ownership, investment, and compensation arrangements. (*See* 42 U.S.C. § 1395nn(f).) Because an overwhelming amount of information could be required under this authority, CMS implemented a sensible regulation that requires entities to provide the required information promptly upon the request of the CMS or the OIG. (*See* 42 C.F.R. § 411.361.) FAH has supported, and continues to support, this regulatory policy.

However, the CMS should consider refining this regulation to require physician-owned specialty hospitals to provide the required information at the time they seek Medicare certification and periodically thereafter. This special treatment is justified due to the unique operating structures of physician-owned specialty hospitals, and the conflict of interest concerns inherent in physician-ownership and self-referral in a limited service context.

Alternatively, the CMS and the OIG should consider using this authority more often to increase their enforcement oversight of physician-owned specialty hospitals. At a minimum, the CMS and the OIG should use this authority to gather information on all physician-owned specialty hospitals to determine whether the facilities are in compliance with current fraud and abuse laws. The implications of the policy research to date and the need for further information about applicable financial arrangements merits strongly the Department's use of this authority more proactively than it has historically.

The CMS and the OIG should collect information such as: (1) the specialty hospital's offering memoranda provided to physician-investors; (2) the projected and/or actual rates of return for physician-investors; (3) the equity contributions from, or debt instruments used by, physician-investors to secure the ownership interest; (4) ownership documents for the real property and building where the specialty hospital is located; and (5) any contracts which require the specialty hospital to provide services "under arrangement" to another hospital in the community.

d. ***Issue Guidance to State Survey Agencies and Medicare Administrative Contractors.*** The CMS should educate state survey agencies and Medicare administrative contractors regarding current enforcement priorities and any policy changes that are adopted. To promote greater compliance, the CMS should identify points of emphasis for those bodies to enforce when conducting their reviews in the marketplace.

2. **New Requirements for Special Certifications by Physician-Owned Specialty Hospitals:**

a. The CMS should impose a requirement upon specialty hospitals to certify that their physician-investors have "bona fide investments" and that their "investment returns are not disproportionate to their investment." The special certifications for specialty hospitals can be located in the certification sections of the Medicare enrollment form and/or the Medicare cost report.

b. Additionally, the CMS should consider revising Form CMS-339, which is the Provider Cost Report Reimbursement Questionnaire, to include questions that gather pertinent information related to the nature of the referring physicians' investments and the returns on those investments. Again, it is important to require specialty hospitals to provide this information affirmatively due to the potential conflict of interest concerns inherent in these facilities. It also is critical that an officer of the specialty hospital certify to the truth, accuracy and completeness of the information in accordance with normal Medicare operating procedures.

3. **Promulgate a Fair Market Value Requirement for the Whole Hospital Exception Regulation:**

a. The whole hospital exception regulation should be modified to include additional standards for determining compliance with the Stark Law. The current exception only requires that a physician's investment be in a hospital itself and not in a subdivision of that hospital. That determination alone does not reach the issue of whether the terms of the physician's investment violates the intent of the Stark Law, the general purpose of which is focused more to guard against inappropriate referrals.

b. We recommend adding a new requirement that the terms of physician investments under the whole hospital exception are fair market value and commercially reasonable to all parties (*i.e.*, co-investors) even if no referrals were made by investing physicians to the specialty hospital. This new standard would bolster the current exception's scope to better satisfy the intent of the Stark Law. The CMS should add other additional standards as it sees fit.

c. Should the CMS be concerned that it lacks the authority to accomplish this objective, we recommend that it forward this objective to Congress as a legislative recommendation.

B. Office of Inspector General

1. **Initiate investigations of specialty hospitals for possible enforcement actions:**

a. In response to Congress's directive to consider "appropriate enforcement," FAH calls for greater enforcement by the OIG of existing federal fraud and abuse laws implicated by physician-owned specialty hospital arrangements.

b. Meaningful targets for investigation are physician-owned specialty hospitals that are developed by transferring / relocating an existing specialty business or revenue stream from a community provider to the specialty hospital.

c. The OIG should investigate whether the arrangements violate both the AKS and/or CMPL.

d. Important factual issues to consider include:

i. Whether physician-owners are "at risk" for some or all of their investments, including whether their investments are guaranteed by the specialty hospital itself or a joint venture partner in the specialty hospital.

ii. Whether the assets contributed by a community hospital that partners with physician-investors to form a specialty hospital are valued at or below fair market value.[1]

[1] For community hospital venture partners that operate as tax-exempt entities, valuing a charitable asset contribution at less than fair market value raises concerns under the Internal Revenue Code. Notably, the Internal Revenue Services' General Counsel has found that a specialty hospital venture that is developed through the sale of an existing service line by a tax-exempt hospital to the specialty hospital raises similar tax and kickback concerns. (*See, e.g.*, IRS General Counsel Memorandum 39,862.)

iii. Whether there are other financial relationships between a specialty hospital and an affiliated acute care hospital that raise compliance concerns. In certain business models, an acute care hospital that is a part-owner of a specialty hospital in combination with physician-owners may send its registered Medicaid and uninsured patients to the specialty hospital joint venture for "under arrangement" services. Physician-owners are paid negotiated fees for these services that are greater than the reimbursement rates that would be charged if the selected patients were registered directly as the specialty hospital's patients. As a result, the physician-investors are protected financially from having to serve patients with less desirable payment sources.

2. **Issue a Special Fraud Alert Outlining Concerns with Specialty Hospital Financial Arrangements:**

a. The OIG should issue a special fraud alert that outlines specific compliance concerns raised by physician ownership and self referral in the context of specialty hospitals that operate as "focused factories" for particular service types.

b. Over the years, the OIG has issued various fraud alerts and bulletins expressing concerns with similar joint venture and other financial relationships between hospitals and physicians. Despite their guidance, these advisories have done little to curb the growth of physician-owned specialty hospitals that often use aggressive financing arrangements to protect their physician-investors.

c. FAH recently made this recommendation to the OIG in response to the annual solicitation of new special fraud alerts and safe harbors. We outline issues in Exhibit A that the OIG should consider including when drafting a fraud alert. We stand ready to discuss this issue with OIG to further explain our thinking.

3. **Designate Audit and Enforcement Activities in Fiscal Year 2007 OIG Work Plan:**

a. Various research organizations have studied different aspects of physician-owned specialty hospitals and have produced a body of data that provides many insights into the policy impact of these facilities.

b. The current body of data lacks information important to understanding the financial arrangements and investment return structures that physician-owned specialty hospitals use currently with their physicians. This type of information is important to understand fully the objectives and outcomes of this business model and its implications under governing fraud and abuse laws.

c. The OIG should implement Work Plan activities to learn more about the impact of physician-owned specialty hospitals from a fraud and abuse perspective, with a particular focus upon how their financial arrangements may impact medical decision making regarding patient care.

4. **Promulgate a Regulatory Safe Harbor that Applies Solely to Physician-Owned Specialty Hospitals:**

a. Beyond the foregoing short term objectives, the OIG should undertake notice and comment rulemaking to promulgate a safe harbor specific to physician-owned specialty hospitals.

b. Specialty hospitals often conclude that they fall in between the small entity joint venture safe harbor and the ambulatory surgical center safe harbor and, as a result, do not attempt to meet either safe harbor.

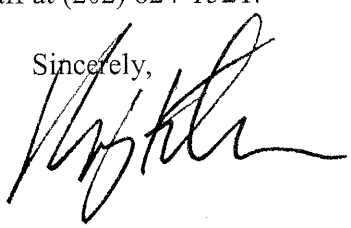
c. Because non-compliance with a safe harbor does not make an arrangement illegal *per se*, many physician-owned specialty hospitals ignore or discount significantly other compliance risks once the Stark Law's whole hospital exception is satisfied.

d. A safe harbor specific to physician-owned specialty hospitals will allow the OIG to speak directly to the unique nature of physician-owned specialty hospitals and identify the protections it views as necessary for these facilities to avoid non-compliance.

e. FAH recently made this recommendation in a letter response to the OIG's annual solicitation of new special fraud alerts and safe harbors. We stand ready to discuss this issue with the OIG to further explain our thinking.

We welcome the opportunity to work with you, your staff, the CMS, and the OIG as HHS implements DRA § 5006. If you have any question about our comments, or would like further information, please contact Jeff Micklos of my staff at (202) 624-1521.

Sincerely,



cc: Senator Charles Grassley (R-IA), Chairman, Senate Finance Committee
Senator Max Baucus (D-MT), Ranking Member, Senate Finance Committee
Representative William Thomas (R-CA), Chairman, House Ways and Means Committee
Representative Charles Rangel (D-NY), Ranking Member, House Ways and Means Committee
Representative Joe Barton (R-TX), Chairman, House Energy and Commerce Committee
Representative John Dingell (D-MI), Ranking Member, House Energy and Commerce Committee
The Honorable Alex Azar, Deputy Secretary, HHS
The Honorable Mark McClellan, CMS Administrator
The Honorable Daniel Levinson, Inspector General, HHS
Donald Romano, CMS

EXHIBIT A

ISSUES FOR A SPECIAL FRAUD ALERT ON SPECIALTY HOSPITALS

A special fraud alert should begin by explaining the inherent conflicts of interest created by physician ownership of so-called specialty hospitals, including the concerns that these conflicts of interest raise regarding undue influence on medical judgment, impact on patient choice, and the adverse affect on competition.

Of special concern under the anti-kickback statute is:

(1) selecting potential investors based on their ability to refer and admit patients to the hospital (and requiring them to remain in a position to refer to retain their investment interest);

(2) permitting these physicians favorable investment terms compared to other investors;

(3) allowing them to acquire their interests at less than fair market value; and,

(4) having related parties underwrite most of the start-up costs through loans or guarantees, as well as offering other "sweetheart" terms, such as sales of items or services at less than fair market value to the facility.

In addition, significant anti-kickback statute concerns are raised when physician investors make nominal capital contributions in exchange for their investments and/or receive disproportionately large returns on their investment compared to what comparable investments (in terms of size, risk and type) typically would yield in arms-length transactions.

Suspect factors also include so-called specialty hospitals where the physician investors:

(1) account for the overwhelming majority of referrals and admissions at the facility,

(2) tend to refer Medicaid, lower paying and sicker patients to a different hospital, and healthier or more lucrative patients to the facility they invest in, and

(3) choose less expensive drugs and supplies, or order fewer expensive services than they would for comparable patients that they refer to other facilities.

In addition to the anti-kickback statute concerns, the OIG could add that it also is concerned about the incentive to underutilize, the potential discrimination against Medicaid patients, and to note that when tax-exempt entities are involved in these transactions, additional concerns apply to the tax-exempt entity.