AdvaMed
Advanced Medical Technology Association

AdvaMed Meeting at
OMB
Thursday, September 25, 2008
11:30 p.m. – 12:00 p.m., ET
Agenda

I. Introductions

II. Improving Health Care Quality

A. Advances in Medical Technology

B. Public-Private Partnership

C. Gainsharing Arrangements

III. Discussion

IV. Conclusion

Comparison of Gainsharing Demonstrations
August 2008

	MMA 646 Demonstration	DRA 5007 Demonstration	ACE Demonstration
Name	Medicare Health Care Quality Demonstration (MHCQ), also known as Physician-Hospital Collaboration	Medicare Hospital Gainsharing Demo	Acute Care Episode Demo (authority under MMA 646)
Purpose	Test gainsharing	Test gainsharing	Test competitive bidding for bundled hospital and physician payments for inpatient stay, *may* test gainsharing
Timing	3-year project: beginning 2007	3-year project: Jan 2007 – Dec 2009	3-year project: Jan 2009 – Dec 2011
Geographic location	Nationwide	Nationwide	4 states: Texas, Oklahoma, New Mexico, Colorado
Applications due	January 9, 2007	Originally November 17, 2006. Reopened and extended until September 4, 2007 for rural hospitals only	August 15, 2008
Number of projects	No more than 72 hospitals.	6 hospitals, 2 must be rural	15-20 sites. A site may include multiple hospitals within a single physician hospital organization. Limited to 1 site per MSA in year 1
Episode of care	Inpatient stay through long-term follow-up (long-term not specified)	Inpatient stay and up to 30 days following discharge	Inpatient stay for 28 cardiovascular and 9 orthopedic surgical procedures. May expand to post-acute care services after year 1
Status	Not yet begun	Not yet begun	Not yet begun

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August 28, 2008

Via Electronic Mail

Kerry Weems, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (CMS-1403-P)

Dear Mr. Weems:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (CMS-1403-P, *Federal Register*, Vol. 73, No. 130, Monday, July 7, 2008, p. 38502). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed supports the establishment of payment rates under the physician fee schedule that are adequate and ensure access to advanced medical technologies by Medicare beneficiaries. We appreciate the considerable effort you and your staff have put into the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others. We will comment on the following issues raised in the proposed 2009 PFS

rule:

I. Physician Self-Referral and Anti-Markup
II. Physician Quality Reporting Initiative
III. Resource-based PE RVUs: Multiple Procedure Payment Reduction (MPPR) for Diagnostic Imaging
IV. Medicare Telehealth Services
V. Independent Diagnostic Testing Facilities (IDTFs)
VI. Potentially Misvalued Services Under the PFS

PROVISIONS

I. Physician Self-Referral and Anti-Markup

A. *Physician Self-Referral*

i. Exception for Incentive Payment and Shared Savings Programs (Proposed § 411.357(x))

AdvaMed strongly supports initiatives to increase the quality of patient care. AdvaMed's commitment to quality improvements includes membership in the National Quality Forum (NQF). In addition, AdvaMed is a very active participant in the AQA, the Hospital Quality Alliance, and other organizations operating in this arena.

AdvaMed is concerned about the short-term and long-term negative impact on patient access and freedom of choice that the proposed exception for incentive payment and shared savings programs will have if CMS chooses to implement it in the final rule. The proposed exception would fundamentally change the physician-patient relationship by permitting hospitals to provide a financial reward to physicians for limiting choices in items and services for Medicare beneficiaries. AdvaMed supports and encourages hospitals and physicians in their efforts to improve quality without limiting patient access and freedom of choice. However, as drafted, the proposed exception would allow arrangements containing financial incentives that could induce physicians to reduce or limit items or services provided to Medicare beneficiaries.

In the comments below, AdvaMed makes the following recommendations:

First, rather than taking the risk of hindering patient care, AdvaMed recommends that CMS complete the Congressionally-mandated CMS gainsharing demonstration and the two additional announced CMS gainsharing demonstration projects before considering a physician self-referral law exception that would allow shared savings or incentive payment arrangements nationwide.

Second, at a minimum, certain fundamental concerns must be considered to protect patient care.

1. Proposed Physician Self-Referral Law Exception Is Premature

The proposed exception to the physician self-referral law would capture two types of arrangements: (i) "shared savings" arrangements; and (ii) "incentive payment" arrangements. These terms are used throughout the proposed rule preamble and in the proposed regulation text. To ensure that AdvaMed's comments are clear, we will use these terms as follows.

CMS refers to arrangements that are typically termed "gainsharing" arrangements as "shared savings" arrangements. CMS states that these arrangements "seek to align physician economic incentives with those of hospitals by offering physicians a share of the hospitals' variable cost savings attributable to the physicians' efforts in controlling the costs of providing patient care." 73 Fed. Reg. 38549. In this letter, the terms "gainsharing" and "shared savings" are used interchangeably.

As proposed, CMS would permit two types of "incentive payment" programs. The first type would be in conjunction with an implemented pay-for-performance (P4P) program. A P4P program would be sponsored by Medicare *if* Congress provides authority to implement a P4P program.[1] A second type of incentive payment program would be done completely independent of an implemented P4P program, and the full scope of arrangements that could potentially be developed is not clear. In the proposed rule preamble, CMS notes potential hospital interest in obtaining physician collaboration to meet performance objectives. In this letter, the term "incentive payment" program or arrangement refers to any program in which a hospital pays a physician or physicians to achieve specified performance objectives. The term "pay-for-performance" or "P4P" programs refers only to programs that vary third party payments to hospitals in recognition of variations in performance.

CMS describes its own P4P initiatives to support quality improvement, but it is important to note that CMS has not yet undertaken a national scale P4P program. To date, it has nationally implemented *pay-for-reporting* programs and has been operating two *P4P demonstration* programs. CMS explains that incentive payment programs employ "quality standards" (also known as "quality measures") to determine whether providers are offering high quality care. However, CMS points out that depending on how the programs are structured (including the ability to accurately measure quality), incentive payment programs may "pose a high risk of program or patient abuse." *See id.*

a. Shared Savings (or "Gainsharing") Arrangements

AdvaMed believes that the proposed physician self-referral law exception for shared savings or "gainsharing" arrangements should not be included in the final regulation for several reasons that may be categorized as follows:

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1 Also known as hospital value-based purchasing.

- **Patient Care Compromised--** Gainsharing arrangements set up a major shift in incentives that have significant and potentially negative ramifications for short-term and long-term patient care;

- **Start, Complete, and Evaluate Congressionally Mandated Gainsharing Demonstration and the Two Other Announced CMS Demonstrations Before Considering a Nationwide Program--**CMS should begin, complete and evaluate its three gainsharing demonstration projects before creating any exception to the law that would permit gainsharing arrangements nationwide, in order to ensure that any short-term and long-term patient impacts are understood and adequately addressed through safeguards; and

- **Legal Concerns/Questions--**There are serious legal questions regarding CMS's ability to create an exception to the physician self-referral law for gainsharing.

AdvaMed elaborates on these three points below.

Patient Care Compromised. AdvaMed is concerned that shared savings (or "gainsharing") arrangements put patient care at risk by fundamentally changing the physician-patient relationship without adequate analysis and understanding of the short-term and long-term impact on patient care.

First, it is well-established that individuals respond to incentives. An offer of payment to physicians based on a percentage of hospital cost savings will create a clear motivation to generate those cost savings. If the arrangement is structured to generate those cost savings through reductions or limitations in patient care items or services, those reductions or limitations put necessary patient care at risk. Although the proposed exception envisions that "patient care quality measures" and "independent medical review" would serve to prevent adverse effect or diminution in quality of patient care, neither of these elements would truly safeguard patient care quality.

Second, the proposed changes would allow a wide range of cost cutting initiatives without regard to the impact on short-term and long-term patient care. The patient care quality measures in the proposed regulation are simply inadequate to ensure quality for the full spectrum of cost cutting initiatives that the exception would permit. These patient quality measures, which are intended to serve as a check on quality, are limited only to those in the CMS Specification Manual for National Hospital Quality Measures; however, in the regulation, the allowable cost savings measures are not limited to that set of quality measures. In fact, cost savings measures could satisfy the proposed exception's requirements and be completely unrelated to the CMS manual's quality measures. Cost savings measures would only need to "use an objective methodology, [be] supported by credible medical evidence, and [be] individually tracked," and be "reasonably related to the hospitals' practices and patient population." 73 Fed. Reg. 38605 (proposed §

411.357(x)(2)). These requirements are vague and could encompass a wide range of diverse cost cutting initiatives that include blocking access to necessary items and services. As proposed, these cost saving measures would not be vetted through an objective, scientific process (such as peer review) or public notice and comment. Proposed requirements that the measures be "monitored throughout the term of the arrangement to protect against inappropriate reductions or limitations in patient care services," did not specify who would perform this monitoring or the episode under consideration. *See id.* A party to the arrangement who stands to gain financially from reductions or limitations in patient care services clearly would not be able to objectively monitor or evaluate whether those reductions or limitations in patient care were "inappropriate" or not.

Third, the proposed exception requires "independent medical review," but that review would be performed by a consultant selected and hired by the hospital. *See* 73 Fed. Reg. 38605 (proposed § 411.357(x)(5)). In the proposed rule, CMS goes to great lengths to make the point that it is concerned that its proposed exception process not negatively impact patient quality. Yet, the protection offered against this potential outcome is woefully inadequate. This relationship between the consultant and the hospital would color the assessment of whether patient care would be, or has been, adversely affected. Moreover, even if one could theoretically find an objective, independent medical reviewer, review by this individual would only be required prior to the start of the program and annually thereafter.

Fourth, as proposed patient access to the full array of treatment options is not assured. Although the proposed exception contains several provisions related to the *physician's* access to the same selection of items, supplies or devices as was available prior to commencement of the program, it is important to note that that the *patient's* access to these items is not guaranteed. The proposed exception does not require a physician to explain and describe all potential treatment or care options for the patient.

Fifth, patient notification provisions are inadequate. The exception requires only patient notification of the physician's participation in the program, patient disclosure that the physician receives payment for meeting targets, and patient receipt of a "reasonable" description of the performance measures. *See* 73 Fed. Reg. 38605 (proposed § 411.357(x)(7)). However, this notice is likely to be ineffective to fully apprise the patient of possible adverse effects on his or her care resulting from limitations on the items or services available.

Sixth, as proposed, patient access to new technologies in the future could be compromised. While the hospitals may not limit the availability of new technology subject to certain requirements, the hospital can offer physicians payment based on the cost savings that would result from the use of older and potentially less effective technology. This offer of payment is powerful and is likely to skew the physicians' incentives to offer new technology if it is more expensive than the older technology.

Moreover, the proposed exception conditions the availability of new technology on the

requirement that it be "linked through objective evidence to improved outcomes" and "[m]eets the same Federal regulatory standards as technology available under the incentive payment or shared savings program." 73 Fed. Reg. at 38605 (proposed (x)(6)(iii)). These requirements hinder patient access to newer technologies that may be particularly "cutting edge." For example, a physician may be incentivized in a shared savings program to use a technology that is FDA approved, but his or her patient has a condition that would be optimally treated using a new technology that is being studied in a Medicare-covered IDE Category B clinical trial. This new technology is technically not yet FDA approved, but is Medicare covered. Would the proposed exception allow the hospital to limit the patient's access to the new technology in the clinical trial, or otherwise prohibit the physician from offering this new technology as an option? This issue highlights the potentially serious and threatening ramifications the proposed new technology subsection of the proposed exception may have for patients with rare conditions. This requirement clearly has a high risk for patient abuse.

In sum, there is a high risk of significant negative short-term and long-term impacts on patient care that results when a hospital offers remuneration to induce a physician to reduce or limit beneficiary care. While AdvaMed supports efforts to improve the quality of care Medicare beneficiaries receive, AdvaMed strongly believes that a physician self-referral law exception for gainsharing poses significant risks of patient abuse because hospital payments to physicians raise the risk of skewing physician incentives and patient care is likely to suffer as a result.

Start, Complete, and Evaluate the Congressionally-Mandated Gainsharing Demonstration and the Two Other Announced Demonstrations Before Considering a Sweeping Nationwide Program. Changes to the current prohibition in the physician self-referral law to fundamentally change the physician-patient relationship should await the results of the three major demonstrations that CMS has announced, but not yet evaluated as well as the other gainsharing demonstrations CMS is currently conducting. The following demonstrations have been announced but have neither been implemented nor evaluated:

- MMA -- The Physician-Hospital Collaboration demonstration was authorized under Section 646 of the Medicare Modernization Act (MMA). It was designed to test gainsharing models across systems of care for episodes consisting of an inpatient stay through long-term follow-up. No more than 72 hospitals across all projects may be included in the demonstration. According to the CMS website, payments must be linked to improved quality and efficiency. Applications were due January 1, 2007. CMS expected to begin the 3-year demonstration in 2007, but it has not yet begun.

- DRA -- The Deficit Reduction Act (DRA) 5007 Medicare Hospital Gainsharing demonstration was designed to test gainsharing arrangements by examining hospital stays and short term follow-up, up to 30 days after discharge. It is limited

to 6 projects, each including one hospital and 2 must be rural. According to the CMS website, payments to physicians must be linked to improved quality, efficiency, operational and financial performance. Applications were originally due by November 17, 2006, but the process was reopened and extended until September 4, 2007 for rural hospitals only. This 3-year demonstration was expected to begin January 1, 2007. It has not yet begun.

- ACE -- The Acute Care Episode (ACE) demonstration was designed to test competitive bidding for bundled hospital and physician payments for an inpatient stay; it may include gainsharing arrangements. After its first year, the demonstration may expand to include post-acute care services. This demonstration focuses on inpatient stays for 9 orthopedic and 28 cardiovascular surgical procedures. It may operate in 15-20 sites and a site may include multiple hospitals within a single physician hospital organization. The demonstration is limited to 4 states: Texas, Oklahoma, Colorado and New Mexico. During its first year, the demonstration will be limited to one site per MSA. According to CMS, the goals of the demonstration goals are to: improve quality; produce savings using market-based mechanisms, improve price and quality transparency for improved decision making, and increase collaboration among providers. Applications to participate in the demonstration were due August 15, 2008. CMS expects to begin this 3-year project in January 2009.

A key focus of these demonstrations is to determine any adverse (short-term and or long-term) effect on patients or the quality of care. To create an exception now – before the most important issue is studied – is premature.

The proposed rule includes a discussion of one recent retrospective study[2] that concluded that certain gainsharing arrangements did not adversely affect patient care. However, the study does not support the broad exception proposed by CMS and should not be the basis for suggesting that gainsharing arrangements are unlikely to negatively impact patient quality of care.[3] Most of the gainsharing arrangements included in the study were reviewed by an independent consultant selected by the HHS Office of the Inspector General prior to implementation to assure that the proposed actions would not have an adverse impact on patient care. Prior to the beginning of any of the gainsharing arrangements, each one was thoroughly reviewed in terms of its likely impact on patient care. As we stated above, instead of a true independent prior review, the CMS proposed exception substitutes review by a consultant selected and hired by the hospital. This relationship between the consultant and the hospital would color the assessment of whether patient care would or has been adversely affected.

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2 Jonathan Ketcham and Michael Furukawa, "Hospital-Physician Gainsharing in Cardiology." Health Affairs, Vol. 27, No. 3 (May/June 2008), 808.

3 Moreover, this study only assessed quality of care during the patient's hospitalization. The study failed to assess the impact on the long-term patient outcomes. For example, it failed to assess the impact on long-term patient outcomes most closely associated with the use of drug-eluting stents compared to bare metal stents (restenosis). This limits the conclusions of the study relevant to patient outcomes.

Advancing this proposal without having even begun the demonstration projects required by Congress for the purpose of understanding the patient care impacts of gainsharing arrangements, and with limited review by an entity hired by the hospital, does not ensure that Medicare beneficiaries will receive appropriate care.

CMS has attempted to safeguard against restricted patient access by requiring that physicians must have access to items or supplies they deem medically necessary for an individual patient's care. Also, a participating hospital would be required to make available under the gainsharing arrangement the same selection of items, supplies, and devices that were available prior to the arrangement. In reality, however, these requirements are unlikely to provide adequate protection against restricted access for patients. At a minimum, the extent to which patient access is restricted under such arrangements should be tested under the required demonstration programs prior to proposing such an expanded exception policy. The potential for restricted patient access that could result from the incentives for hospitals and physicians to steer patients toward the least expensive care should be cause for CMS to withdraw this entire proposal.

AdvaMed strongly encourages CMS to complete the independent evaluation of the announced demonstrations before initiating a nationwide program that would fundamentally change the physician-patient relationship and increase the risk to patients.

Legal Concerns/Questions. AdvaMed has a number of serious legal concerns and questions regarding the proposed exception for shared savings or gainsharing arrangements and has obtained the attached legal opinion that provides a thorough analysis of CMS's proposal (see attached document). It raises a number of significant legal and attendant policy issues that AdvaMed submits as part of this comment letter. In this regard, AdvaMed underscores the following points:

There is simply no reasonable basis on which CMS or the Secretary can conclude that there is no risk of program or patient abuse. Gainsharing arrangements that involve product standardization in particular present a clear and present risk of patient abuse. These arrangements implicate the anti-kickback statute, § 1128B(b) of the Social Security Act (hereinafter the "Act") and the physician self-referral prohibition, § 1877 of the Act. More importantly, the OIG has repeatedly acknowledged that gainsharing arrangements violate the civil money penalty law prohibiting hospitals from offering remuneration to physicians for limiting medical care to their patients, § 1128A(b) of the Act ("CMP"). The CMP is an important protection for Medicare patients.[4] The OIG has stated that "gainsharing arrangements pose a high risk of abuse." OIG, Special Advisory Bulletin:

4 As the House Committee Report that accompanied the CMP provision stated: "[t]he Committee believes that such incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients." H.R. Rep. No. 99-727, at 441 (1986).

Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, July 1999.[5]

Additionally, AdvaMed has received information about a number of gainsharing-like arrangements between hospitals and physicians that are indicative of the legal and patient care risks attendant to gainsharing. The following are two examples:

> (i) hospitals subsidizing physician office leases or administrative support staff expenses in exchange for physician use of the lowest cost device without regard to quality or individual patient needs; and
>
> (ii) hospitals and physicians entering into co-management agreements or other joint venture arrangements that enable profit-sharing, in exchange for physician use of the lowest cost device without regard to quality or individual patient needs.

These arrangements are as legally problematic as traditional gainsharing arrangements and AdvaMed commends CMS for designing the proposed exception so that these arrangements are not protected. We note, however, that these types of arrangements reflect the wide range of ways hospitals and physicians may structure their financial relationships. It demonstrates the difficulty in crafting an exception that would assure transparency and provide sufficient protection to patients, and further supports the importance of CMS taking no action until its demonstration projects are completed and evaluated.

b. Incentive Payment Arrangements

The proposed exception would also protect incentive payment arrangements between hospitals and physicians. AdvaMed believes that the proposed physician self-referral law exception for incentive payment arrangements should not be included in the final regulation for several reasons that are similar to the issues that were summarized above. These include: 1) the shift in incentives that could have significant and potentially negative ramifications for short-term and long-term patient care; 2) the movement from a

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5 The only federal district court to address such arrangements reached the same conclusion. In Robert Wood Johnson University Hospital, Inc v. Tommy Thompson, 2004 WL 3210732 (D.N.J. April 15, 2004),, the court stated:

> [T]he same concerns Congress held in 1986 when the CMP was enacted and the OIG had in 1999 when the OIG Bulletin was released necessarily remain today – "no combination of features could guarantee that such plans would not be subject to abuse." Although the Secretary now "guarantee[s] that the quality of patient care [will] not [be] adversely affected by the financial incentives designed to promote cost-efficiency', such a guarantee was previously found by Congress as untenable.

Importantly, the gainsharing arrangement rejected by the court in Robert Wood Johnson University Hospital, Inc. was significantly more protective of patients than CMS's proposed exception because it was subject to independent monitoring by a consultant selected and paid by CMS.

CMS pay-for-*reporting* program to permitting hospital-based incentive payment programs nationwide without the benefit of having first implementing a national P4P program and the information gathered during the gainsharing demonstrations; and 3) the serious legal questions regarding CMS's ability to create an exception to the physician self-referral law for incentive payment programs.

AdvaMed notes that to date, CMS has implemented pay-for-**reporting** on quality measures for physicians, hospitals, and other providers. The results for some providers are then released on the CMS website for use by patients and their families. CMS has neither implemented hospital nor physician pay-for-**performance** programs on a national scale. To begin protecting incentive payments made by hospitals to physicians under an exception to the physician self-referral law essentially allows hospitals and physicians to initiate their own pay-for-performance programs in a fashion that is not tested or evaluated. The full range of possible arrangements that may be created is not clear and AdvaMed is concerned that these may place patient care at risk.

Furthermore, AdvaMed questions the necessity of arrangements that seek to align incentives under pay-for-performance programs or non-payer-based incentive programs by allowing a hospital to pay physicians to assist the hospital in meeting its performance targets. CMS is capable of harmonizing hospital and physician quality measures to align incentives for hospitals and physicians, without hospitals having to pay physicians separately and directly. The following are a few examples where CMS has already aligned hospital and physician incentives and where further CMS alignment could take place:

- *Heart attack.* Currently there are eight hospital measures and four physician measures related to heart attack. The hospital and physician measures overlap in incentivizing the use of aspirin, ACE inhibitor or Angiotensin Receptor Blocker (ARB) for left ventricular systolic dysfunction (LVSD), use of beta blockers, and counseling on smoking cessation. There are, however, unique measures for hospitals concerning receipt of thrombolytic agent within 30 minutes of arrival and percutaneous coronary intervention (PCI), within 120 minutes.

- *Pneumonia.* Currently there are seven hospital measures and five physician measures related to pneumonia. The hospital and physician measures overlap in relation to pneumonia vaccination status, oxygenation assessment, smoking cessation, appropriate initial antibiotic selection, and flu vaccine status. There are two measures unique to hospitals: timing of initial antibiotic administration and blood culture prior to giving antibiotic.

- *Surgical care.* Currently, there are nine hospital measures and four physician measures related to surgical care. The hospital and physician measures overlap in the timing, selection and discontinuation of prophylactic antibiotic, and in whether recommended venous thromboembolism prophylaxis (VTP) was ordered. There are unique measures for hospitals concerning cardiac surgery patients with

controlled 6 am post-op serum glucose, appropriate hair removal, colorectal surgery patients with immediate post op normothermia, patients on beta blockers who received them during peri-operative period, and whether patients received VTP.

As these examples illustrate, CMS already has programs in place that can align hospital and physician incentives to improve performance and quality of care. One need not create a regulatory exception to the physician self-referral law to align these incentives.

As CMS points out in the preamble to the proposed rule, in any arrangement where a hospital offers remuneration to physicians as an incentive to engage in certain process improvements or to change behavior, these arrangements may run afoul of the physician self-referral law and may potentially fail to satisfy an existing exception to that law. These arrangements may also potentially violate the anti-kickback statute and the CMP. 73 Fed. Reg. at 38549.

Since there are often numerous referral relationships that exist between hospitals and physicians, testing these incentive payment program arrangements through the CMS demonstration projects before going forward with creating any regulatory exception is important. There may be serious, unintended and harmful consequences for patients that arise by allowing hospitals to provide payments to physicians. Ensuring that quality of care can be maintained for patients through careful execution and evaluation of the demonstration projects is key. Without testing and evaluating these arrangements, it is impossible to say for certain whether there are risks of patient or program abuse.

2. Other Fundamental Concerns

As noted above, AdvaMed strongly believes that the proposed new exception to the physician self-referral rules for payments provided to a physician participant in an incentive payment or shared savings program should not be included in the upcoming final rule. Below, we discuss other fundamental concerns regarding the proposal which would need to be considered to ensure the protection of beneficiary and patient care.

First, the patient disclosure and notice requirements of the proposed exception are inadequate and at a minimum would need to be significantly enhanced to ensure that patients are fully informed of the payments being made by the hospital to the patient's physician(s), and the specific choices or limitations in patient care that have been made. Section 411.357(x)(7) of the proposed exception would require "effective prior written notice to patients affected by the incentive payment or shared savings program." The preamble to the proposed rule (but not the regulatory text) further notes that such disclosure should be made prior to admission to the hospital, or, if pre-admission disclosure is not feasible, prior to the procedure or other treatment to which the program is applicable. CMS also says it is considering whether patients should be permitted to opt out of a measure that might otherwise apply to their care and seeks comments regarding whether and how this would work in practice, but this matter is also not addressed in the

regulatory text.

Furthermore, effective prior written notice can only be provided to patients prior to their admission to the hospital, not after admission. At a minimum, such notice would need to be provided at least 10 days prior to the patient's admission to the hospital. This would allow patients the opportunity to consider alternative hospitals and physicians. Once a patient is admitted, and given all the information and disclosures patients now receive upon admission, AdvaMed believes it would be unreasonable to expect that notice given after admission would be "effective" or give Medicare beneficiaries a real choice in the matter.

Accordingly, AdvaMed believes that effective prior written notice cannot be made to patients admitted from a hospital's emergency department. Any exception for incentive payment or shared savings programs would, at a minimum, not be applied to the care of such patients.

Moreover, AdvaMed is concerned that, as proposed, the level of specificity of the notice would likely be inadequate. AdvaMed believes that, at a minimum, the notice would need a level of specificity similar to that provided to beneficiaries in the "Advance Beneficiary Notice of Noncoverage." This specific notice should inform the patient of the specific choices or limitations in care that have been made, and the alternative treatment options that could be made available to the patient. This approach would help assure that affected beneficiaries more fully understand how the incentive payment or shared savings program could affect the care they receive.

If applicable, the disclosure of the physician payments in shared savings or incentive payment arrangements would need to state specifically that a physician's compensation may be influenced by his or her selection of treatment modality or product brand.

Taken together, these changes would better assure that Medicare beneficiaries are fully informed about new incentive payments or shared savings programs that may impact their care.

Second, in the proposed rule, CMS notes that an incentive payment or shared savings program may not limit the discretion of physicians to make medically appropriate decisions for their patients. CMS goes on to state that a hospital must not limit the availability of any specific item, supply or device, including new technology, that is linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient, and must permit individual physicians access to the same selection of items, supplies, and devices that was available prior to the physician's participation in the program. However, CMS says nothing about how this requirement would be enforced and what the penalties would be for failure to meet it. Moreover, there is no mention of how a patient or physician might be able to obtain redress if any requirement of the exception were not complied with, or if patient access to care was denied in bad faith.

AdvaMed believes that, at a minimum, a full appeals process similar to the type of appeal processes required under federal and state managed care laws would need to be provided to protect patients served under incentive payment or shared savings programs. Given that physician incentive payment and shared savings arrangements are tantamount to micro-level managed care arrangements, such an appeals mechanism would be an important element to ensure patient access and protect against inappropriate actions. The appeals process should provide a vehicle for physicians and/or patients to file a complaint regarding a hospital's failure to comply with the critically important requirements of the exception and to provide beneficiaries timely relief in the event that patient access is denied unjustifiably. CMS estimates that relatively few hospitals will avail themselves of the new exception, and thus it should not be terribly costly or difficult to provide an opportunity for affected physicians and patients to file a complaint and receive timely redress.

Third, **AdvaMed is concerned that beneficiaries would not be included in the design, implementation and evaluation of incentive payment or shared savings programs. At a minimum, there should be a requirement that in any of these incentive payment or shared savings programs at least two independent Medicare beneficiaries (one qualifying as a senior beneficiary and another as a disabled beneficiary) should be included in the design of the program prior to its commencement, and in implementation and evaluation at least annually.** Beneficiary representation would serve as a check on the potential short-term and long-term impact on patient care that may be either unforeseen or unintended.

Fourth, in the proposed rule, CMS expresses considerable concern regarding the potential negative consequences of product standardization as a means of generating savings and AdvaMed shares these concerns. In fact, as stated above, in the absence of information from the three CMS gainsharing demonstration projects, AdvaMed believes that it would be premature to try to develop a regulation that attempts to distinguish between arguably benign product standardization from riskier product standardization practices. AdvaMed reiterates its belief that any regulation for incentive payment or shared savings programs should explicitly preclude product standardization as a means for generating savings. In addition, any CMS regulation should preclude any limitations on the use of discretionary items or medical technologies. Not only is it impossible to ensure that quality of care would not be threatened by these limitations, any such limitations would be violations of the civil money penalty provision (§ 1128A(b) of the Act).

Fifth, AdvaMed is concerned that the greater the financial rewards physicians may receive in these programs, the greater the potential for hospital and/or physician decisions that are not in the best interests of Medicare beneficiaries. The proposed regulation does not require that the hospital's payment to the physician be fair market value for the services rendered and set in advance. Allowing a percentage-based compensation approach for these arrangements enables the payments to vary with the volume or value of referrals, enabling physicians to obtain increasing financial rewards based on their referrals to the

hospital.

AdvaMed believes that there should be specific limits on the amount of payment hospitals can make to physicians in gainsharing programs. The proposed rule notes that various options are under consideration including a flat 50 percent limit on the sharing of cost savings, a scaled limits approach under which payments to physicians decrease over the course of the performance measure, and re-basing, under which a program must take into account the progress made to date on a particular measure (that is, progress made on a measure during the first year of a program would be ignored in calculating physician payments in the second year; only further progress on that measure could be rewarded). All of these options, however, are relatively open-ended; in a specific instance, the financial rewards available to an individual physician could become very substantial. It is worthy of note that an analysis of the gainsharing arrangements approved by the Office of Inspector General in advisory opinions issued before June 2008 found that payouts to individual physicians averaged $17,000 per physician and ranged from $0 to $59,000 per physician.[6] These arrangements allowed physicians to share in 50 percent of the cost savings gleaned from gainsharing arrangements, with compensation shared by the physicians on a per capita basis. These dollar figures are remarkably high compared to existing benchmarks that may be found in existing physician self-referral law exceptions. For example, the so-called "de minimis" non-monetary compensation sets a ceiling of $300 in aggregate per year per physician. 42 C.F.R. § 411.357(k). In addition, it is important to note that the not yet implemented or evaluated CMS gainsharing demonstration projects would cap physician payments at 25 percent of the amount that the physicians would normally be paid.

In the absence of a specific requirement that remuneration under an arrangement be fair market value, set in advance, and not determined in a manner that takes into account the volume or value of referrals, AdvaMed believes that any exception should set forth a cap on the percentage savings allowed and a maximum dollar amount that could be paid to an individual physician in any one year in aggregate as a result of his or her participation in incentive payment or shared savings programs. Given the approaches taken in the OIG and CMS announced demonstration gainsharing arrangements – allowing up to 50 percent of cost savings to be paid to physicians in the OIG gainsharing advisory opinions, and no more than 25 percent of the amount that the physicians would normally be paid – AdvaMed recommends that CMS cap the percentage of cost savings *well below* these government limits. Further, until the results of the demonstrations have been evaluated, AdvaMed recommends that the compensation for each physician be held to a modest and prudent specific dollar amount maximum for each physician in aggregate. The objective of these limitations would be to reward physicians adequately for their involvement in the design and implementation of an incentive payment or shared savings program while minimizing the potential for payments to inappropriately influence physician behavior and judgment.

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6 Ketcham and Furukawa, "Hospital-Physician Gainsharing in Cardiology." Health Affairs, Vol. 27, No. 3 (May/June 2008), at 804.

Sixth, AdvaMed is concerned that the proposed rule's requirements do not provide clear, bright-line rules. Proposed section 411.357(x)(16) of the proposed rule specifies that any incentive payment or shared savings program must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. As noted in the attached legal opinion, AdvaMed believes that this requirement would be almost impossible to meet given that the anti-kickback statute is an intent-based statute. At a minimum, CMS would need to provide a clear rule specifying that a hospital be required to obtain an OIG advisory opinion stating that OIG would not impose sanctions on its incentive payment or shared savings program.[7]

In addition, the regulatory text would need to state more clearly that any arrangement must meet all Federal and State laws, not just those governing "billing and claims submission." For example, the current language might be viewed as implying that the arrangement need not meet all elements of the civil money penalty law (specifically § 1128A(b) of the Act), which prohibits payment to a physician as an inducement to reduce or limit items or services provided to Medicare beneficiaries. Further, the current language might be viewed as implying that the arrangement need not meet other pertinent Federal and State laws not directly related to billing and claims submission, such as Federal antitrust laws, and those which prohibit private benefit or inurement by tax-exempt hospitals to physicians. The existing regulatory language would need either to refer specifically to other relevant laws, not just the anti-kickback statute, or simply require compliance with all applicable Federal and State laws, not just those governing billing and claims submission.

Seventh, AdvaMed is concerned that CMS inadequately addresses the following quality issues. The extremely narrow and limited scope of the performance measures that are available as a check on quality of care (specifically, those in CMS's Specification Manual for National Hospital Quality Measures), coupled with the potentially broad array of potential cost savings initiatives that one could potentially build into a gainsharing arrangement is disconcerting. The exception appears to allow arrangements where cost saving actions could be numerous, diverse, and completely unrelated to the quality measures used in the arrangements. AdvaMed believes that performance measures must be specific and directly related to the arrangement. For example, if the arrangement involves care in the Intensive Care Unit (ICU), the performance measures must address quality and actions taken in the ICU. Measures of hospital-wide patient satisfaction, for example, would not be sufficiently targeted to address the needs of an arrangement involving care in an ICU.

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7 It is important to note that even if CMS issues a final regulatory exception to the physician self-referral law for incentive payments and/or shared savings arrangements, such arrangements would still be subject to the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the civil money penalty statute, 42 U.S.C. § 1320a-7a(b). These provisions of law are under the authority of the HHS Office of Inspector General, not CMS.

AdvaMed would urge CMS, at a minimum, to require that all performance measures in shared savings or incentive payment programs be endorsed by the National Quality Forum (NQF) or another organization that meets the important definitions of transparency and representativeness found in the definition of a voluntary consensus standards body according to the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular No. A-119 (OMB A-119). In addition, any incentive payment arrangement should use a federal notice and comment rulemaking process to propose measures for inclusion in a pay for reporting programs.

Aside from these patient care quality measures, quality of care would only be checked through "independent medical review." As stated above, AdvaMed is concerned that this "independent medical review" will not truly be independent or objective because it will be paid for by the parties to the shared savings or gainsharing program or arrangement.

Furthermore, CMS should make clear in its preamble to the final rule that while quality *improvement* may be the objective in "incentive payment" arrangements, the goal in many "shared savings" or gainsharing arrangements is achieving cost savings through various means while only *maintaining quality*. This was not made clear from the description in CMS's preamble to the proposed rule.

Eighth, AdvaMed has concerns regarding the manner in which physician payments are calculated. The proposed regulation requires the use of baseline data and target levels based on previous experience. The regulations should make clear that these data must be valid, pertain to the same severity-adjusted case mix, and cover a sufficient period of time, or episode, that captures all costs and benefits of care.

Moreover, CMS should require a participating hospital to document the source of any cost savings, using valid methodologies. This would help to provide insight into how the program is working and, if items or services are reduced, what those reduced or limited items or services are. To allow full transparency into the impacts of the programs, CMS should require that a detailed accounting of the savings from gainsharing be made publicly available. This would also help to ensure that any incentive payments to doctors are related to the program and not inappropriate incentive payments beyond those related to the program.

Finally, the proposed rule leaves open the possibility that many of the proposed exception-related safeguards and conditions could be substantially changed in any final rule, perhaps significantly relaxed or even eliminated altogether. In light of this, AdvaMed wishes to take this opportunity to emphasize the importance of the following features discussed in the proposed rule.

- Any payments to physicians should only be made on a per-capita basis since this would minimize the possibility of providing any single physician with excessive financial gains.

- Consistent with the OIG advisory opinion approach, payments should not include any amount that takes into account procedure/service volume greater than the one provided by the participating physician during the period of the same length immediately preceding the start of the program since this would reduce the likelihood that hospitals would adopt an incentive payment and/or shared savings program mainly to encourage more physician referrals to their facilities.

- Payments should not be protected under an exception if they were made for actions that resulted in performance below (or above) a predetermined target (for example, for reducing the use of a supply below some target minimum level of utilization).

- To prevent participating physicians that may have the admission privileges in several hospitals from 'steering' their patients inappropriately, the case severity, and the ages and payers of the patient population treated by each participating physician must be monitored using generally-accepted standards. In addition, a physician should be terminated from the incentive payment or shared savings program if there are significant changes from the hospital's historical measures. If there are significant changes in the aggregate across participating physicians, the program must be terminated.

While AdvaMed has made a number of specific proposals above, these do not mean to imply that the final rule should include a specific exception to the physician self-referral rules relating to incentive payment and/or shared savings programs. Moreover, AdvaMed does not believe that inclusion of these specific proposals in the final rule would be sufficient to satisfy our concerns about finalizing the creation of an exception. Instead, given the concerns expressed regarding the impact on patients, the attached legal opinion regarding the high risk of patient abuse that serves as an insurmountable hurdle toward creation of a regulatory exception and the insufficiency of notice provided by the proposed rule, AdvaMed recommends that CMS not finalize the exception to the physician self-referral law pending the results of the independent evaluation of the two Congressionally mandated demonstrations and the CMS demonstration described above. Depending on the results of that evaluation, AdvaMed's comments and those submitted by other stakeholders may be considered to develop a revised proposal, and provide the public a fresh opportunity to comment on a revised proposal and the data upon which it is based. Such an approach has a greater chance of adequately protecting the interests of seniors and disabled Medicare beneficiaries.

B. Anti-markup

In the CY 2008 PFS final rule with comment period, CMS stated that it would apply anti-markup provisions to the technical component (TC) of certain diagnostic tests if the TC was purchased outright or the TC was not performed in the billing physician's office. Subsequent to issuance of the final rule, CMS delayed applicability of the revised anti-markup provision until January 2009 except for anatomic pathology diagnostic testing services or for any purchased diagnostic test.

AdvaMed supports adoption of the clarification to the definition of outside supplier as used in the anti-markup provisions. CMS would clarify that a TC of a diagnostic test is not purchased from an outside supplier if the TC is both conducted and supervised in the office of the billing physician or other supplier, and the supervising physician is an employee or independent contractor of the billing physician or other supplier. CMS declares that the performance of the TC includes both the technician's work in conducting the test and the physician's supervision of the technician. CMS also notes that for anti-markup purposes only, the performing supplier with respect to the TC would be the physician who supervised the TC. AdvaMed presumes this would be true even when the technician is not an employee of the billing physician or physician organization, but we believe the final rule should make this clear.

II. Physician Quality Reporting Initiative: PQRI

CMS began its Physician Quality Reporting Initiative (PQRI) in 2007, with physicians beginning to report on quality in July for a bonus payment in 2008. CMS proposes to continue the program in 2009, MIPAA extends this program through 2010. We appreciate the efforts of CMS to implement the PQRI. We urge CMS to include in the PQRI only measures that have been endorsed by the National Quality Forum (NQF) or another organization that meets the important definitions of transparency and representativeness found in the definition of a voluntary consensus standards body according to the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular No. A-119 (OMB A-119). We agree with CMS that the AQA is not a voluntary consensus standards body according to this definition.

AdvaMed continues to have concerns about the transparency of the measure development process. The proposed rule demonstrates the many routes that physician quality measures may take during the measure development process (e.g., the National Committee for Quality Assurance, the American Medical Association Physician Consortium for Performance Improvement, the Society of Thoracic Surgeons, Quality Insights of Pennsylvania and others). This array of sources for new measures makes it very difficult for anyone trying to stay informed about the development and review of new measures.

Therefore, we again encourage CMS to consider ways to ensure that this critical process is fully transparent. In that regard, we would encourage the agency to consider establishing on its web site an updated listing of measures under formal consideration by the various organizations. CMS would be the logical collection point for this information, and it could be a requirement for inclusion in the PQRI that each organization make this information available to CMS for posting on its site. AdvaMed would also encourage CMS to continue managing the PQRI process in a manner that allows input from the public, especially patient advocacy groups and device manufacturers.

To inform the public, we recommend that CMS provide detailed information about all proposed measures, including:

- A complete definition of the measure, including the numerator and

denominator, if appropriate;
- A complete definition of any proposed risk adjustment methodology;
- Status of NQF endorsement;
- Status of endorsement by other organizations such as the Hospital Quality Alliance and AQA;
- Whether the measure has been field tested, by which organizations, and with what results; and
- Citations for related evidence-based practice guidelines.

Reporting PQRI Measures

AdvaMed supports CMS efforts to expand reporting of data for PQRI via registries and electronic medical records (EMR). We urge CMS to allow EMR submission for 2009, and to publish the submission standards as soon as possible to allow vendors and practitioners time to modify their systems. We ask for further clarification of standard-based specifications for EMR submission.

We are concerned that CMS may continue the registry self-nomination process well into 2009. Such a late date for announcement of participation would introduce uncertainty that may limit the usefulness of the registry option, forcing physicians to begin claims-based submission pending designation of an applicable registry. At a minimum, we urge CMS to carry forward designated 2008 registries into 2009 so long as they indicate acceptance of the revised CMS registry requirements and specifications that will be published in November.

We also support CMS decisions about alternate reporting periods, which increase flexibility under PQRI that should enhance usefulness and reporting rates.

AdvaMed supports flexibility in reporting measure groups, including three options using claims-based reporting and three options using registry-based submission. Specifically, we applaud the agency decision to consider as satisfactory the reporting of one measures group for 30 consecutive patients, and especially the flexibility in registry-based reporting of including non-Medicare patients. As the proposed rule indicates, there is benefit to achieving a full picture of the care provided by a health care professional to all patients. We urge CMS to, as it proposes, continue to refine sample sizes based on additional experience and accepted statistical principles.

Proposed 2009 PQRI Quality Measures

AdvaMed appreciates CMS outlining its considerations for identifying proposed 2009 measures including measure functionality, increased scope of services covered by measures, measure support for improved quality and efficiency of care, measures that align with healthcare goals across government healthcare programs, and measures of various aspects of clinical quality. We recognize that CMS does not develop measures, and is constrained to select measures from among those developed and endorsed by others. Nevertheless, we urge CMS to select measures that are most appropriate for seniors and/or

disabled Medicare beneficiaries, represent the highest quality of care, and capture the outcome of treatment.

For 2009, CMS proposes to select from among 175 measures. AdvaMed has the following comments on specific measures:

- *T144 Radiology: Computed Tomography Radiation Dose Reduction*-- AdvaMed opposes inclusion of this measure because it was not recommended for use by the National Quality Forum's (NQF) Steering Committee on Outpatient Imaging Efficiency.
- *T145 Radiology: Exposure Time Reported for Procedures Using Fluoroscopy*-- AdvaMed notes that this measure was recommended for endorsement by the NQF Steering Committee on Outpatient Imaging Efficiency. AdvaMed supports inclusion of this measure in the 2009 PQRI measure set if it receives full endorsement by the NQF and demonstrations as noted above.
  Radiology: Inappropriate Use of "Probably benign" Assessment Category in Mammography Screening-- AdvaMed supports efforts to improve patient management clarity in order to further improve the overall accuracy of screening mammography. AdvaMed notes that this measure was recommended for endorsement by the NQF Steering Committee on Outpatient Imaging Efficiency. AdvaMed supports inclusion of this measure in the 2009 PQRI measure set if it receives full endorsement by the NQF. AdvaMed recommends that CMS consider additional metrics directed at the formation of a CMS "reporting group" to additionally monitor cancer detection and screening recall rates to further ensure more consistent and appropriate use of all BIRADS codes to improve the accuracy of mammography.
- *Nuclear Medicine: Correlation with Existing Imaging Studies for all Patients Undergoing Bone Scintigraphy*-- AdvaMed notes that this measure was recommended for endorsement by the NQF Steering Committee on Outpatient Imaging Efficiency. AdvaMed supports inclusion of this measure in the 2009 PQRI measure set if it receives full endorsement by the NQF.
- *Chronic Wound Care: Use of Compression System in Patient with Venous Ulcers*--AdvaMed supports inclusion of this measure in the 2009 PQRI measure set if it receives full endorsement by the NQF.
- *Chronic Wound Care: Offloading of Diabetic Foot Ulcers*-- AdvaMed supports inclusion of this measure in the 2009 PQRI measure set if it receives full endorsement by the NQF.
- *Back Pain Measures Group*--AdvaMed opposes inclusion of this measures group because it has not received NQF endorsement, among other reasons outlined below.

In its discussion of "measures groups," CMS notes that the measures within a "measures

group" have a particular clinical condition or focus in common, such as diabetes mellitus or chronic kidney disease. The agency explains that measures in a measures group must have a common set of denominator specifications. The agency also notes that this need for a common denominator means that some measures in a measures group may be modified from their original specification as individual measures, to ensure a common denominator for the group. CMS notes that the specifications and instructions for measures groups will be provided separately from the specification and instructions for the individual 2009 PQRI measures.

AdvaMed understands that measure developers carefully consider the specifications of both the numerator and denominator of the measure. We have witnessed lengthy and contentious discussions in the AQA where some stakeholders questioned the measure developer's exclusion of certain patients from the denominator of a measure. Given the intense scrutiny of the denominator's specification, we believe that modifications, however small, change the measure. Therefore, we believe that if CMS modifies a measure's denominator, the measure should be sent back to a consensus-based organization for review and endorsement.

CMS proposes to add a back pain measures group comprising 5 measures. CMS also proposes that these 5 measures could only be reportable as a measures group, not as individual measures. First, AdvaMed notes that only 4 of the 5 measures that CMS proposes for the back pain measures group have consistent specifications for their denominators. The denominator for the first measure, use of imaging studies, is all patients with back pain lasting 6 weeks or less. The denominator for the 4 other measures is all patients with a diagnosis of back pain. If CMS proposes to modify the denominator for any of these 5 measures, it should seek new endorsement by a consensus-based organization.

AdvaMed opposes CMS use of the back pain measures group. When considering low back pain measures, at the request of the measure developer, the NQF decided not to consider endorsement of low back pain measures as a group, and only to consider endorsement of individual measures. While the NQF Steering Committee included a strong suggestion that the measures be used together as a group, NQF members did not vote on this suggestion, and a measures group was not endorsed. The measure developer indicated an interest in submitting a composite measure at a later date based on the individual low back pain measures.[8] Given this history, it is premature for CMS to use this measures group.

Before CMS considers public reporting of physician performance on measures groups, it should describe its method for combining individual measures into a composite measure, such as the weights assigned to individual measures, and provide for public comment on the proposed method. A consensus-based organization needs to endorse the method used

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8 See National Quality Forum, Revised voting draft for *National Voluntary Consensus Standards for Ambulatory Care: Cycle 3,* October 1, 2007, page 2.

to build the composite before CMS uses the measure.

Public Reporting of Physician Quality Data

CMS invites comments on a number of issues relating to the use and disclosure of PQRI data. AdvaMed urges CMS to proceed slowly in public reporting of PQRI data. Unlike the other public reporting programs that CMS operates for hospitals, nursing homes, and home health agencies, which are relatively large organizations, accurate public reporting for physicians may depend on sufficient numbers of patients and the healthcare risks of these patients. We believe that CMS should provide confidential reports to physicians for a sufficient period of time, perhaps several years, to assess the accuracy of the reporting process and results. We note that some measures that have been endorsed by the NQF and AQA, and included in the PQRI, have not undergone comprehensive field testing. This should occur before public reporting.

CMS should involve providers, vendors, patients and employers in the development and evaluation of a valid and reliable public reporting system. A web-based venue makes sense for public reporting, but the reports must be very clear on what the data do and do not show, and the limitations on conclusions that can be drawn from the reported data. CMS should prospectively establish standards by which they and other stakeholders could determine when public reporting makes sense. CMS should also design its website to allow data to be viewed/organized in multiple ways, such as by physician specialty, patient condition, and type of measure (e.g., structure, process, and outcome). CMS might consider reporting PQRI data at the physician group level.

III. Resource-based PE RVUs: Multiple Procedure Payment Reduction (MPPR) for Diagnostic Imaging

CMS proposes to add ten procedures to the list of procedures subject to multiple procedure payment reductions (MPPR). These are codes that have been created since the original list of procedures subject to the MPRR was established. CMS also proposes to remove one procedure with a code that was deleted from the CPT. AdvaMed believes that CMS should study the impact of the MPPR, to ensure that reductions in payments for these services have not created access problems for beneficiaries, prior to extending this reduction to additional procedures. This analysis should also examine any shifts in site of service that may have occurred as beneficiaries may be forced to receive imaging procedures in hospital outpatient departments, as well as changes in beneficiary travel times and costs to procure these services.

IV. Medicare Telehealth Services—Critical Care Services

In the proposed rule CMS does not propose to add critical care services to the list of approved telehealth services. In making this decision, CMS notes significantly greater acuity of critical care patients and says it has no evidence to evaluate whether critical care telehealth services are an adequate substitute for a face-to face encounter. AdvaMed urges CMS to reconsider this decision.

Remote critical care is the direct delivery by a physician(s) of medical care for a critically ill or critically injured patient from an off-site location. Remote critical care is intended to supplement on-site critical care services at times when a critically ill or injured patient requires additional critical care resources beyond those available on-site and is provided according to hospital policy and/or at the request of the patient's attending physician.

We bring to CMS's attention the remote ICU care model, which has been available for eight years and can effectively leverage limited caregiver resources across any geographic or physician shortage region. Several studies suggest that remote ICU care is comparable to on-site care.[9] Additionally, a major healthcare quality organization has created recommendations for the core functionalities of these systems and has found the remote critical care model to be in accordance with their standards.[10]

AdvaMed believes that remote critical care services are comparable to the on-site provision of these services. We are hopeful that CMS will reconsider adding these services to the list of approved telehealth services.

V. Independent Diagnostic Testing Facilities (IDTFs)

In the proposed rule CMS recommends further expansion of quality safeguard programs it previously put in place for independent diagnostic testing facilities (IDTFs). CMS expresses concern about some physician entities furnishing diagnostic tests without the benefit of qualified non-physician personnel and evidence of enrollment tactics which are used to circumvent the application of IDTF performance standards. CMS proposes a requirement that physician or nonphysician organizations that furnish diagnostic testing services, except diagnostic mammography services, must enroll as an IDTF. When applying IDTF standards to physician entities, CMS proposes to eliminate some of the IDTF requirements, including maintaining additional comprehensive liability insurance, signage, and a formal clinic complaint process, due to belief that physician organizations already meet or exceed the standards. Lastly, CMS proposes to require entities that furnish mobile diagnostic services to enroll in Medicare and bill directly for the mobile diagnostic services that they furnish.

Advanced Imaging Diagnostic Services

AdvaMed believes strongly that the concerns expressed in the proposed rule regarding the quality of advanced diagnostic imaging services were addressed in Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275). MIPPA requires that any supplier, including physicians and nonphysician practitioners, that performs the technical component of advanced diagnostic imaging services must be

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9 *See* Angus D, Kelley M, Schmitz R et al.: *Current and projected workforce requirements for care of the critically ill with pulmonary disease: Can we meet the requirements of an aging population?* JAMA, December 6, 2000: 284(21): 2762-2770; *see also* The Critical Care Workforce: A study of the supply and demand for critical care physicians. Report to Congress – Health Resources and Services Administration, May 2006.

10 Leapfrog Group website: http://www.leapfroggroup.org

accredited before receiving Medicare payment for these services. Accreditation applies to medical personnel who are not physicians and who furnish the technical component of advanced imaging services, medical directors and supervising physicians, and diagnostic imaging equipment. Accreditation is required by January 1, 2012. Advanced diagnostic imaging services are defined as diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine, including positron emission tomography (PET). This change in law effectively eliminates the need for CMS regulation to extend IDTF performance standards for advanced diagnostic imaging to physicians and nonphysician practitioners.

MIPPA delineates a detailed plan for designating accrediting organizations and establishing accreditation criteria. We note that one major commercial insurer, UnitedHealthcare, has announced that it will alter the schedule of its own accreditation program so that it more closely parallels the timeline that MIPPA specifies.[11] AdvaMed also notes that in a number of areas, MIPPA would result in requirements more exacting than the IDTF standards that the Proposed Rule would impose.

Under MIPPA, Congress has required accreditation for advanced diagnostic imaging services, and has chosen not to extend requirements to other diagnostic imaging services including x-ray, ultrasound, or fluoroscopy at this time. Providers who use these modalities receive specialty and other medical education training that provides them with the skills needed to safely and effectively operate this equipment. Given clear Congressional intent on accreditation of only advanced imaging modalities, AdvaMed opposes expansion to other modalities.

Should CMS decide to extend the IDTF requirements to physicians and nonphysician practitioners, we agree that modifications to the current standards are appropriate as many of them are less stringent than current requirements. We support the need to properly maintain and insure the operability of the equipment used in IDTFs. However, we believe that some of the other proposals are burdensome and overly broad in scope. For example, variations in current supervision requirements make compliance difficult while delays in site inspection create the need to hire additional staff. In addition, there are other costs associated with assessing regional IDTF requirements and variations for entities under multiple jurisdictions. We encourage CMS to take these variations into account when implementing accreditation criteria under MIPPA.

Non-Imaging Procedures

Physicians and nonphysicians who perform non-imaging diagnostic testing such as electrocardiograms (ECG) should not be included in the requirements to register as IDTFs. A significant number of physicians offices, including those providing primary care, perform these tests to rule out potential cardiac issues. The administrative burden required by registering as an IDTF would significantly limit the number of physicians providing these front-line diagnostic tools, thus potentially limiting patient access and shifting

11 UnitedHealthcare Press Release, August 20, 2008.

services to more costly sites of care.

With regard to other diagnostic testing services AdvaMed has some concerns that the current proposal, as drafted goes beyond the scope of why the IDTF provisions were initially developed. For instance, as written the proposal would require that certain physician-directed services such as home prothrombin time monitoring (codes G0248 and G0249) would require physicians to enroll as IDTFs. This requirement, if imposed, will increase administrative burdens and could hinder patient access to critical therapy.[12]

We urge CMS to be deliberative in making any decisions regarding the types of diagnostic testing services to which the standards should be applied prior to expanding the IDTF requirements to physician and non-physician providers performing diagnostic services. We do not think that cost alone is an adequate barometer of the need for standards but would instead encourage CMS to evaluate each of the technologies to most fairly determine the need to subject it to IDTF standardization requirements. AdvaMed also urges CMS to consider patient access to equipment and services as it considers further regulation.

Mobile Entity Billing Requirements

CMS proposes to require entities furnishing mobile diagnostic services to comply with IDTF standards, enroll in Medicare, and bill directly for the services that they furnish, regardless of where the services are performed. AdvaMed believes that MIPPA requires practitioners that use mobile diagnostic equipment for advanced imaging services to comply with accreditation standards for nonphysician medical personnel, medical directors and supervising physicians, and equipment. Accreditation, as required by law, will ensure that entities furnishing mobile services provide quality services, and eliminate the need for additional regulation of mobile diagnostic services. Therefore, AdvaMed opposes this provision. Moreover, AdvaMed believes that changes to the billing process for mobile entities would further and unnecessarily complicate the billing process.

AdvaMed would urge CMS to exclude from the definition of entities furnishing mobile diagnostic services those entities that lease equipment and provide technicians who conduct diagnostic tests in the office of the billing physician or physician organization, and under the supervision of a physician who shares an office with billing physician or physician organization. This interpretation would be consistent with the proposed CMS clarification to the anti-markup provisions which state that the performing supplier, with respect to the TC of a diagnostic test, is the physician who supervises the TC. Consequently, because the supervising physician shares an office with the billing physician, the TC would be performed by the physician not the mobile entity.

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12 Physicians who provide home anticoagulation monitoring should not be required to separately enroll as Independent Diagnostic Testing Facilities and to comply with IDTF standards. Requiring dual enrollment and compliance with IDTF standards for this home monitoring service will create an unnecessary disincentive to adoption of this new technology.

VI. Potentially Misvalued Services Under the PFS

Review of Services Billed Together and Possibility of Expanding MPPR
AdvaMed urges CMS to postpone its review of services that are often billed together and instead rely on the work that is already being done in this area by the Relative Value Update Committee (RUC). We believe the RUC work in this area will be extremely informative to CMS regarding which services it may consider in the future for the purposes of bundling or multiple services reduction.

We believe that the criteria established by the RUC for services that are typically billed together more appropriately addresses this concern. The RUC recommends that services which are billed together 90 percent of the time on the same day, for the same patient, and for the same indication be considered for some type of payment efficiency policy. CMS's proposed lower thresholds of 60-70 percent could mean that certain high quality procedures that can be provided at a lower cost may be abandoned in favor of more expensive, invasive procedures that are higher risk.

Approaches for Identifying Misvalued Services
While AdvaMed shares CMS concerns about wasteful medical care and spending, we urge CMS to consider the impact of factors including improved patient care and outcomes, underuse and the possibility of data errors when analyzing growth in the volume and costs of care.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by our member companies, as they provide a unique source of information in developing appropriate PFS payment rates. We appreciate the opportunity to submit comments on the proposed 2009 PFS rule, and look forward to working with CMS to address our concerns.

Sincerely,

Ann-Marie Lynch
Executive Vice President

Enclosure

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MEMORANDUM

TO: Christopher White
Teresa Lee

FROM: Dennis M. Barry

DATE: August 26, 2008

PRIVILEGED AND CONFIDENTIAL: SUBJECT TO ATTORNEY-CLIENT PRIVILEGE AND ATTORNEY WORK PRODUCT DOCTRINE

RE: CMS's Proposed Rule Creating a Stark Exception for Gainsharing

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I. SCOPE OF MEMORANDUM

This Memorandum responds to your request for a legal analysis of a proposed rule published by CMS to create a new exception to the "Stark Law" for gainsharing with physicians. 73 Fed. Reg. 38502 (July 7, 2008) (with preamble discussion on the proposed Stark exception beginning at 38548.) A copy of relevant portions of the Notice of Proposed Rulemaking is attached for the reader's convenience. The term "gainsharing," as used in both this Memorandum and in the proposed regulation, refers to payments by a provider to physicians who have ordered health care services from the provider for the physicians' patients. The gainsharing payments are based on cost savings realized by the physicians ordering fewer items or services or ordering less costly items or services.

"Gainsharing" refers to financial arrangements in which hospitals seek to align physician incentives with hospital incentives by financially rewarding physicians for their cooperation. The hospital payments to physicians pursuant to gainsharing plans are typically a percentage of the hospitals' cost savings achieved by the physicians' cost-reduction behavior. This Memorandum generally refers to all such programs as gainsharing programs.

This Memorandum focuses on legal issues and is not intended analyze the proposed rule on the basis of whether or not it is good public policy. To the extent, however, that public policy positions have been incorporated into the law and Medicare policy, this Memorandum addresses those matters. Since this Memorandum does not address policy issues except to the extent that a policy position has been adopted as a matter of law, there may be a number of matters that should be raised in comments to the proposed rule that are not addressed in this Memorandum.

II. SUMMARY OF CONCLUSIONS

We believe that creating a Stark exception for gainsharing is inconsistent with the standard Congress has set for exceptions created by the Secretary to the prohibitions in the Stark Law because the purpose of gainsharing payments is to induce or reward physicians for limiting or reducing services to Medicare patients. The issuance of favorable opinions on gainsharing by the Office of the Inspector General ("OIG") is not dispositive since OIG's statutory authority to decide on a case-by-case basis to protect conduct that otherwise violates the law is more broad than the authority that Congress has delegated to the Secretary to create Stark exceptions. In addition, there are significant differences between the case-by-case, in-depth review that OIG gives to advisory opinion requests and a generally applicable exception for which no additional approval is needed. There are a number of other serious issues raised by the proposed regulation including:

- The statute has a clear prohibition on offering incentives to physicians to reduce or limit services to Medicare beneficiaries. While OIG has issued a handful of favorable advisory opinions after intensive case-by-case analysis of specific proposals, each OIG opinion on gainsharing states that, but for the favorable opinion, the statutory prohibition on incentives to limit or reduce services would be violated. In addition, OIG has noted that small differences in gainsharing programs could affect its decision on whether to issue a favorable advisory opinion. Although OIG has an annual process for considering the issuance of additional safe harbor regulations that would have general applicability, such as the proposed Stark exception for gainsharing, OIG has not availed itself of that process.

- In contrast to many other Stark exceptions, this rule has no requirement that the amounts paid to referring physicians be fair market value for the cost savings realized in a gainsharing program. While the proposed regulation requires that any gainsharing program be compliant with the anti-kickback statute, the lack of a fair market value requirement makes it much more likely that a gainsharing program meeting the requirements of the proposed rule will raise material concerns under the anti-kickback statute.

- An essential element of rulemaking is the inclusion of factual findings by the agency in the preamble to the proposed rule along with the data or information supporting those factual findings. It is the agency's responsibility to include these factual findings in the proposed rulemaking so that the public is on notice of those findings and can comment on them. This proposed rule fails to identify the relevant factual questions, is not supported by sufficient factual findings, and does not cite data or information to support the rule. In our opinion, this is an irredeemable deficiency in the proposed rule, and it would be improper to proceed to a final rule without issuing another proposed rule.

- The proposed rule is inconsistent in several ways with closely analogous CMS policies and regulatory schemes. Despite the longstanding legal doctrines that agencies must, at the very least, explain their reasons for departing from prior

policies and standards, the proposed gainsharing rule is not consistent with current CMS polices regarding advance notice to beneficiaries, qualifications and standards for quality review organizations, and standards for cost-reducing activities that affect patient quality of care. Although CMS has implemented and required numerous beneficiary protection provisions in other programs and rules, such protections are glaringly absent or wholly unspecific in the proposed gainsharing rule.

- At any time, Congress could have created a statutory exception to the Stark Law for gainsharing. Congress has not done so; instead, Congress has authorized demonstration projects on gainsharing. Those demonstration projects have the stated goal of answering the factual questions that this rulemaking ignores. Proceeding with this rulemaking without the information that the demonstration projects were designed to produce seems to be inconsistent with Congressional intent.

- The case law establishes that agencies should consider alternatives when proposing rules. The preamble to this proposed rule does not discuss any alternatives or options including whether the same or similar results in cost saving could be achieved with considerably smaller payments from hospitals.

- This proposed rulemaking is deficient since it leaves open a number of issues and does not even have proposed regulation text on some issues discussed in the preamble. Under the Administrative Procedure Act, it is incumbent upon the agency to put forward a fully-developed proposal so that the public knows what the proposal is for which comments are sought. CMS's failure to state its proposal raises serious questions on whether the proposal is sufficient to meet the standards of the Administrative Procedure Act.

- Rules must not be vague; they need to establish clear standards under which the regulated community can conduct itself. The proposed rule arguably fails to meet this standard with respect to its quality criteria. As is apparent from CMS's process in selecting and implementing quality reporting standards and a value purchasing program, there is a dearth of evidence for most diagnoses and procedures on what standards of care are most likely to lead to the best possible outcomes. In short, "quality" is not a standard for which there are objective criteria, and as a result, the proposed regulation does not offer a clear standard of conduct.

- The original statutory amendments establishing the Medicare program in 1965 established the principle that beneficiaries must have freedom of choice. Freedom of choice, however, is meaningless unless the beneficiary knows what his or her choices are. While many providers have incentives to cut costs, Medicare has relied upon physicians to be advocates for their patients and to inform patients of the full range of treatment options available to the patient. Similarly, the statute and regulations repeat the principle that beneficiaries should have access to the full range of Medicare-covered services. The research is clear that physicians do

react to incentives. Hence both freedom of choice and access to services could be limited by the proposed regulation.

- Although physician incentive payments by Medicare Advantage plans are permitted under an existing Stark exception, the OIG has previously noted that such payment arrangements are permissible because of the unique nature of the managed care environment. In the managed care context, beneficiaries know that physicians will have financial incentives to manage their care to minimize costs, and beneficiaries consciously choose managed care plans in order to share in any plan savings themselves in terms of lowered costs. In addition, CMS has built in numerous safeguards to protect managed care beneficiaries, including notice requirements, clear and comprehensive appeal rights, and mandatory quality improvement programs. None of these factors permitting physician incentive plans and controlling the risk of program abuse are present in the gainsharing proposal.

III. ANALYSIS

3.1. Inconsistency Between the Proposed Rule and Statutes Designed to Maintain Program Integrity and to Protect Patients

In addition to enumerating certain statutory exceptions, the Stark Law authorizes CMS to promulgate regulations excepting additional financial relationships, *provided that* the Secretary has determined that any financial relationship to be protected by such an exception "does not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). The statute does not say a "low" risk; it does not say "minimal" risk; and it does not say a risk that the Secretary deems acceptable. Rather, the statue says that the Secretary can create an exception to the Stark Law if the exception will not "pose *a* risk," *id.* (emphasis added), i.e., *any* risk. Thus, by the plain language of CMS's statutory authority to promulgate regulations specifying additional exceptions, the Stark Law tolerates *no* risk of program or patient abuse for agency-created exceptions.

CMS has stated that it will fulfill this statutory mandate by "protect[ing] arrangements that, in most situations, would not pose a risk, and rely[ing] on the anti-kickback statute or other fraud and abuse laws to address any residual risk." 66 Fed. Reg. 856, 863 (Jan. 4, 2001). In other words, according to CMS, the threshold requirement that a financial relationship must meet in order to be eligible for an agency-created exception is that the relationship "in most situations would not pose a risk," *prior* to consideration of whether the anti-kickback statute or other fraud and abuse laws, such as the civil money penalty statute, might be sufficient to resolve "any residual risk."

A. Gainsharing Programs Violate the Statute Prohibiting Rewarding Physicians for Reducing or Limiting Services

The civil money penalty statute ("CMP Statute") speaks in absolutes – payments by a hospital to a physician "as an inducement to reduce or limit services" subject the hospital to sanctions. 42 U.S.C. § 1320a-7a(b). The statute does not say "unwarranted" reductions in

services; it does not say reductions in service that do not adversely affect quality. Yet the proposed gainsharing rule abandons the clear bright line established by the CMP statute, and expressly permits payments to physicians to induce physicians to reduce or limit services if those reductions or limitations are not "inappropriate." *See* Prop. Reg. 42 C.F.R. § 411.357(x)(2)(iv), 73 Fed. Reg. at 38605. As discussed more fully below, at least one federal court has considered, and rejected, an argument by the Secretary that limitations in service that do not lead to "sacrificing" patient quality-of-care should be permitted under the CMP Statute. *See Robert Wood Johnson Univ. Hosp., Inc. v. Thompson*, No.Civ.A. 04-142 (JWB), 2004 WL 3210732, at *9-*10 (D.N.J. April 15, 2004). Congress's grant of statutory authority to the Secretary to create Stark law exceptions is quite clear and quite limited – the Secretary may promulgate regulations to except certain financial arrangements from the Stark law's prohibition only when there is *no* risk of program abuse.

CMS's proposed rule does not explain how the proposal meets CMS's own standard that gainsharing arrangements "in most situations, would not pose a risk" of program or patient abuse. To the contrary, the typical gainsharing arrangement presents such a risk in *all* situations. In fact, the HHS Office of the Inspector General's ("OIG's") longstanding and consistent position, and hence the Secretary's position, is that gainsharing arrangements *always* are subject to the prohibition of the civil money penalty law that forbids hospitals from making any payment to a physician, directly or indirectly, as an inducement to reduce or limit services provided to a Medicare or Medicaid beneficiary. 42 U.S.C. § 1320a-7a(b).

In its Special Advisory Bulletin on gainsharing arrangements issued in 1999, OIG concluded not only that the CMP Statute "clearly prohibits such arrangements" without requiring any finding of abuse, but also that gainsharing arrangements in fact *do* "pose a high risk of abuse." OIG Special Advisory Bulletin, *Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries* (July 8, 1999), available online at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm. The breadth of the CMP Statute is not inadvertent but instead embodies precisely the legislative intent expressed in the House Committee Report accompanying the CMP Statute, that gainsharing "incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients." H.R. Rep. No. 99-727, at 441 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3607, 3841.

Since issuing the 1999 Special Advisory Bulletin, the OIG has had the opportunity as part of its advisory opinion process to consider in detail the specific cost saving measures that comprise typical gainsharing arrangements. OIG consistently has determined that all or virtually all such measures implicate the CMP Statute, including those cost savings programs that have protections similar to those in the proposed rule. *See, e.g.*, OIG Advisory Op. No. 08-09 at 9 (July 31, 2008) (each of the 36 individual cost savings recommendations "implicated the CMP"). In particular, OIG consistently has concluded that the prohibition of the CMP Statute applies to "product standardization" features of a gainsharing arrangement. *Id.* at 4-5, 9. That most features of most gainsharing arrangements (including product standardization features) run afoul of the CMP Statute is alone sufficient to prevent a gainsharing exception from falling within CMS's statutory authority.

Moreover, even favorable OIG advisory opinions on gainsharing arrangements come with a strong caution about the fraud and abuse risk inherent in gainsharing arrangements:

> [W]e reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud and abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. *Other apparently similar arrangements could raise different concerns and lead to a different result.*

Id. at 13-14 (emphasis added).

It appears that CMS has relied heavily upon the safeguards that have been included in the physician incentive plans for which OIG has granted favorable advisory opinions. There are significant differences, however, between safeguards included in individual plans for which OIG advisory opinions have been issued and the global exception that CMS has proposed to the Stark Law.

First, the OIG advisory opinion process is a case-by-case approval process. *See* 42 C.F.R. Part 1008. The party seeking an opinion must submit all relevant documents. 42 C.F.R. § 1008.36. The written submission is often followed by additional queries from OIG and discussions. *See* 42 C.F.R. §§ 1008.39, 1008.41. Finally, the opinion, if favorable, protects the addressee only and OIG has been very clear that other parties not only may not rely upon an opinion, but may not even cite it in their defense in an enforcement action. 42 C.F.R. §§ 1008.53, 1008.55. OIG's case-by-case approach stands in marked contrast to the global exception that CMS proposes to create. Under the proposed Stark exception, there will be no scrutiny of the documents. There will be no opportunity to probe for subtleties that may, as OIG notes in its most recent opinion quoted above, "lead to a different result." Finally, there will be no certification as is required for the advisory opinion process. 42 C.F.R. § 1008.38.

OIG has shown that the case-by-case approach is its preferred approach because it has *not* done what CMS now proposes to do – create a generally applicable safe harbor for gainsharing arrangements. Thus, even though OIG has been addressing cost savings physician incentive arrangements in advisory opinions dating back to 2005 (and requests dating to 2003), OIG still has chosen to continue a case-by-case review in lieu of establishing generally applicable criteria. This is not merely bureaucratic inertia since OIG annually considers whether and how to add to its existing safe harbor regulations. *See, e.g.*, 72 Fed. Reg. 71868 (Dec. 19, 2007). Although OIG has not explained why it has not created a safe harbor for gainsharing programs, it may be awaiting data from the demonstration projects discussed below.

In addition, the proposed gainsharing exception goes well beyond OIG's advisory opinions since it would permit a three-year term for a cost savings plan while OIG has only granted advisory opinions for one-year periods.

Finally, there is a huge difference between permitting gainsharing in a handful of short term instances that are subject to OIG advisory opinions and giving a "green light" for gainsharing to be implemented nationally by any entity that, on its own, interprets its conduct as fitting within CMS's standards. The risk of harm if OIG has misestimated the degree of risk in a handful of instances cannot compare to the harm that could be caused by implementing a broad, nationally applicable exception prematurely.

The only federal district court to have considered the issue of gainsharing arrangements and the civil money penalty statute similarly concluded that such arrangements would, in attempting to cut costs, reduce services in exchange for payment and would therefore "directly violate the [civil money penalty statute] and appear to endorse the very conduct (*e.g.*, "encourage premature discharge to the financial advantage of the hospital") that Congress sought to deter." *Robert Wood Johnson Univ. Hosp., Inc. v. Thompson* ("*Robert Wood Johnson*"), No. Civ.A. 04-142 (JWB), 2004 WL 3210732 at *9 (D.N.J. Apr. 15, 2004). In *Robert Wood Johnson*, the Secretary approved a gainsharing demonstration project pursuant to the Medicare Demonstration Project Statute, 42 U.S.C. § 1395b-1(b). The project was awarded to eight members of the New Jersey Hospital Association ("NJHA"), which was made up of 107 member hospitals. Several NJHA hospitals which were not chosen to participate in the demonstration project filed suit to enjoin the demonstration, arguing that the financial incentives offered by the proposed gainsharing arrangement would cause physicians to refer patients to hospitals participating in the demonstration to the detriment of non-participating hospitals. The court agreed, and further concluded that it was undisputed that the cost-saving measures of the gainsharing arrangements, such as "shorter inpatient stays, fewer marginal but costly diagnostic tests, conversion to generic drugs, shorter operating room times, more cost effective use of intensive care units, etc.," could constitute a reduction in services to Medicare beneficiaries, though the Secretary argued that this would not "sacrific[e] the quality of patient care." *Robert Wood Johnson* at *9. The court held, therefore, that the gainsharing arrangements constituted payment to physicians in order to reduce services to patients – precisely the type of conduct Congress explicitly forbade under the civil money penalty statute. *Id.* at *9-*10.

In summation, CMS's incorporation of standards similar to those used in OIG advisory opinions does not assure that arrangements fitting those criteria meet the Stark statutory standard for exceptions not posing "a risk of program or patient abuse." Moreover, in light of the OIG's considered judgment that "apparently similar arrangements could raise different concerns and lead to a different result," OIG Advisory Op. No. 08-09 at 14 (July 31, 2008), gainsharing arrangements cannot in any event satisfy the statutorily mandated zero risk tolerance standard based on compliance with a fixed and uniform set of criteria, like those in the proposed exception, regardless of the specificity of the criteria.

B. Risk of Violating the Anti-Kickback Statute

As noted above, the Stark Law, while generally prohibiting physicians from making referrals to an entity with which the physician has a financial relationship, grants the Secretary

the authority to craft exceptions to the prohibition, which serve to protect certain types of financial relationships. *See* 42 U.S.C. § 1395nn(b)(4). The Secretary's power to promulgate regulations creating Stark exceptions is limited, however, to protecting a financial relationship "which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." *Id.* The statute does not say a "low" risk; it does not say "minimal" risk; and it does not say a risk that the Secretary deems acceptable. Rather, the statute says that the Secretary can create an exception to the Stark Law if the exception will not "pose *a* risk," *id.* (emphasis added), i.e., *any* risk. Thus, by the plain language of CMS's statutory authority to promulgate regulations specifying additional exceptions, the Stark Law tolerates *no* risk of program or patient abuse for agency-created exceptions.

CMS has taken the position that it will fulfill this statutory mandate by "protect[ing] arrangements that, in most situations, would not pose a risk, and rely[ing] on the anti-kickback statute or other fraud and abuse laws to address any *residual* risk." 66 Fed. Reg. 856, 863 (Jan. 4, 2001) (emphasis added). In other words, the primary mechanism by which CMS addresses the risk posed by a proposed Stark exception is by crafting the terms of the exception itself, to limit the financial relationship protected by the exception. The anti-kickback statute, the civil money penalty statute, and other fraud and abuse laws serve as a redundant backup to control residual risk. Only after controlling the risk of program or patient abuse by crafting protections into the Stark exceptions does CMS turn to these other laws to control residual risk caused by situations that might fall through the cracks of the exceptions' own terms.

This approach is consistent with the fact that the great majority of Stark exceptions contain a fair market value provision, which requires that the amount of payment to (or from) the physician be at fair market value. *See, e.g.*, 42 C.F.R. § 411.357(c)(2) (bona fide employment relationships).[1] Such a requirement both directly lessens the risk of program fraud and abuse, by ensuring that payments made under the protection of the Stark exception are consistent with the services rendered, and also lowers the risk of violation of the anti-kickback statute, by ensuring that the financial relationship protected under the exception does not contain an inducement to reduce the services offered to the patient. The OIG recognized the importance of a fair market value requirement in its 1999 Special Advisory Bulletin on gainsharing, when it noted that an alternative approach to aligning hospital and physician financial incentives would be for hospitals and physicians to "enter into personal services contracts where hospitals pay physicians based on a fixed fee that is fair market value for services rendered, rather than a percentage of cost savings." The OIG opined that such arrangements would not violate the civil money penalty statute, although they would still have to meet the requirements of the anti-kickback statute.

In contrast, the proposed gainsharing exception does *not* contain a fair market value requirement. Such an omission would be problematic even when there is not a heightened risk of program or patient abuse, given that it places an increased burden of controlling such risk on

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[1] The bona fide employment relationship exception provides that payment from an employer to a physician (or immediate family member) for identifiable services is permissible, as long as:

(2) The amount of the remuneration under the employment is –

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

the anti-kickback statute, rather than crafting protections directly into the Stark exception itself. However, in the context of gainsharing arrangements, this omission is even more glaring, given the longstanding position of the OIG that such arrangements *do* pose a heightened risk of program abuse.

For example, one major problem inherent with gainsharing programs is that the amount of payment is determined on a percentage basis. In many contexts, CMS and OIG have identified percentage payment arrangements as being much more subject to abuse than fixed fee arrangements. CMS may believe that the other safeguards in its proposed rule render it unnecessary to include the limitation that the amount of payment must be at fair market value, but this assumption is not correct. As noted below, one of the deficiencies in the basis and purpose statement for this rule is that CMS offers no findings or supporting data on whether the savings at issue could be achieved through a method other than a percentage payment. While CMS discusses in the preamble to the proposed rule that payments to physicians be up to 50 percent of the cost-savings achieved under the gainsharing arrangement, a requirement that payments not exceed this 50 percent limitation does not appear in the regulation text. *See* 73 Fed. Reg. 38555. CMS also has not analyzed whether the payments to physicians of as much as 50 percent of savings reflects fair market value for percentage arrangements. Indeed, on its face, the 50 percent limitation appears to be too high given that the expenses for the program are borne by the hospital and those expenses are substantial. The amounts paid to physicians plus the substantial expenses of a gainsharing program borne by the hospital would exceed 50 percent of the total savings; indeed, could exceed 50 percent by a large margin. Thus, CMS's proposal would permit a hospital to pay out far in excess of 50 percent in gross compared to the savings realized. There is no reason to pay physicians more than fair market value for achieving cost savings. If payment to physicians for cost savings is to be based on a percentage of savings, the market for contingency fee arrangements would be an appropriate measure of the reasonableness of physician fees. Contingency fees, which reflect the value assigned by the market when the vendor accepts all risk and bears all expenses, are substantially less than 50 percent.[2]

In summation, the proposed rule departs from the Secretary's practice with respect to other Stark exceptions since it does not require that the payment to referring physicians be at fair market value. By itself, that omission is problematic since it would protect arrangements when the hospital could have achieved a net greater benefit with a smaller payment. The only reason that a hospital would want to enter into an arrangement where its net savings, after taking into account the costs of establishing a gainsharing program and paying a percentage of savings to physicians, would be less than other approaches to cost savings, would be to induce or reward referrals. This is exactly the conduct that is targeted by the anti-kickback statute. One solution to this problem is to require that a hospital establishing a gainsharing program obtain a fair market value opinion from a valuation expert. An alternative solution is to require a hospital establishing a gainsharing program to obtain a favorable advisory opinion from OIG that covers the duration of the program.

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[2] There is considerable case law on factors to be taken into account in evaluating the reasonableness of legal contingency fees. *See, e.g., Blum v. Stenson*, 465 U.S. 886, 893-94 (1984); *Save Our Cumberland Mountains, Inc. v. Hodel*, 857 F.2d 1516, 1517 (D.C. Cir. 1988). The principles in the case law for the reasonableness of legal fees could be a good starting point for CMS to set forth principles for judging the reasonableness of percentage fees paid to physicians for cost savings.

3.2. Rules Must Be Supported with Relevant Factual Data and Information

A. The Courts Require Agencies to Identify Relevant Factual Questions, Make Factual Findings with Respect to Those Questions, and to Cite the Factual Data and Information Supporting the Agency's Findings

Public policy issues do not exist in a sterile environment filled solely with ideas. Rather, rational decision-making can occur only after taking into account relevant *facts*, and those facts, which are supported with credible, reliable data or other information, must be part of the rulemaking record. This is why Congress routinely holds hearings prior to legislating, and directs CMS, the General Accountability Office, and the Congressional Research Service to prepare factual studies for Congress on issues affecting Medicare. It is also why Congress has created the Medicare Payment Advisory Commission ("MedPAC"). Informed decision-making can, by definition, occur only when there is information.

The indispensable need for information and data as a foundation for rulemaking is a well-established legal requirement. The Administrative Procedure Act requires agencies to publish in the Federal Register a notice of proposed rulemaking with a supporting basis and purpose statement. The notice of proposed rulemaking must be sufficiently detailed to permit interested parties the ability to comment meaningfully on the terms and provisions of the proposed rule. *See Florida Power & Light Co. v. U.S.*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied,* 490 U.S. 1045 (1989). In order to permit meaningful comment, as necessary for a detailed factual record for judicial review, informed rulemaking on the part of the agency, and fairness to the affected parties, the notice must "disclose in detail the thinking that has animated the form of a proposed rule and the *data* upon which that rule is based." *See Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977) (emphasis added).

Similarly, the familiar "arbitrary and capricious" standard by which courts review administrative agency action requires that agency rulemaking be supported by substantial evidence in the rulemaking record. 5 U.S.C. § 706; *see Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413-15 (1971). The applicability of these general principles to Medicare rulemaking arose in the case of *Walter O. Boswell Memorial Hosp. v. Heckler,* 749 F.2d 788 (D.C. Cir. 1984). That case involved a challenge by a hospital to a rule that changed how Medicare would cost-reimburse hospitals for the costs of malpractice insurance. Prior to the "malpractice rule" that was the subject of *Boswell,* Medicare paid for malpractice insurance costs based on Medicare utilization of hospital services. For example, if 35 percent of hospital services were used by Medicare patients, then Medicare cost-reimbursed approximately 35 percent of the hospital's malpractice insurance costs. The "malpractice rule" changed that apportionment formula and in its place cost-reimbursed malpractice insurance costs on the basis of the ratio of malpractice losses paid to Medicare patients to total malpractice insurance losses. The D.C. Circuit Court of Appeals reversed a lower court decision that had upheld the validity of the rule, and remanded the case to the lower court for a new decision on the basis of the entire rulemaking record. The court's analysis of what should be in the administrative record is directly pertinent to this proposed rule on gainsharing.

In *Boswell*, the court identified three factual issues relevant to the Medicare payment of malpractice insurance costs: 1) whether the overall pool of general and administrative costs was over-allocated to Medicare such that Medicare was subsidizing the care of non-Medicare patients; 2) whether the study supporting the agency's argument that malpractice insurance costs were disproportionately attributable to Medicare patients actually supported that conclusion; and 3) whether the agency had considered reasonable alternatives to its policy. 749 F.2d at 794. Thus, a rule based on the reasonable hypothesis that malpractice losses for Medicare patients were less than for other patients because of the shorter remaining life expectancy and lower remaining lifetime earnings expectations could not stand without hard facts to support that hypothesis as well as fact-finding on related issues.

With respect to the first factual question that the court in *Boswell* said should have been addressed in the rulemaking record, the court noted that the agency had made a finding that malpractice costs were significant and the disproportionate allocation of malpractice costs to Medicare was great. The court held that the agency's finding was inadequate because "*the precise factual basis for this conclusion*, however, remains obscure from the record...." 749 F.2d at 795 (emphasis added). With respect to the second issue, the adequacy of the study purported to support the rule, the court found many flaws in the agency's reliance on the study. Finally, the court held an agency must "consider 'reasonably obvious alternative ... rules and explain its reasons for rejecting alternatives in sufficient detail....'" 749 F.2d at 797 (*quoting NAACP v. FCC*, 682 F. 2d 993, 998 (D.C. Cir. 1982)).

In summary, the standard applied in *Boswell* entails three elements:

1. The relevant factual questions must be identified;

2. There must be credible, reliable factual findings with respect to the relevant factual questions; and

3. Reasonable alternatives to the proposed rule must also be considered.

Boswell is in the mainstream of case law applying the rulemaking requirements of the Administrative Procedure Act. *See Int'l Fabricare Inst. v. U.S. E.P.A.*, 972 F.2d 384, 389 (D.C. Cir. 1992) (The agency "is required to give reasoned responses to all significant comments in a rulemaking proceeding."); *Am. Maritime Ass'n v. U.S.*, 766 F.2d 545, 567 n.30 (D.C. Cir. 1985) ("In a rulemaking... an agency must justify the assumptions essential to its actions, not withstanding a party's failure to challenge those assumptions before the agency, as part of its affirmative duty to engage in rational decision-making.").

B. Relevant Factual Questions for Gainsharing Exception

In the instance of the proposed gainsharing exception to the Stark law prohibition on financial relationships between physicians and the entities to whom the physicians refer Medicare and Medicaid patients, CMS's proposed rulemaking neither identifies the relevant factual questions that should be addressed nor does it make findings with respect to those questions. (If CMS had made such findings, they would have to be supported by reliable evidence.) It is apparent, however, that there are a number of important factual questions that

should be addressed prior to creating a generally applicable gainsharing exception to the Stark rule, including:

- What are the opportunities for cost savings in hospitals for which physician input is needed?

  Hospital prospective payment commenced in 1983 and has expanded since then to include virtually all hospital services. Thus, hospitals have had a strong incentive for 25 years to reduce costs and increase efficiency. What opportunities for cost savings exist now that necessitate physician involvement?

- To the extent that opportunities for such cost savings exist, can they be achieved at less expense to hospitals, and hence to the health care system in total, than through gainsharing?[3]

  As discussed above, the exception that CMS proposes permits rewarding physicians 50 percent of cost savings *and* imposes on the hospital significant costs for establishing and maintaining cost savings programs. There is an established market for contingency fee arrangements but the rulemaking includes no data on what the going rate is for contingency fee arrangements. It also does not include any requirement that the hospital show that it had to reward physicians at a 50 percent payment level in order to obtain physician cooperation. Hospitals are required by the Medicare conditions of participation to formulate drug formularies, 42 C.F.R. § 482.25(b)(9), and have done so for years without paying a percentage to physicians. Hospitals have developed clinical pathways by paying on other than a percentage of cost savings basis. The rulemaking is devoid of any discussion of where the 50 percent figure came from.

- How do the costs of a gainsharing program, both the cost savings channeled to physicians as well as the transactional costs in establishing a gainsharing program, compare to the amount of total savings that are expected to be achieved? A related issue is whether up to 50 percent of cost savings is fair market value for the physician effort involved in achieving cost savings.

  The exception that CMS has created is complex in an attempt to minimize inappropriate cost-cutting and to protect the quality of services. The necessary corollary of that complexity is that it will be very expensive for a hospital to implement a cost savings incentive program. One can easily hypothesize a situation where the cost of establishing a cost savings incentive program plus the

[3] The consideration of other options for accomplishing the same or similar results is an essential element of avoiding having a rule determined to be "arbitrary and capricious." *Indep. U.S. Tanker Owners Comm. v. Dole,* 809 F.2d 847, 854 (D.C. Cir. 1987).

payout of half the savings to physicians is a very high percentage of the total cost savings. If that is the case, the purpose of the program would appear to be to find a legal way to funnel money to physicians rather than to achieve cost savings. As noted above, the rulemaking contains no information on the potential cost savings to be achieved. In addition, there is no explanation of the proportionality of the costs and physician payments to total savings achieved, yet the proportionality of total costs and savings reveals a great deal about the underlying intent of a hospital establishing a cost savings incentive program.

- After a gainsharing program terminates, what is the duration of cost savings achieved under the program and are there any changes in physician admitting and ordering practices then?

  At present, the proposed rule requires that any gainsharing arrangement be for a minimum of 1 year and a maximum of 3 years. Whether cost savings caused by incentives to physicians to alter their conduct will last when the incentive no longer exists is completely unknown.

- How common is it for physicians to have active medical staff privileges at more than one hospital so that the implementation of a gainsharing program at one hospital may create incentives for shifting admissions or "cherry-picking"?

  There is data[4] that suggests that many physicians have admitting privileges at more than one hospital, and actually do admit to more than one hospital yet that is not mentioned at all in the preamble. This is important because physicians can "cherry-pick" their patients so as to reduce the cost at a hospital with a cost savings incentive program and it is virtually impossible for CMS or anyone else to monitor such conduct effectively.

- Are there objective measures of quality that are extant by which a meaningful evaluation of whether gainsharing has affected quality can be measured?

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[4] *See, e.g.*, William J. Lynk & Heather R. Spang, *The Balance of Power in Hospital Staff Privileges Disputes*, Antitrust Bulletin, Fall-Winter 2007 ("First, these data are not consistent with the idea that multihospital practice is unusual for physicians. In fact, about half . . . [of the physicians in the sample] practice at multiple hospitals; the average physician practices at 1.84 hospitals. Second, for the multihospital physicians--those who are nonexclusive to their primary hospitals--their secondary practices typically are not limited to just one alternate hospital."); Mark E. Miller, Pete W. Welch, & Gilbert H. Welch, *The Impact of Practicing in Multiple Hospitals on Physician Profiles*, Vol. 34(5), Medical Care, 445 (1996) ("On average, attending physicians in [the sample] worked in 1.55 hospitals during the... period of observation-almost precisely the same figure we obtained from a national Medicare sample for an entire year (1.56)...."). *See also Robert Wood Johnson*, 2004 WL 3210732 at *2 (noting that St. Francis Medical Center was able to demonstrate standing, and "financially devastating" imminent injury by showing that there was a significant pool of physicians with admitting privileges both at St. Francis, a non-participating demonstration project hospital, and a direct competitor, Capital Health System, a participating hospital.

> CMS appropriately emphasizes that cost savings programs must not reduce quality and provides for a baseline quality analysis along with annual reviews of quality. What CMS has not analyzed in the rulemaking is whether "quality" is measurable. In the context of CMS's hospital quality reporting program, there are currently only 42 quality measures and they cover only a minority of the conditions treated at most acute care hospitals. *See* FY2009 IPPS Final Rule, available online at http://www.cms.hhs.gov/AcuteInpatientPPS/downloads, at 657-59. Thus, the missing factual analysis is the extent to which there are objective measures that are adequate to assure that quality is not adversely affected by cost savings programs.

In summary, the proposed rule presents what CMS appears to think *could* be a good idea without reflecting research, without including information on the actual effect of gainsharing programs, and without any findings on factual questions of obvious importance. These omissions have *legal* significance since they show that CMS has not met the well-established standards in the case law for having a sound factual basis for rulemaking. To the extent that commenters have relevant factual information on these issues, we recommend that they submit that information. Regardless, however, what information commenters submit, we believe that the proposal is irredeemably flawed since the factual findings, and the supporting data and information, should have been included in the proposed rulemaking so that the public would have an adequate opportunity to comment on those findings and the support.

C. Ongoing Demonstration Project Is Not Completed and Information from that Project Is Not Available

The only inference that can be drawn from prior Congressional action with respect to gainsharing is that Congress has concluded that it is premature to embark on a nationwide, generally applicable gainsharing experiment. Instead, Congress has directed CMS to engage in demonstration projects designed to collect exactly the factual data and information that is lacking in the proposed rulemaking. Congress first provided for gainsharing in 2005 statutory amendments and has revisited the issue since then. Since Congress first directed the Secretary to conduct a gainsharing demonstration project in 2005, it has amended the Social Security Act legislation in 2006, 2007, and 2008. In 2005 and each successive year, it was fully within Congress's power to create a statutory exception for gainsharing. Congress has not done so and did not direct the Secretary to do so. Rather, Congress directed CMS to conduct demonstration projects to *study* gainsharing.

The most logical source of data to support the factual findings required for rulemaking purposes is the ongoing three-year demonstration project on gainsharing authorized by section 5007 of the Deficit Reduction Act of 2005 (Pub. L. No. 109-171)("DRA"). This demonstration project was to begin January 1, 2007 and end December 31, 2009. It seems clear, therefore, that Congress has necessarily indicated that it believes that three years of data from the demonstration project should be gathered and analyzed prior to further action implementing a new gainsharing rule. For its part, the agency has stated that the "demonstration will determine if gainsharing aligns incentives between hospitals and physicians in order to improve the quality and efficiency

of care, and to improve hospital operational and financial performance." Such a determination, as well as other findings, are essential prior to implementation of a gainsharing rule, in order to ascertain if such a rule would further the agency's stated purpose. Accordingly, prior to CMS proceeding with rulemaking on this issue, the demonstration project should be completed and fully evaluated by the third party already engaged by CMS.

To move forward with the proposed gainsharing rulemaking prior to completion and review of the demonstration projects would be contrary to Congressional direction in the DRA by failing to analyze and consider the demonstration program results. Further, to move forward now would be unfair to participants of the ongoing demonstration project. These participants were required to submit detailed proposals to participate in the project, at significant cost. They did so with the expectation of being able to participate in a unique program that would not be available to other facilities until at least some time in 2010, the point at which data from the project could be gathered, analyzed, and incorporated into a fully informed rulemaking process. Finally, both the OIG and CMS itself have expressed concerns about the potential for fraud and abuse inherent with hospital-physician gainsharing arrangements, and have chosen to permit such arrangements only in very fact-specific, controlled situations under a series of advisory opinions and demonstration projects in order to control the risks of potential abuse. Proceeding with a Stark exception for gainsharing before reliable results of these demonstration projects is available is unwise.

In section 5007 of the DRA, Congress directed the Secretary of Health and Human Services to establish demonstration projects to permit and study gainsharing arrangements:

> The Secretary shall establish under this section a qualified gainsharing demonstration program under which the Secretary shall approve demonstration projects by not later than November 1, 2006, to test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of renumeration as specified in the project. Such projects shall be operational by not later than January 1, 2007.

DRA § 5007(a).

CMS initially solicited applications for the program, known as the DRA 5007 Medicare Hospital Gainsharing Demonstration ("MHGD") to be submitted by November 17, 2006. Each proposal was required to include a detailed description of the proposed program design, including how the program would insure quality of care, increase hospital efficiency, and produce savings to the Medicare program; an organizational structure of the proposed program, identifying key personnel and the functions and duties of each, describing the formal relationship between the hospital, related organizations and physicians, and describing how and by whom oversight of the program would be conducted; the structure of quality indicators employed by the program and how the indicators would be used to improve the overall quality and efficiency of care delivered to beneficiaries; and a detailed implementation plan, including a detailed schedule

with timeframes. *See* DRA 5007 MHGD Solicitation, *available online at*: http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/DRA5007_Solicitation.pdf.

In short, CMS required an immense level of factual detail and planning from each applicant to the program, in order to ensure the best and most complete level of information coming out of the demonstration project. As further evidence of the agency's and Congress's desire for a broad spectrum of information, CMS issued a further solicitation in order to ensure that two of the participants in the program were rural hospitals, as required by the DRA. *See* DRA § 5007(d)(2); *see also* 72 Fed. Reg. 36710, 36710-11 (July 5, 2007).[5]

The DRA mandated that the MHGD projects be operational by no later than January 1, 2007, and run from January 1, 2007 to December 31, 2009. *See* DRA § 5007(a), (d)(3). Congress also required as part of its statutory authorization that the demonstration project programs be reviewed by an independent organization, with yearly project updates and reports to Congress due not later than December 1, 2007, and December 1, 2008. *See* DRA § 5007(b)(5), (e)(2)-(3). The statute also directs the Secretary to submit a final report on the quality improvement and savings achieved by the program not later than May 1, 2010. *See* DRA § 5007(e)(4). Finally, the statute allocates $6 million in funding for fiscal year 2006 to implement the demonstration project. *See* DRA § 5007(f).

In addition to the MHGD Demonstration Project, CMS also announced plans to implement gainsharing test provisions through the Physician-Hospital Collaboration Demonstration Project ("PHCD"), as authorized by section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA")[6]. *See* 71 Fed. Reg. 53455, 53455 (Sept. 11, 2006). Unlike the MHGD project, which focuses on six hospitals and the effects of gainsharing on quality and efficiency of care during the inpatient stay and immediately after discharge, the PHCD was designed to test the long-term effect of gainsharing arrangements "well beyond a hospital episode, to determine the impact of hospital-physician collaborations on preventing short- and longer-term complications, duplication of services, coordination of care across settings, and other quality improvements that hold great promise for eliminating preventable complications and unnecessary costs." *See id.*; *see also* PHCD FAQ, *available online at* http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_pv=4.930.

Finally, CMS has authorized gainsharing programs as an optional portion of the Acute Care Episode Demonstration Project ("ACE"). Under the ACE demonstration project, a global payment will be issued for an entire episode of care, defined as "Part A and Part B services provided during an inpatient stay for Medicare fee-for-service (FFS) beneficiaries for selected procedures." *See* ACE Demonstration Solicitation for Applications, *available online at*: http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACESolicitation.pdf. Just as the MHGD and PHCD projects seek to align financial incentives between hospitals and physicians, the ACE demonstration project seeks to align financial incentives between physician-hospital

[5] The second solicitation for rural hospital applications to the demonstration project closed September 4, 2007. CMS has not issued a new timetable for the demonstration project.

[6] Although section 646 of the MMA authorized a 5-year demonstration project on the delivery of improved quality in patient care, the Secretary authorized the PHCD project as a three-year project, with applications due January 9, 2007. 71 Fed. Reg. at 53455.

organizations, comprised of at least one physician group and one physician hospital. As part of the project, the hospitals and physician groups may enter into gainsharing arrangements to share renumeration for improvements and efficiency and quality. The choice of whether to include a gainsharing incentive program is left to the discretion of the individual ACE demonstration project sites. *See* Provider Incentive, or Gainsharing, Program Rules and Proposal Requirements, ACE Demonstration, *available online at* http://www.cms.hhs.gov/demoprojectsevalrpts/md/list.asp.

3.3. The Proposed Rule Is Inconsistent in Several Ways with Closely Analogous CMS Policies

It is a well-established principle that there should be consistency within a regulatory scheme. For example, the same term is presumed to have the same meaning within the same regulatory scheme. *See, e.g., Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 570 (1995) (adhering to "the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning."). Similarly, agencies are expected to be consistent with prior policy or, at least, explain departures from prior policy. *See Morton v. Ruiz*, 415 U.S. 199, 235 (1974) ("Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures."); *see also Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999) ("When an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment."); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute.") (footnotes omitted).

The proposed rule is inconsistent with existing agency policy in the following respects:

- There are no standards for the competence of the organization that the provider must retain to conduct quality reviews and insufficient standards for its independence;
- There are no standards for measuring quality in gainsharing programs;
- CMS has excluded only one cost-reducing item from gainsharing incentive plans – reductions in the length of stay – thus showing an inconsistent and greater concern with cost-reducing activity that *may affect CMS* with increased post-acute care costs and not having the same level of concern with the effect of cost-reducing *activity affecting the quality of care for beneficiaries*; and
- The notice to beneficiaries that CMS requires for gainsharing programs that could affect a beneficiary's health and safety does not meet the specificity requirements that CMS has established for ABNs and notices of coinsurance which affect only the beneficiary's financial liability.

A. Standards for Independence of the Organization Reviewing Quality

The proposed regulation requires that there be "independent medical review" and defines that term in a general manner. The reviewers will be paid by the hospital. Absent strong protections, it is predictable that the reviewers will feel beholden to the hospitals paying them. There is a directly analogous type of review that occurs in the context of corporate integrity agreements entered into between providers and OIG. Those agreements require that the provider hire an "independent review organization" ("IRO") to monitor the provider's corporate integrity program, policies and procedures, and compliance. OIG has in place a number of safeguards to assure that the IROs are truly independent notwithstanding that their source of payment is the provider they are charged with monitoring.

First, OIG must approve the IRO selected by the provider. This is a universal term in all corporate integrity agreements. *See* http://oig.hhs.gov/fraud/cia/index.html. When exercising its review authority, OIG assures itself of the reviewer's competence in the specific areas to be reviewed as well as its independence.[7] OIG has published standards that IROs must meet. *See* http://oig.hhs.gov/fraud/cia/docs/ciafaqiro.pdf. OIG considers IROs to be conducting performance audits and thus holds them to the standards for performance set forth in the General Accountability Office (GAO), *Government Auditing Standards* (referred to commonly as the "Yellow Book"). Included in those standards are requirements that the reviewers must have internal quality control systems to assure that individuals assigned to an engagement do not have any financial or other relationships that could affect even the appearance of impartiality. To the extent that CMS proceeds with creating a Stark exception for gainsharing, it should require all independent reviewers to meet the "Yellow Book" standards for performance reviews. Another safeguard is that OIG insists that the IRO draft reports be made available to it.

In contrast to OIG's standards for IROs, nowhere does the proposed gainsharing regulation set forth any competence standards for the independent reviewer that is to be entrusted with the vital role of assuring quality. In addition, this is not consistent with other CMS's regulations dealing with medical review. Quality Improvement Organizations ("QIOs") are, as their name makes clear, concerned with quality. For QIOs, CMS requires that review decisions must be made not only by physicians, but by physicians in the specialty area being reviewed. 42 C.F.R. § 476.98. Further, the reviewing physicians must not have a conflict of interest. *Id.* Standards for the reviewers' qualifications should be included in any gainsharing regulation that CMS publishes.

B. Standards to Be Applied in Quality Reviews

For QIOs, CMS requires that the QIO must "[e]stablish written criteria based upon typical patterns of practice in the QIO area, or use national criteria where appropriate." 42 C.F.R. § 476.100(c). Here, CMS has not required that the independent reviewer establish or apply any criteria, much less the standards such criteria should meet.

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[7] When quality is an issue, the OIG Chief Counsel has stated from the podium at AHLA meetings that OIG is quite prescriptive in limiting who will satisfy them.

A more fundamental problem is that there is a dearth of data on what treatment leads to the best outcomes. CMS's own cautious and relatively slow adoption of quality indicators, and the preamble discussions pointing out difficulties in identifying appropriate quality indicators, demonstrate the uncertainty of what is "quality" care for many diagnoses and procedures. CMS's concerns for maintaining quality of care in gainsharing programs are commendable, but may be unenforceably vague until there is considerable advancement in the state of knowledge of the link between particular treatment choices and enhanced patient quality of care. *See, e.g.*, 72 Fed. Reg. 47130, 47345 *et seq.* (Aug. 22, 2007).

There is a general lack of objective, evidence-based standards that are agreed to enhance, maintain, or measure patient quality. For example, in a journal article cited by CMS in the proposed rulemaking, the authors admitted that the increased information-sharing between physicians involved in the programs only "might" have been the reason for the maintenance in quality that they observed, and noted that:

> Quality might have suffered if gainsharing promoted the use of cheaper, less effective devices/drugs, or if the reductions in utilization reflected stinting patients on beneficial products. Further consideration of this as well as analysis of other out-of-lab quality measures would produce a clearer understanding of gainsharing's effect on quality.

Jonathan D. Ketcham and Michael F. Furukawa, "Hospital-Physician Gainsharing in Cardiology," *Health Affairs*, Vol. 27, No. 3 (May/June 2008), 809. In addition, the authors noted that their study raised a number of additional questions not only about the effect of the gainsharing programs upon patient quality, but on exactly how the programs operated to reduce costs. *See id.* at 810. In short, an article relied upon by CMS shows that more information is necessary in order to determine the effect such arrangements have on patient quality of care and cost savings, and the link between the implementation mechanisms of such arrangements and these effects.

There are a limited number of objective quality measures on which both CMS and providers agree, such as the measures listed in the joint CMS/Joint Commission Specifications Manual for National Hospital Quality Measures. CMS has developed a standardized approach for developing and maintaining these standards, known as the Measures Management System. The full Measures Management System is documented in the System Blueprint, version 6, which will be available summer 2008. The multi-step process is a lengthy one, requiring the development of a work plan, convening a Technical Expert Panel ("TEP"), information gathering for potential quality measures, evaluation by the TEP, further evaluation by CMS, testing of the measures to determine feasibility and reliability, solicitation of public comment on the measures, and CMS approval and consensus endorsement. The length and complexity of the process reflects CMS's acknowledgment that quality measures are difficult to identify and implement.

C. CMS's Concern with the Changes in Length of Stay Shows that CMS Will Not Risk Any Incentives that May Affect Medicare Payment

The proposed rule would prohibit hospitals from making any gainsharing payments to physicians for cost savings resulting from a decline in the length of stay. Prop. Reg. § 411.357(x)(13)(ii), 73 Fed. Reg. at 38605. The obvious explanation for this is that CMS is concerned that a decline in the length of stay will increase post-acute care costs paid by CMS. In short, when it comes to protecting the Medicare trust funds, CMS' view is that it is impossible to build in sufficient safeguards. On the other hand, when it comes to the quality of care for Medicare beneficiaries, CMS seems much more confident that the safeguards that it has included in the proposed rule are sufficient. This inconsistency in CMS's greater vigilance in protecting Medicare's money than beneficiaries' quality of care is glaring and unexplainable.

D. The Notice to Beneficiaries Subject to Gainsharing Experiments Does Not Meet CMS's Standards for Specificity for ABNs

The proposed regulation requires that notice be given to all affected beneficiaries informing them that there is an incentive program, the physicians participating, the possibility that physicians will receive payments if they meet performance standards, and what those performance standards are. Prop. Reg. § 411.357(x)(7), 73 Fed. Reg. at 38605. At a very practical level, the effectiveness of this notice is questionable. What action is the patient who is lying in a bed and about to undergo a device-implanting procedure likely to take when he or she receives this notice? The required notice is so unspecific that the patient has no clue whether there are other devices that may be suitable for him or her and what the pros and cons are of those other devices. In the managed care arena, CMS bars Medicare Advantage plans from limiting in any way what a physician may say to a patient about treatment options or whether the plan's limitations on coverage are appropriate. 42 C.F.R. § 422.206. Here, CMS is giving physicians a financial incentive to censor themselves.

The unspecific notice required under the proposed regulation stands in stark contrast to CMS's requirements in other circumstances. For example, when a provider furnishes a service to a Medicare beneficiary that may not be covered, the provider bears the risk of noncoverage unless the provider has given an advance notice to the beneficiary ("ABN"). CMS has been very clear that ABNs must be specific and a "generic" notice will not suffice:

> "Generic ABNs" are routine ABNs to beneficiaries which do no more than state that Medicare denial of payment **is possible**, or that the notifier never knows whether Medicare will deny payment. Such "generic ABNs" are not considered to be acceptable evidence of advance beneficiary notice. The ABN must specify the service and a genuine reason that denial by Medicare is expected. ABN standards likewise are not satisfied by a generic document that is little more than a signed statement by the beneficiary to the effect that, should Medicare deny payment for anything, the beneficiary agrees to pay for the service. "Generic ABNs" are defective notices and will not protect the notifier from liability.

Medicare Claims Processing Manual (CMS Pub.100-04), Ch. 30, § 40.3.6.1. Similarly, when hospitals must give notice of a coinsurance liability in off-campus provider-based sites, CMS's regulation requires specificity. 42 C.F.R. § 413.65(g)(7).

If CMS proceeds with this gainsharing exception, it should amend the notice requirement to make it consistent with other beneficiary notice requirements so that it is tailored to each patient as to what items and services they could be receiving but are not receiving because of the gainsharing experiment at that hospital.

3.4. The Administrative Procedure Act Requires Full Notice of Proposed AgencyAction, and the Agency May Not Rely on Commenters to Fill Gaps in the Agency's Proposal

CMS's proposed rule on gainsharing and other shared savings programs creates an issue of whether sufficient notice has been given of the substance of the rule to comply with the rulemaking requirements of the Administrative Procedure Act. Under the Administrative Procedure Act, agencies are required to publish a notice of proposed rulemaking which includes either the terms or substance of the proposed rule, or a description of the subjects and issues involved. The courts have interpreted the Administrative Procedure Act as requiring sufficient notice of terms of the proposed rule so as to permit interested parties to comment meaningfully on the rule. CMS's proposed rule on gainsharing, however, fails to provide proposed regulation text on a number of the proposed requirements and safeguards. The proposal also leaves open a number of issues, such as standards for allowable quality care measures, whether physicians who join the staff of hospitals with a gainsharing program would be eligible to participate in the program, and how payments under gainsharing programs would be distributed. Given the lack of specificity as to the terms and substance of the proposed rule, and the fact that a number of central issues are left open to be determined after the submission of comments, it is doubtful the proposed gainsharing rule meets Administrative Procedure Act rulemaking requirements.

A. Legal Standard

Under the Administrative Procedure Act, agencies are required to publish in the Federal Register a general notice of proposed rulemaking including either the terms or substance of the proposed rule, or a description of the subjects and issues involved. *See* 5 U.S.C. § 553(b)(3). After providing the required notice, the agency issuing the proposed rule is also required to give an opportunity for interested persons to "participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. § 553(c).

Merely providing notice and an opportunity to comment on a proposed rule is in itself insufficient, however, if the notice lacks sufficient detail. As the D.C. Circuit Court has explained, prospective rulemaking "must provide sufficient factual detail and rationale for the rule to permit interested parties to comment *meaningfully*." *Florida Power & Light Co. v. U.S.*, 846 F.2d 765, 771 (D.C. Cir. 1988) (emphasis added), *cert. denied,* 490 U.S. 1045 (1989). This procedural requirement is necessary both for fair treatment of those who might be affected by the proposed rule, and to facilitate judicial review of the rule as finally enacted. *See Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977). "Consequently, the notice required by the [Administrative Procedure Act], or information subsequently supplied to the public, must

disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based." *Id.*

In general, courts have held that a proposed rule gives sufficient notice of the final rule "only insofar as the latter is a 'logical outgrowth' of the former." *See Environmental Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). The court noted, however, that:

> The 'logical outgrowth' doctrine does not extend to a final rule that finds no roots in the agency's proposal because something is not a logical outgrowth of nothing, nor does it apply where interested parties would have had to divine the agency's unspoken thoughts because the final rule was 'surprisingly distant' from the Agency's proposal.

Id. (internal citations omitted). For example, the D.C. Circuit Court has invalidated a final rule where the proposed rule provided for a *minimum* air velocity ventilation standard, and the final rule instead promulgated a *maximum* air velocity standard. *See Int'l Union, United Mine Workers of Amer. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1261 (D.C. Cir. 2005). Similarly, in *Small Refiner Lead Phase-Down Task Force v. EPA ("Small Refiner")*, 705 F.2d 506 (D.C. Cir. 1983) the court struck down a final rule wherein the EPA instituted an immediate interim reduction in lead content in gasoline, after promulgating a proposed rule wherein a different standard and time-table for implementation was provided. Although the agency argued that the standard contained in the final rule was a "logical outgrowth" of the proposed rule because it was "within the range of alternative standards" being considered by the agency, the court held that because the proposed rule did not provide for the immediate implementation of any interim standard, the agency had not provided sufficient notice for meaningful comment and preparation by the affected parties. *See id.* at 543-44.

The court in *Small Refiner* also noted that it is the agency itself that must provide the statutorily required notice, and it may not rely upon commenters to supply the necessary information of the final rule. In *Small Refiner*, the agency argued that it gave "general notice" that it might make unspecified changes with respect to the standards and regulations governing small refineries. *Id.* at 549. The agency also adopted a "past ownership" requirement in the final rule that was not contained in the proposed rule, but rather adopted in response to one of the comments. *Id.* The agency argued that because the comment was discussed in a trade publication, and because comments regarding rules promulgated under the Clean Air Act are contained within a public record, that the affected parties were provided with sufficient notice of the issue. *See id.* at 549-50. The court rejected both arguments. As to the "general notice," the court held that "[a]gency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking." *Id.* at 549. As to the idea that notice can be derived from comments in the public record, the court noted that the Administrative Procedure Act itself does not require comments to be entered into a public record, and so notice must be provided by the agency, not the affected parties. The court held "[a]s a general rule, [the agency] must *itself* provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment." *Id.* (emphasis in original).

B. Missing and Insufficient Notice in the Proposed Rule

CMS acknowledges in the rulemaking notice that it has not provided proposed regulatory text as to how a number of issues raised by the proposed rule will be implemented, choosing instead to "solicit[] comments regarding how best to incorporate them into the regulatory text of the exception." 73 Fed. Reg. 38502, 38552 (July 7, 2008). Specifically, CMS mentions the possibility of outside monitoring of patient data, including case severity, ages, and payers of the patient population using "generally-accepted" standards, in order to guard against physicians "cherry-picking" patients in order to maximize savings for the gainsharing practices. *Id.* at 38557. However, the agency provides no regulatory text to suggest how the monitoring entity would be chosen, how the patient data would be recorded or retained, or what the "generally-accepted" standards regarding the monitoring would be. Similarly, the notice of proposed rulemaking proposes to require that physicians be eligible for gainsharing payment only with respect to savings that are related to their own efforts and those of the other physicians in their "pool," without determining how such a requirement would be implemented. *Id.* at 38558. The proposed rule would require that procedures and treatments eligible for savings under gainsharing or related savings programs not be performed disproportionately on Medicare or other Federal health care program beneficiaries. Finally, the agency notes that it is "interested" in comments regarding a possible regulatory provision that hospitals operating gainsharing or related shared savings programs be required to audit cost savings and payment under the programs. *Id.* at 38558.

For all of these proposed requirements, CMS has failed to provide any concrete regulatory language suggesting how, if at all, the issues would be implemented, preferring instead to solicit comments on how such requirements could be incorporated into the final rule. Without sufficient detail as to the proposed requirements, however, commenters are forced to guess as to what the final rule might be, and are severely hampered in their ability to play an informed part in the rulemaking process. As the courts have ruled, in order to provide sufficient notice for informed comments, the agency must disclose in detail the reasoning supporting the rule, as well as the data upon which that reasoning is based. Instead, here the agency attempts to reverse the burden, placing upon the commenters the onus of developing implementation strategies for the agency's loosely-phrased and ill-formed ideas. Again, however, it is the agency that must supply the detailed notice required by the Administrative Procedure Act, not the commenters.

In addition to the provisions where the agency has provided no regulatory language whatsoever, there are also a number of broad issues where CMS has provided one possible regulatory implementation, but also indicated that it is leaving the issues open pending further comments. Without some indication of the range of alternatives the agency is considering, these issues also raise questions as to the sufficiency of the notice given to meet the purpose of Administrative Procedure Act rulemaking procedures.

For example, the proposed rule and regulatory text would provide that participation in gainsharing programs be limited to physicians who are members of the participating hospital's medical staff at the commencement of the gainsharing program. *See* 73 Fed. Reg. at 38604-05 (proposed § 411.357(x)(4)). The limitation is designed to protect against hospitals using the gainsharing programs as inducements to lure physicians from competing hospitals. However, the

proposed rule also solicits comments as to whether newly hired physicians should be allowed to participate in existing gainsharing programs in place before they joined a hospital's medical staff, and if so, how such participation should be implemented and governed. *See* 73 Fed. Reg. 38554.

The proposed rule and regulatory text also provides that gainsharing programs operate with a "pool" of at least five physicians for each for each savings program or performance measure within a shared savings or incentive payment program. *See id.* Each pool would be formed at the commencement of the gainsharing program, and each participating physician would be paid on a per capita basis based on savings generated by the efforts of the pool. However, once again, CMS is leaving open the possibility of how these requirements would be implemented in the final rule, as to the number of physicians per pool, when the pool would have to be set up, if, when and how physicians might be added to the pool, and whether hospitals should be required to permit all physicians in on the medical staff in relevant programs or departments the opportunity to participate in the gainsharing programs.

Finally, CMS' proposed rule leaves open a number of issues as to how payments under gainsharing programs would be distributed to physicians, or to "qualified physician organizations." As currently proposed, a qualified physician organization would be limited to those in which all member physicians would participate in the same gainsharing program. *See* 73 Fed. Reg. 38604 (proposed 42 C.F.R. § 411.351). CMS notes, however, that it is considering alternatives to this requirement to permit physician organizations in which only some member physicians would participate in the program, and alternatives to how gainsharing payments would be distributed to such organizations. One alternative outlined by CMS would be to permit hospitals to distribute payments to individual physicians through the physician organizations, with the organizations serving as a pass-through entity for purposes of distribution. The agency acknowledges, however, that this in turn raises issues of monitoring and compliance to ensure that the physician organizations accurately and fully distributes all payments to the participating physicians and not to non-participating member physicians, as well as the problem of organizations potentially retaining gainsharing benefits for themselves. Offsetting these potential problems is the fact that hospitals distributing gainsharing payments directly to the individual physicians raises implications under the "stand in the shoes" provisions of the Stark regulations, 42 C.F.R. § 411.354(c)(2), wherein a physician is considered to "stand in the shoes" of the physician organization of which he is a part for purposes of compensation arrangements. CMS is soliciting comments on how the current payment distribution proposal implicates the stand in the shoes relationship between physicians and physician organizations, without detailing how the agency itself believes the relationship would be affected by a new gainsharing exception.

C. Conclusion

Overall, the issues raised in the proposed rule and regulatory text regarding a possible gainsharing exception to the physician self-referral prohibition can be divided into two categories: issues for which CMS has issued no regulatory text whatsoever; and issues where the agency has specifically indicated that it is leaving specific provisions open for changes without detailing what possible alternatives, or even range of alternatives, are under consideration. Both approaches raise serious concerns as to the sufficiency of notice given by the proposed rule. As

explained by the courts, the purpose of the Administrative Procedure Act's notice requirement is three-fold: to improve rulemaking by providing exposure to public comment and therefore further information to the rulemaking agency; to offer fairness to the parties who would be bound by the final rule; and to develop a sufficient rulemaking record for judicial review. *See Small Refiner*, 705 F.2d at 547. These purposes are only fulfilled, however, if sufficient detail is given in the notice of the issues raised and the agency's proposed actions to permit informed and meaningful comment. The courts have struck down agency final rules when the notice of proposed rulemaking did not sufficiently forecast the provisions of the final rule, even when a final standard was within a "range of alternatives" under consideration by the agency. Furthermore, courts have been emphatic that the Administrative Procedure Act required notice must be issued by the agency, and not appropriated by the agency from public comment. Here, with so many open and complex issues raised by the proposed rulemaking lacking any or sufficient regulatory language to guide affected parties in making informed comments, there seems to be a strong argument that any final rule implementing these issues would be deemed as lacking sufficient notice from the proposed rulemaking.

3.5. Rules Must Have Objective Standards So That the Regulated Community Knows What Is Compliant

The Stark Law provides for significant penalties for noncompliance. When there is a prohibited referral from a physician with a financial interest in a hospital, the law bars payment to the hospital for the service. 42 U.S.C. § 1395nn(g). This nonpayment provision penalty is applied without regard to the medical necessity for the admission or services furnished and without regard to what other physicians with no financial interest would have done in the same circumstances. While the nonpayment provision is punitive in itself, the law also provides for penalties of $100,000 per improper referral if the physician knows the claim is pursuant to an arrangement which the physician knows or should know has a principal purpose of generating improper referrals. 42 U.S.C. § 1395nn(g)(4). With such dire consequences, it is vital that providers can determine what conduct fits within a Stark exception and what conduct does not fit within an exception.[8] This is not simply a self-evident observation but is well-established legal principle that standards of conduct cannot be vague, but must be sufficiently clear so that the regulated community knows what is compliant. *See, e.g., Kolender v. Lawson*, 461 U.S. 352, 357-58 (1983)(noting that under the void-for-vagueness doctrine, a criminal statute must define an offense in such a way that ordinary people can understand what conduct is prohibited); *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)("[W]e insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.").[9]

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[8] It is also preferable that providers be able to do this without incurring substantial legal and/or consulting fees. The costs of compliance add materially to health care costs, and complex exceptions such as the proposed exception for gainsharing programs add to hospital overhead costs.

[9] While the void-for-vagueness doctrine applies primarily to criminal statutes, the Supreme Court has noted that a similar standard might apply to "quasi-criminal" regulations with punitive effect. *See Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 499 (1982). While the Stark law is itself a civil regulation, the proposed gainsharing exception would implicate both civil and criminal penalties under other statutes, and therefore a clear standard outlining the difference between permitted and proscribed conduct is required.

Incentive programs based on objective, agreed upon quality standards, such as those for which CMS requires reporting, do not appear to present a much lower level of risk than cost savings programs. CMS's quality standards are objective and generally agreed upon within the medical community, in part because of the painstaking and lengthy process under which CMS adopts these standards. It is notable, however, that there are relatively few CMS quality standards. Moreover, as noted above in Section 3.3, the proposed regulation does not require the review organization to adopt quality criteria that it will apply. Thus, the quality standards for gainsharing plans are vague and there is no requirement that they be made less vague when a provider implements such a plan. Thus, the requirement that quality not be adversely affected is so vague as to be of questionable enforceability in specific situations.

3.6. Protecting Beneficiary Freedom of Choice and Access to Services

The proposed exception to the Stark rule for gainsharing does not ensure that two longstanding and important policies reflected in the Medicare program, freedom of choice and access to services, are adequately protected. The difference between this cost savings incentive and all others is that this incentive is actually designed to reward physicians and hospitals for limiting choices in selecting appropriate care. At present, the proposed rule would even permit physicians who have an ownership or investment interest in particular treatment items or products to participate in the design of cost savings arrangements protected under the arrangement. *See* 73 Fed. Reg. at 38555.

There are two related themes that permeate Medicare policy, as reflected in the statute, regulations, and subregulatory guidance: 1) beneficiary freedom of choice must be preserved; and 2) affirmative steps must be taken to assure that beneficiary access to the full range of Medicare-covered services is protected. The gainsharing proposal threatens both of these goals. It seeks to protect and financially reward arrangements that limit beneficiary access to items and services. Further, while giving lip service to the principle of patient access to care, the affirmative safeguards of the proposed rule, such as the required quality monitoring, fail to assure that freedom of choice and access to the full range Medicare covered services will be enjoyed by Medicare beneficiaries.

The importance of "freedom of choice" is reflected in its placement in the statute. Freedom of choice was included in the Social Security Act Amendments of 1965 which created the Medicare program by adding Title XVIII to the Social Security Act. The second section of Title XVIII, Section 1802, is devoted entirely to freedom of choice:

> BASIC FREEDOM OF CHOICE – Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services.

42 U.S.C. § 1395a(a).

Medicare's emphasis on beneficiary access to care is reflected in multiple requirements, including:

- Assuring access to an adequate network of providers, physicians, and suppliers for beneficiaries enrolled in managed care plans, 42 U.S.C. § 1395w-22(d); 42 C.F.R. § 422.112;

- Assuring access to an adequate range of drugs and pharmacies under Medicare Part D, 42 U.S.C. §§ 1395w-104(b)(1)(C), 1395w-103(a), 1395w-111(g);

- Assuring access to a choice of multiple suppliers of durable medical equipment even when the Secretary uses competitive bidding for those services, 42 U.S.C. § 1395w-3(b)(2)(A)(iv);

- Encouraging telehealth services, 42 U.S.C. § 1395m(m); and

- Authorizing rural hospital flexibility programs, 42 U.S.C. § 1395i-4(b)(1)(A)(iii).

Congress's interest in ensuring access has been reflected most recently in its passage, by more than two-thirds of the members, of the Medicare Improvements for Patients and Providers Act of 2008, which forestalled a 10 percent cut in physician payment that would have adversely affected beneficiary access to physician services.

Congress's concern with beneficiary access to a full range of services extends to new technology since Congress has specifically required the Secretary to adjust hospital rates to render it financially feasible for hospitals to make new technology available to their patients. 42 U.S.C. § 1395ww(d)(5)(K), (L). CMS adjusts both inpatient and outpatient rates to reflect partially the costs of new technology (although there remain incentives for hospitals not to use costly new technology).

The proposed regulation, if finalized as it stands, could go a long way to creating a new, and lower, standard of care for Medicare patients. Presently, physicians are patient advocates who protect their patients from undue cost-cutting. If the physician is co-opted so that his or her financial incentives are aligned with the hospital, the patient's protection will evaporate. Study after study has shown that, like the rest of us, physicians respond to incentives.[10] The proposed exception's requirement that the hospital must make available all items or services available at the outset of the gainsharing program is not adequate to protect patients since the very goal of the program is to deter physicians from ordering the full range of items and services that they

[10] Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA's Scrutiny (GO/HEHS-95-2, Oct. 20, 1994); Medicare Diagnostic Imaging Rates (GAO/HEHS-94-129R, Apr. 5, 1994); Medicare: Physicians Who Invest in Imaging Centers Refer More Patients for More Costly Services (GAO/T-HRD-93-14, Apr. 20, 1993); Medicare: Referring Physicians' Ownership of Laboratories and Imaging Centers (GAO/T-HRD-89-26, June 8, 1989); Financial Arrangements Between Physicians and Health Care Businesses: Perspective of Health Care Professionals (OAI-12-88-01411, May 1989); Health Care: Physician Self-Referrals "Stark I and II," O'Sullivan, 97-5 EPW (Dec. 6. 1996); Scholastic Articles; "Relative Procedure Intensity with Self-Referral and Radiologist Referral: Extremity Radiography," Litt, *et al.*, Radiology, 2005; 235:142-147; "Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population," Hillman, *et al.*, The Journal of the American Medical Association, Vol. 268, No. 15, Oct. 21, 1992; "Physician Ownership of Physical Therapy Services," Mitchell and Scott, The Journal of the American Medical Association, Vol. 268, No. 15, Oct 21, 1992; "Effect of On-site Facilities on Use of Diagnostic Radiology by Non-radiologists," Radecki and Steele, Investigative Radiology, Vol. 25, Issue 2, Feb. 1990, at 190-193.

ordered historically. Similarly, quality monitoring by an independent party is not adequate protection since the standards to be applied by the monitor are subjective. Indeed, with the present state of research on evidence-based medicine, quality standards are necessarily subjective for the broad range of services. The requirement of an initial quality review at the outset of the gainsharing program is not adequate to protect patients, since the very goal of the program is to deter physicians from ordering the full range of items and services that they ordered historically. Similarly, the proposed quality monitoring by an independent party through the duration of a program is not adequate protection either, since the standards to be applied by the monitor are subjective. Indeed, with the present state of research on evidence-based medicine, quality standards are necessarily subjective for the broad range of services.

Some may note that physician incentive payments by Medicare Advantage plans are expressly permitted under 42 C.F.R. § 422.208. However, there are significant differences between the proposed Stark exception and the incentive payments permitted for Medicare Advantage plans, the unique nature of managed care being the most important distinguishing factor. As OIG noted:

> A basic premise of the Medicare risk-based managed care program is that beneficiaries who choose to enroll understand that their physicians will have economic incentives with respect to managing their care. In return, however, these managed care beneficiaries share in any savings through increased benefits, such as reduced copayments and outpatient prescription drug coverage. By contrast, fee-for-service beneficiaries incur substantial additional financial obligations (not borne by their managed care counterparts) in exchange for unfettered access to physicians of their choice.

Recent Commentary Distorts HHS IG's Gainsharing Bulletin, available online at http://oig.hhs.gov/fraud/docs/alertsandbulletins/bnagain.htm OIG's comments are equally applicable here. Medicare fee-for-service patients have not taken the affirmative step of investigating and selecting a managed care plan with an intent to benefit from cost savings realized by such plans. Instead, fee-for-service beneficiaries rely on their physicians to protect their interests, and will not share in any benefits yielded by the implementation of gainsharing plans.

In addition, Medicare Advantage plans must contain numerous safeguards to protect a patient's freedom of choice that are not present in CMS's proposed regulation. For example, Medicare Advantage plans must provide plan beneficiaries exhaustive rights to appeal any determination affecting access to care and must ensure that beneficiaries are informed of these procedures. *See* Managed Care Manual (CMS Pub. 100-16), Chp. 13, § 10.2 (requiring Medicare Advantage plans to alert beneficiaries to the appeal procedures "at initial enrollment, upon notification of an adverse organization determination, upon notification of a service or coverage termination . . . and annually thereafter."). If the Medicare Advantage plan upholds its original determination, there is an "automatic reconsideration by an [Independent Review Entity] contracted by CMS. . . ." Managed Care Manual (CMS Pub. 100-16), Ch. 13, § 10.3.3. A beneficiary that remains dissatisfied with a decision may appeal to an Administrative Law Judge, to the Medicare Appeals Council, and ultimately to federal court. Managed Care Manual (CMS Pub. 100-16), Ch. 13, § 10.1. Holding determinations affecting access to care to multiple levels

of independent review provides an indispensable safeguard against financial concerns unduly motivating patient care decisions. The mandated appeal procedures contain clear deadlines and time-frames for each level of review ensuring timely responses. None of these protections are afforded under the vague review requirements proposed by CMS.

In addition to exhaustive and independent appeal procedures, the manual that governs Medicare Advantage plans has an entire chapter detailing "Quality Assessment" to ensure that beneficiary care does not suffer under the plan. Managed Care Manual (CMS Pub. 100-16), Ch. 5. All Medicare Advantage plans must have a quality improvement program that meets the following four requirements: 1) follow written policies and procedures that reflect current standards of medical practice in processing requests for initial or continued authorization of services; 2) have in effect mechanisms to detect both under utilization and over utilization of services; 3) measure performance under the plan using the measurement tools required by CMS and report its performance to CMS; and 4) make available to CMS information on quality and outcomes measures that will enable current and potential beneficiaries to compare health coverage options and make informed decisions with respect to the available choices for Medicare coverage. *See* Managed Care Manual (CMS Pub. 100-16), Ch. 5, § 20; *see also* 42 C.F.R. § 422.152(b). Furthermore, recognizing the particular risks associated with providing incentives to physicians, the Managed Care Manual requires that whenever a physician incentive plan exists, the Managed Care entity must "review utilization data to identify patterns of possible under-utilization of services that may be related to the incentive plan." Managed Care Manual (CMS. Pub. 100-16), Ch. 5, § 20.2.1. None of these safeguards, which CMS has called "critical elements of each M+C organization's quality-related responsibility," 63 Fed Reg. 34968, 34991 (June 26, 1998), are present under CMS's proposed gainsharing plan.

IV. LIMITATIONS

At your request, we have focused on Medicare issues raised by the proposed regulation. We have not considered any other issues that may arise under other federal law such as limitations applicable to hospitals that are tax-exempt under Internal Revenue Code § 501(c)(3). Similarly, we have not considered any issues arising under state laws including state laws barring financial relationships between physicians and the entities to which they refer patients or state medical practice acts.