



By Messenger

February 17, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: CMS-1403-FC, Medicare Program; Section II.N.1 of final rule with comment period, EXCEPTION FOR INCENTIVE PAYMENT AND SHARED SAVINGS PROGRAMS.

Dear Ms. Frizzera:

On behalf of the American Hospital Association's (AHA) more than 5,000 member hospitals, health systems and other health care organizations; the Association of American Medical Colleges' (AAMC) nearly 400 major teaching hospital and health system members and 125,000 faculty members; and the Federation of American Hospitals' (FAH) more than 1,000 investor-owned and -managed hospital members, we appreciate this additional opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed exception to the physician self-referral law for incentive payment and shared-savings programs.

We welcome CMS' decision to reopen the comment period and appreciate its willingness to create a new exception to enhance the ability of hospitals and physicians to work together to foster high-quality, cost-effective patient care using economic incentives. As CMS stated in the Preamble to the proposed rule, the use of incentives to foster improvement in quality and efficiency is embedded in many private and government health care initiatives. At the federal level, these include the Institute of Medicine's reports on quality, CMS' Medicare pay-for-reporting and value-based purchasing proposals, and many of the delivery reform proposals recommended by the Medicare Payment Advisory Commission.

We have raised significant concerns about the complexity and limitations of the proposed exception. Specifically, we do not believe that the proposed exception would foster the types of hospital-physician relationships that lead to the best quality health care delivery. In addition, the proposal's complexity, burden and cost make it unlikely that most providers could use the exception. Significant changes are needed to address those concerns, and to better reflect the variety of legitimate, innovative initiatives hospitals and physicians want to implement. In the detailed comments attached to this letter, we offer our specific recommendations for an exception that strikes the right balance between protection for the Medicare program and flexibility for hospitals of different sizes, locations and resources to work with physicians to structure arrangements to meet the quality, patient safety and efficiency goals that public policy demands.

In advancing our recommendations, we are mindful of the concerns underlying the self-referral law. Over the past few years, CMS has engaged in multiple rulemakings to improve the regulatory framework and to provide greater clarity to existing rules. Those rulemakings have also shown the practical limitations and difficulties which CMS encounters in enforcing the strict liability statute, and additional difficulties created by tying compliance with self-referral exceptions to compliance with other unrelated federal and state laws with their own enforcement schemes.

As a result, the framework currently used by CMS to develop self-referral regulations is not well suited for this new exception. While our systemic concerns with the overall framework apply beyond the current incentive payment and shared savings exception, we nevertheless identify those areas of concern here and make recommendations regarding alternate approaches. In some instances, our recommendations address issues of general applicability that remain outstanding after the recent self-referral rulemakings. In sum, our comments are intended both to describe our view of a better framework for implementing the self-referral statute and to address the merits of the proposed exception under consideration.

CHANGE IS NEEDED IN THE DESIGN OF THE EXCEPTION

The goals of the statute can be met through an approach that specifies only the essential requirements of an exception while permitting flexibility for how they are met. As proposed, CMS' exception establishes not only the essential requirements but also the specific means it deems necessary to achieve them, as well as additional audit-like requirements. This approach creates unnecessary barriers to designing arrangements that benefit patient care.

First, CMS' proposal stifles innovation. The level of specificity and detail in the proposed regulation results in a very narrow exception. By regulating not only the "what" but the "how" of an incentive payment or shared-savings program, CMS limits hospitals' ability to incorporate the health care community's evolving understanding of what contributes to patient quality and safety. Unless the precise letter of the regulation is met, a hospital would not qualify for the exception.

Second, the significant burden imposed by CMS' current approach is redundant. It requires specific processes and recordkeeping without regard to the systems already in place at hospitals. A hospital may have equally good or effective ways to accomplish what is intended; however, it must conform to the specifics of the regulation.

Third, the inclusion of so many requirements that are not essential to determining whether an arrangement is for a legitimate purpose creates undue legal risk for hospitals. The design of the self-referral law does not give providers room to argue that any aspect of non-compliance creates more or less risk of harm to the Medicare program. Form requirements – which clearly do not have the same weight as core requirements in determining whether an arrangement is legitimate – should not be included in the regulation.

The exception for incentive and shared-savings programs differs substantially from other exceptions where the focus is on the legitimacy of the remuneration. Because these programs strive to improve the quality and efficiency of care delivery, CMS should evaluate the arrangement based on whether the hospital demonstrates that it is pursuing legitimate quality or efficiency initiatives. The very dynamic field of quality and efficiency practices presents a broad universe against which the arrangements could be assessed.

We recommend the following framework for developing the regulation:

- Establish only those requirements that are essential or material to reasonably ensure that the arrangement is not to induce referrals.
- Establish accountabilities for hospitals to demonstrate goals for improving quality and efficiency, but do not regulate the specific means by which they are achieved.
- Use the Preamble to the rule to provide non-exclusive illustrations of potential ways to demonstrate compliance with elements of the exception. Guidance on ways to comply with the exception is welcome, but the current proposal creates mandates that are significantly limiting.

CHANGE IS NEEDED IN THE CONTENT OF THE EXCEPTION

The regulation should focus on the broader construct for an exception and establish the essential obligations. CMS' proposed regulation has 16 sections and multiple requirements within each (more than 40 specific requirements overall). Most of the requirements detail the ways in which a program must be implemented, including identifying recordkeeping or documentation requirements. The net effect is that a self-referral regulation is transformed into an inflexible process for organizing and operating quality improvement and care delivery improvement programs rather than being a process that allows for innovation.

The regulatory exception should be written instead with an expectation that qualifying incentive payment and shared-savings programs covered by the rule will be conducted in a manner that is consistent with best practices for delivering high-quality care. These programs will be established within the larger quality program at a hospital. Every day, hospitals strive to improve the quality of the care they provide. Hospital quality processes include quality improvement committees composed of a variety of professionals with the clinical expertise to help set quality goals for the hospital and oversee progress toward their achievement. Hospital boards play an important role in reviewing the quality agenda for the hospital. Accrediting organizations, state licensure agencies and Medicare quality improvement organizations all have roles in overseeing the quality of care provided to patients. The ultimate test and burden for a hospital will be to demonstrate that its programs are designed in keeping with best practice and best evidence. The regulation need not, and should not, try to supplant, duplicate or recreate existing quality improvement processes or the structures for monitoring quality of care.

Specifically:

- Incentive payment and shared-savings programs should be based on patient care or cost-saving practices that are supported by credible medical evidence;

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- Incentive payment and shared-savings programs should be monitored by the hospital to protect against inappropriate reductions or limitations in patient care services;
- Payments to physicians should reflect a physician's contributions and achievements;
- The payment should be made pursuant to a legally binding written agreement; and
- Documentation should be maintained on the design of a program and the amount and calculation of payments to be made under the program.

For all of these reasons, outlined in further detail in our attached comments, we urge CMS to issue a new proposed rule.

Thank you for the opportunity to comment on this topic. If you have any questions, please feel free to contact us. You may contact Maureen Mudron, the AHA's deputy general counsel, at 202-626-2301 or mmudron@aha.org; or Ivy Baer, AAMC's director and regulatory counsel at 202-828-0499 or ibaer@aamc.org; or Jeffrey Micklos, FAH's executive vice president, management, compliance and general counsel at 202-624-1521 or jmicklos@fah.org.

Sincerely,

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Executive Vice President
American Hospital
Association

Joanne Conroy, MD
Chief Health Care Officer
Association of American
Medical Colleges

Charles N. Kahn III
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Attachment

Detailed Comments of the American Hospital Association, Association of American Medical Colleges and Federation of American Hospitals on CMS' Proposed Exception to the Physician Self-referral Law for Incentive-payment and Shared-savings Programs

In the discussion that follows, we present draft language for a regulation that creates two new self-referral exceptions for hospital payments to physicians under: (1) quality improvement incentive-payment programs and (2) shared-savings programs. We recommend that a separate exception be created for each type of program. While many of the same requirements will apply, the fundamental purpose of each type of program is different and requires a different analytical framework. For incentive-payment programs, such as quality improvement programs, the purpose is to encourage adherence to sound practices that achieve patient safety and quality improvement goals; if any savings result they are incidental. For shared-savings programs, the purpose is to achieve cost savings through reduction in the inefficiencies in the delivery of care, without adversely affecting the quality of care.

We propose five core requirements for each exception. All are taken from, or are variations on, elements in the Centers for Medicare & Medicaid Services' (CMS) proposed exception. For this purpose we present a consolidated exception, noting where there are separate provisions for the incentive exception or the shared-savings exception. Our recommended language is in bold text.

RECOMMENDATIONS FOR INCENTIVE-PAYMENT AND SHARED-SAVINGS PROGRAMS EXCEPTIONS

Remuneration provided by a hospital to a physician on the hospital's medical staff is covered under the exception if all of the following conditions are met.

(1) Structure.

(A) For incentive-payment programs –

(i) The remuneration is provided as part of a documented incentive-payment program to achieve improvement of the quality of hospital patient care services through the adoption or performance of clinical practices designed to achieve patient safety or quality improvement goals (quality practices);

(ii) Remuneration is in the form of cash or cash equivalent payments, including nonmonetary remuneration.

(B) For shared-savings programs –

(i) The remuneration is provided as part of a documented shared-savings program to achieve actual cost savings for the hospital resulting from the adoption or performance of practices designed to reduce inefficiencies in the delivery of care without an adverse effect on or diminution in the quality of hospital patient care services (cost savings practices); and

(ii) Remuneration is in the form of cash or cash equivalent payments, but not including nonmonetary remuneration.

The exception protects the use of incentive payments when their purpose is to improve the quality of care or achieve cost savings without adversely affecting the quality of care. Items (A)(i) and (B)(i) in our suggested language generally reflect the concepts from CMS' proposal. They establish two accountabilities for a hospital: (1) to demonstrate that the purpose of its program is to improve the quality of care or achieve cost savings; and (2) to maintain documentation of the creation and implementation of the program.

Item (A)(ii) permits the use of non-monetary remuneration for incentive-payment programs only, an expansion of what CMS proposed, which would cover only cash or cash equivalent payments. For quality improvement programs, prohibiting the use of non-monetary remuneration is unreasonably limiting. For example, many community-based physicians who practice alone or with a small number of physicians would find it helpful to have access to clinical databases and decision tools to equip them to make the best treatment recommendations for their patients, or to have the services of a nurse who will make follow-up contacts with patients. The exception should enable a hospital to make such resources, which further quality improvement activities, available to a physician.

The clinical or practical content of quality-improvement and shared-savings programs should not be regulated by an exception. By specifying baselines and targets for performance practices and thresholds for when payments may be made, CMS' proposal (section (3)) creates an overly restrictive framework for managing the programs. This should be avoided for two reasons:

1. It is not in the purview of the self-referral law to establish quality policy or practices.
2. Attempting to incorporate specific examples or acceptable types of quality and efficiency processes into a "static" fraud and abuse regulation will limit the ability of a program to stay up-to-date with developments in the quality field.

We strongly believe that other requirements in this exception (e.g., the credibility of the selected practices, the appropriateness of the practices for the hospital's services and the linkage of a physician's payment to achievement of quality improvements) provide CMS the tools needed to evaluate the legitimacy of a program.

(2) The performance practices under the incentive-payment or shared-savings programs –

(A) Use an objective methodology, are verifiable, and are supported by credible medical evidence;

(B) Are individually tracked;

(C) In the aggregate are reasonable for patient care purposes;

(D) Are monitored throughout the term of the arrangement to protect against reductions or limitations of medically necessary patient care services; and

(E) Can be audited through the use of documentation that is retained by the hospital to support the program as established and implemented.

This provision goes to the heart of the exception's purpose and sets the standard for practices that may become part of an incentive-payment or shared-savings program. All of the provisions are drawn from CMS' proposal.

However, our recommendation does not prescribe, as CMS' proposal does, which specific practices are acceptable for compliance purposes. CMS' approach would unreasonably limit the quality improvements that could be achieved. For example, by only allowing practices that are part of CMS' *Specification Manual for National Quality Measures*, CMS would preclude the use of hundreds of practices that meet the standard of the exception, including many endorsed by other nationally recognized organizations.

- A variety of patient-safety and quality-improvement practices have been demonstrated to improve the quality of care. For example, the National Quality Forum (NQF) has adopted 30 safe practices that are based on good clinical evidence but unrelated to the measures included in CMS' *Specifications Manual*. The Joint Commission has adopted 16 national patient safety goals, and the World Health Organization is pursuing five safety goals. In addition, the Agency for Healthcare Research and Quality has included hundreds of practice guidelines, all with a sound evidence base and leading to better patient outcomes, in the National Guidelines Clearinghouse. Conversely, CMS' manual includes only a small subset of the nationally recognized patient-safety and quality-improvement practices that clinicians should be encouraged to adopt to improve quality or patient safety.
- We believe the Preamble of the rule should be used to provide examples of practices that CMS would "deem" to satisfy the criteria of the exception. These examples should be illustrations only and not represent the exclusive list. Because research and knowledge regarding quality and efficiency practices will continue to evolve, hospitals need the flexibility to use other practices that meet the criteria in the exception.

We recommend that "independent medical review" (a requirement included in CMS' proposal (section (5)), not be mandated in an exception. Including such a mandate would ignore the independent reviews and external reviews that currently occur at hospitals. Tying these efforts to credible medical evidence should be sufficient. Upon audit, a hospital would be expected to provide documentation establishing the link between the quality program and the credible medical evidence.

- Quality and efficiency programs are developed as part of the larger quality and patient-safety programs at hospitals. A quality improvement committee composed of a variety of professionals with clinical expertise identifies quality goals and objectives, adopts appropriate practices, and monitors progress towards their achievement. These efforts involve senior hospital leadership and the governing body. Requiring external review would result in the creation of a new infrastructure that unnecessarily duplicates the safeguards already in place at hospitals and lead to delays in implementing innovations as they become available.

- Requiring independent medical review also fails to recognize not only the internal oversight, but also the external, already in place to ensure quality care and patient safety. State licensing agencies and accrediting organizations have an ongoing role, and a variety of Medicare contractors are involved in medical necessity decisions. In addition, Medicare Quality Improvement Organizations continuously review the quality of care for beneficiaries. Also, as part of their quality-improvement programs, hospitals share a significant amount of information about their practices with organizations that review hospitals and assist with their improvements in the care provided (e.g., the National Surgical Quality Improvement Project and patient safety organizations).
- If CMS wants to consider external review as a positive factor in evaluating whether the exception is met, it could so state in the Preamble to the rule. It should serve only as an illustration and not the exclusive means to demonstrate the exception is met.

We recommend that an exception should not mandate what items, supplies, devices or new technology a hospital uses for patient care, as CMS' proposal would require (section (6)). Our recommended exception includes multiple protections to ensure that the programs do not adversely affect patient care.

- Hospitals may not be able to meet the requirement that physicians "have access to the same selection of items, supplies or devices as was available at the hospital prior to commencement of the program." For example, a device may be recalled or no longer available. Physicians may stop using a particular item for reasons unrelated to the program; a hospital should not be required to continue stocking it. Hospitals, working with their medical staffs, should have the ability to monitor the items, supplies and devices that are used and make decisions about their availability without fear of violating a physician self-referral requirement.
- CMS' proposal does not take into account that hospitals and their governing boards continually make business decisions about which purchases to make, and weigh the merits of significant investments in new technology. Mandating the circumstances in which new technology must be purchased by a hospital is beyond the scope of the self-referral law. Such an approach would undermine the authority and responsibility of the hospital's governing body to use resources well and exercise judgment in conducting the affairs of the hospital.

(3) Payments must reflect the physician's achievements, and accurate documentation of the amount and calculation of payments made under a program must be maintained.

The exception requires that the amount paid to a physician must be evaluated against his or her achievements under the program or, if the incentive is tied to an achievement by a group, the physician's payment is evaluated against the group's collective achievement. Payment on a *per capita* basis should not, as CMS' proposal would require, be the only permitted form of payment. This approach would not allow programs to fully achieve the goals of the exception. Instead, other types of distributions should be permitted, which can be evaluated on a case-by-case basis

and an assessment of all the facts and circumstances. The exception also assures accountability by requiring documentation of the amounts paid and the calculation of those payments.

To be most effective in achieving quality improvement goals, the incentive must be as closely connected as possible to the individual physician's performance of the designated quality-improvement practice. When merited by the particular circumstances, and as reflected in the protocol for the practice, hospitals should have the option of reducing or eliminating payments to physicians whose personal contribution or effort did not meet the program's goals, or whose efforts resulted in a decrease in quality. Permitting *per capita* payments only would mean that all physicians are paid the same amount regardless of their individual performance. Mandating per capita payment is not necessary to protect against improper referrals. Notably, our recommendations already address that concern by requiring that remuneration not be related to the volume or value of referrals or other business generated by a physician. (See Recommendation (5), below.)

Our recommendation does not preclude, as CMS' proposal (section (11)) would, payments to encourage maintenance of effort. CMS' proposal fails to recognize that significant effort often is needed to maintain the achievements of prior years.

- Quality-improvement and efficiency programs often include progressive goals. After achieving a preliminary goal, performance must be sustained for a period of time. A higher standard is then set, which, once achieved, also must be sustained. This type of improvement cycle could continue for some time under a given program, depending on the practices adopted, the organization's level of performance at the outset, and performance expectations.

Our recommendation also does not include, as CMS' proposal (Section (13)) does, an absolute ban on a hospital's quality improvement efforts that could lead to a shorter length of stay as a patient in the hospital. Many quality-improvement practices will lead to an appropriate reduction in a patient's length of stay, e.g., coordination of tests and enhanced discharge planning. The hospital should be permitted to use these practices.

We decline to include in our recommendation a series of payment-related provisions in CMS' proposal that do not constitute core elements for determining whether an arrangement is legitimate and, in some cases, also are confusing or counterproductive.

- CMS' proposal (Section (11)) prohibits payment for cost savings that result in a diminution in quality care. Whether a cost-savings practice – as opposed to other unrelated factors – lowered quality may be difficult to determine through medical evidence. The exception already includes the most important protection – to monitor patient care under the program.
- CMS' proposal (section (12)) appears to dictate how the cost of an item is calculated. However, it is possible that cost savings can accrue in other ways. For example, one device may require fewer supplies (such as less anesthesia) for implantation than another

device that is equally effective. The hospital should be permitted to capture such savings and incorporate them into the calculation of payments to the physicians.

- CMS' proposal (Section (13)(iv)) appears to regulate the pass-through of payment by a group practice to an individual physician. A participating physician should have the flexibility to assign the payment to his or her practice. For purposes of this exception, the focus should be on whether the objectives of a program were met and whether the physician's payment was calculated consistent with a predetermined rate or formula, not on where the payment is sent.

Our recommendation does not attempt, as CMS' proposal does (section (6)(ii)), to regulate financial relationships between non-employee physicians and third parties. CMS' proposal would prohibit payment to a physician for the use of an item, supply or device if he or she has any financial relationship with the manufacturer, distributor or group purchasing organization that arranges for the purchase of the item, supply or device. Those relationships are beyond the scope of the hospital's relationship with a physician and should not be a condition of meeting an exception.

- Financial relationships between physicians and these non-hospital entities are being scrutinized by Congress and the Office of the Inspector General (OIG), and both have made it clear that they are considering the manner in which the federal law should deal with any problems those relationships create. We and our members are sensitive to the potential conflicts of interest and other important issues at the heart of these inquiries. But resolving these issues by means of a CMS rulemaking would inappropriately intrude into and possibly constrain these policy reviews.
- We also are concerned that the proposed rule would require hospitals to police financial relationships between non-employee physicians and third-parties, and subject hospitals to potential liability for any undisclosed relationships, even lawful undisclosed relationships, between them. Hospitals should not be required to investigate relationships between non-employed physicians and third parties.

(4) Payments must be made under a legally binding agreement, with a minimum term of one year, which is reduced to writing.

A core requirement of the exception is that the relationship between the hospital and a participating physician be governed by a legally enforceable agreement that is reduced to writing. In contrast to CMS' proposal (section (8)), which specifies at a detailed level what must be included, the exception relies on the long established body of law in individual states to control what is required for a binding agreement.

Specifying the detail for an agreement also exposes the hospital to the risk of non-compliance, even though these are audit-like requirements and clearly not necessary for demonstrating that core requirements of an exception are met. Non-compliance with a recordkeeping requirement should not be a trip wire for a violation when the consequence is recoupment of Medicare

payments, particularly for payments that were made for medically appropriate services to Medicare beneficiaries.

The detailed documentation requirements in CMS' proposal (section (15)) are similarly unnecessary and only add to increasing the risk of non-compliance with non-essential requirements. In our recommended exception, documentation is required for all the core requirements and accountabilities.

Similarly, the exception does not, as CMS proposes (section (10)), fix a maximum time period for an agreement. The exception's focus on establishing and implementing appropriate programs and practices, and ensuring that payments to physicians relate to their achievements, are the core requirements for determining that the arrangement has a legitimate purpose.

(5) The remuneration to be paid over the term of the arrangement (or the formula for the remuneration) is set in advance, does not vary during the term of the arrangement and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

This core requirement of the exception, taken from CMS' proposal (section (13)(i)), prohibits making payments that are related to referrals or other Medicare business generated between the hospital and the physician.

Our recommendation does not include an apparently redundant provision in CMS' proposal (section (14)) on payments related to volume. This recommendation incorporates CMS' general prohibition on payment that takes into account the volume or value of referrals or other business generated by a physician, as that standard has traditionally been articulated in other self-referral exceptions.

COMMENTS ON OTHER REQUIREMENTS IN CMS' PROPOSAL

Our recommendations do not include, as CMS' proposal does (section (4)), an attempt to regulate which physicians on the medical staff may participate in an incentive or shared-savings program. CMS' approach does not recognize the realities at many hospitals and will frustrate the achievement of quality and efficiency goals. There should not be a requirement for an arbitrary minimum number of physician participants (five is proposed); nor should participation in a program be limited only to physicians on the staff at the start of a program; and there should not be a requirement that all physicians are eligible to participate.

- Having fewer than five participating physicians (or any minimum number unrelated to achieving the goals of a program) should not prevent a quality-improvement or efficiency program from moving forward. In many cases, a hospital will not have five practicing physicians in a particular area of focus. This is especially the case for rural hospitals. It also will be the case for improvement efforts that involve specialty services where often there are fewer than five, and maybe only one or two, specialists in the entire community.

Having a large pool of physicians is not necessary to protect against the risk of payments for referrals. The core elements of the exception (e.g., legitimate goals of quality measures and payment not related to volume or value of services) address that concern.

- Restricting participation to only those physicians on staff at the commencement of a program will hinder a hospital's quality improvement activities and limit the benefit to patients. The composition of a hospital's medical staff ebbs and flows due to a variety of factors, but the need for quality measures does not, making it important that a hospital can involve all members of the staff in meeting those quality and efficiency objectives, regardless of when they join. A hospital should have the ability to include physicians who join their medical staffs at any time, subject to an adjustment in the expectations and rewards to reflect the period of their participation.
- It may be impossible for hospitals to meet the requirement that all physicians in a department or specialty be eligible for a program. For example, a program may involve a particular procedure for which not every physician in a department or specialty has privileges to perform. This requirement also would appear to require that medical residents be eligible for these programs as members of the medical staff, yet their privileges are generally restricted. Not all physicians will have the level of interest necessary to support the goals of the program, and they will vary in their use of the hospital and commitment to achieving its goals. The objective of the program is to achieve improved care for the most patients. The hospital should be able to develop an incentive-payment program designed to efficiently and effectively achieve the desired quality outcomes.

Our recommendation does not include, as CMS' proposal (section (7)) does, a requirement for written notice to patients affected by a program, including a possible "opt out" provision. Adopting CMS' approach would create the wrong impression for patients that the use of recognized quality or effectiveness protocols would mean lesser care and would not be useful to patients.

- Physicians would continue to have the same professional responsibility to make medically appropriate treatment decisions in consultation with the individual patient. Disclosures related to treatment decisions should not be treated any differently when they are part of a quality-improvement protocol or shared-savings program.

Our recommendations do not include several of CMS' proposals that relate to compliance with other laws. In each instance, we believe the combination of the requirements in our proposal and legal obligations already imposed on hospitals address the underlying concerns. It is redundant to include, as CMS does (section (9)), that a practice that encourages violation of a federal or state law is prohibited. Any practice that violates federal or state law already creates liability for a hospital. Additionally, requiring, as CMS' proposal does (section (16)), that an arrangement not violate the Antikickback statute, or other federal or state laws governing billing or claims submission, is unnecessary. Its inclusion also suggests, incorrectly, that participants have a higher compliance obligation than they otherwise would.

- We recognize that this requirement has appeared in a number of exceptions promulgated by the Secretary. In the context of hospital-physician financial relationships, however, the requirement adds a confusing degree of redundancy that implies hospitals must go beyond their normal compliance regimes to assure compliance in some unspecified manner. Hospitals already are required to certify their compliance with the Antikickback statute and other relevant statutes, regulations and rules when they submit Medicare enrollment forms and annual cost reports. By including compliance as a separate element of this exception, the regulation implies, incorrectly, that participants in acceptable shared-savings or incentive plans have some different or additional affirmative duty to ensure compliance. No such duty need be imposed.
- In addition, in the absence of general guidance from the OIG on the propriety of shared-savings and/or incentive plans, a strict interpretation of this element could require that participants obtain an OIG Advisory Opinion before implementing the plan. All OIG Advisory Opinions on such plans indicate that they implicate the statute, but that OIG will not prosecute a particular provider for engaging in a particular transaction. The opinions prohibit, by their own terms, reliance by non-parties. Obtaining an Advisory Opinion as a condition precedent to implementing a Stark-compliant plan would undermine the utility of the exception. The delay inherent in such a procedure will no doubt discourage the adoption of clinical integration models our members believe are essential to improving the efficient delivery of quality health care services.