



**American Hospital
Association**

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Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1403-P, Medicare Program; Proposed Rule, PHYSICIAN SELF-REFERRAL AND ANTI-MARKUP ISSUES.

Dear Mr. Weems:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the 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.

The AHA welcomes CMS' willingness to consider a new exception under the physician self-referral law to improve the delivery of health care services by allowing hospitals and physicians to use economic incentives to foster high-quality, cost-effective care. The use of incentives is essential to achieve the quality, patient safety and efficiency objectives embedded in many current federal health care initiatives – from the Institute of Medicine's reports on quality, to CMS' Medicare pay-for-performance and value-based purchasing proposals, to many of the delivery reform proposals recently recommended by the Medicare Payment Advisory Commission.

OVERALL COMMENTS

Hospital care depends on the ability of hospital leaders and physicians to work together to efficiently get patients the right care, at the right time, in the right setting. The use of incentives is critically important. Hospital privileges and membership on the medical staff no longer provide hospitals the same ability to engage physicians in the kind of system-based efforts necessary to achieve quality and efficiency goals for health care. With care increasingly shifting to the outpatient setting, many physicians are less dependent on hospitals as a place to practice. Combined with growing economic



pressures on their practices, physicians often are less willing to devote the necessary time and energy to major delivery reform efforts. Through clinical integration, hospitals and physicians can work together to achieve care goals. The use of incentives plays a critical role.

In prior comments, we urged CMS to “view the application of physician self-referral prohibitions not only from the perspective of controlling abusive behavior, but also from the perspective of encouraging care improvement initiatives that would benefit patients, hospitals and physicians.” We appreciate CMS’ attempt to move in that direction.

The federal government should encourage the use of incentives and adapt the regulatory environment to enable their use with appropriate safeguards. **The AHA supports the creation of a new exception that would establish basic principles for the appropriate use of incentive or efficiency programs. However, we are concerned that the proposal, as written, is so complex, costly and limiting that it will not realistically advance the goals for health care delivery. Further, its use will likely be out of the reach of most providers.** The primary audience for this exception is hospitals and physicians who must adopt and implement programs to meet these requirements. **The exception should be simple, straightforward and not so costly as to negate its value or become prohibitive to implement.**

In particular, the proposal does not recognize or take advantage of the way practice protocols are developed and used today. It also fails to build on the quality improvement (QI) processes hospitals already have in place, some of which are required by regulation and monitored.

It is especially important that the exception recognize the role of evidence-based work. To a large extent, the protections that should be included in this exception are the same ones embedded in the process for developing quality and patient safety improvement protocols and efficiency programs. The proposed exception, as written, is primarily a statement of specific means to achieve implied but unstated goals. The exception must provide greater clarity on these goals and give latitude for a variety of means to meet them. **It should utilize the processes (both internal and external) that are present in a well-functioning delivery system to the maximum extent possible, rather than superimposing a separate infrastructure that would require hiring outside entities to duplicate functions already being performed.** When evidence-based patient safety or quality improvement practices are in place, the checks and balances in those systems should drive the exception.

The proposed exception follows the traditional physician self-referral rule approach of controlling payment. This approach needs to be re-evaluated in the new context of quality improvement. The proposed payment constraints, especially the limiting of allowed payment to only per capita approaches, will frustrate rather than foster achievement of the objectives in many instances. When the objective is to change specific physician practices, the incentive must be as closely connected to encouraging

that result as possible – in other words, it must focus on performance. **Incentive payments should be permitted to reflect different levels of individual performance, not simply reward participation.**

We believe that the basic precepts of the exception should be: permit the use of incentives to encourage adherence to sound practices that achieve patient safety and quality improvement goals (evidence based, determined by qualified professionals, with an independent voice in decision-making); use existing processes to safeguard quality; and allow incentives that are clearly linked to an organization's patient safety and quality improvement goals and specifically tailored to an individual physician's role in achieving those goals. We evaluate the specifics of the proposed exception using this framework in the comments that follow.

SPECIFIC COMMENTS

Appropriate Patient Safety and Quality Improvement Practices

Permitted performance measures are too limited. Section 2 of the proposed exception establishes requirements for performance measures related to an incentive or shared-savings program. These requirements include limiting quality measures to those listed in CMS' *Specification Manual for National Hospital Quality Measures*. This proposed approach has the wrong focus. The Manual includes only a small subset of nationally recognized patient safety and quality improvement measures that are related to a few behaviors that clinicians should be encouraged to adopt to improve quality or patient safety. The measures in the Manual originally were developed to support the specific quality improvement projects of interest to CMS. These also now are used for public reporting purposes. However, no one would suggest that they constitute the universe of safety or quality improvement activities in which hospitals and their medical staffs should be engaged. Thus, the exception should not limit the acceptable patient safety and quality improvement practices to just those for which CMS has included measures in its Specifications Manual.

There are a variety of patient safety and quality improvement practices that have been shown by credible, scientific evidence 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 has five safety goals that it is pursuing. In addition, the Agency for Healthcare Research and Quality has included hundreds of practice guidelines in the National Guidelines Clearinghouse, all having a sound evidence base and leading to better patient outcomes.

The picture is different with respect to the existence of a national body or authority to evaluate the comparative effectiveness of drugs, devices, supplies and equipment. Peer-reviewed research, scientific publications or well-vetted best practices or evaluations from knowledgeable professionals are available in some cases, however. Congress and other parties have taken interest in the creation of a national entity charged with synthesizing and making readily available evaluations of comparative effectiveness. The current lack of such a national entity should not be an insurmountable barrier.

The final exception should recognize and allow the use of any patient safety or quality improvement or efficiency practice with a sound scientific basis, whether adopted by a nationally recognized body or authority or derived from research, scientific publications or professional experience, where there are appropriate processes providing oversight to their use. See the comments below under “appropriate oversight” for our process recommendations.

Requiring that all existing and new technology be made available is counterproductive. Section 6 of the proposed exception requires that the “same selection of items, supplies or devices as was available” to a physician prior to the program must be continued, and that the hospital may not limit the availability of new technology (that meets certain conditions). We agree that physicians participating in an incentive or shared-savings program must not be restricted in making medically appropriate decisions for their patients. However, it is important to keep in mind that doing something “different” does not mean it is either less appropriate or inappropriate. Safety literature makes clear that “sameness” drives safety. Reducing variation that has no demonstrated value for patient care is an improvement.

The provisions in Section 6 should be modified to:

- **Permit incentives to encourage the use of preferred items or disincentives for the use of non-preferred items based on patient safety and quality improvement or efficiency practices adopted through an appropriate process** (see comments below under “appropriate oversight”). An effective program, for example, may include an exception process involving peer review when a physician seeks to use a non-preferred item and still receive an incentive payment.
- **Recognize that hospitals and their governing boards are continually making business decisions about what to purchase and from whom, as well as weighing the merits of significant investments in new technology.** The fact that new technology is available in the marketplace does not mean it is better or more suited for delivering quality patient care.

Appropriate Oversight

Requiring independent medical review will result in the creation of an unnecessary infrastructure. Section 5 of the proposed exception requires independent medical review at all stages of a program. The AHA agrees that patient safety and quality improvement practices must be appropriate and that their evaluation and selection should include the

views of those who will not financially benefit from a program. Ultimately, the hospital's governing board is responsible for making such judgments. The requirement that independence can only be satisfied by someone with no affiliation with the hospital or the participating physicians is unreasonably restrictive. As proposed, the exception would unnecessarily require a new infrastructure for review and approval of quality improvement or efficiency activities and generate a new and unnecessary cottage industry to perform these functions.

Hospitals are adopting and implementing quality protocols and efficiency activities that are not only expected by regulators and payers (e.g., state licensure agencies, the Medicare program and commercial payers) but are relied upon to assure the protection of patients and quality care. There is no reason to assume that they are not suited to, or do not provide adequate protections for, the quality, safety and efficiency programs contemplated by the exception.

Hospitals' internal processes ensure independent judgment and effective oversight in the creation and operation of efficiency and quality improvement activities. Internal QI committees consisting of a variety of professionals with relevant clinical expertise identify quality goals and objectives, adopt appropriate practices, and oversee progress toward the chosen goals. As part of this process, the QI committee receives critique and feedback from clinicians and relevant specialty medical departments to ensure the practices adopted are based on sound clinical judgment.

The use of patient safety and quality improvement practices also permits the reporting to, and monitoring by, hospital governing boards and external quality improvement, accreditation and regulatory agencies. Hospital governing boards can – and do – play an important role in oversight. They have a unique role in hospital quality improvement activities because their membership includes representatives of the community served by the hospital. They have a fiduciary duty to ensure that the hospital is meeting its obligations to its patients, community and other stakeholders. In carrying out this duty, the governing board takes an active role in monitoring and evaluating the hospital's quality improvement activities. In doing so, the board brings independence and ensures that appropriate changes and refinements are implemented to assure that the quality and safety or efficiency goals are being met.

Oversight, however, does not stop at the QI committee or hospital board level. Hospitals share data with various patient data registries, such as the National Surgical Quality Improvement Project. While these registries do not necessarily make reported data public, they exert a powerful influence over improvement activities because they offer a national basis for peer comparison and recognition. This oversight helps to ensure that desirable behaviors are achieved, reinforced and expanded. Hospitals also must report various patient safety and quality improvement measures to accrediting bodies such as The Joint Commission, state health department surveyors (in both their state and Medicare roles), Medicare's quality improvement organizations and myriad other Medicare contractors overseeing medical necessity decisions. All of these groups are

engaged in active oversight of the care rendered in hospitals. In carrying out these responsibilities, they also may have access to information about hospitals' use of incentive programs.

The final exception should recognize hospitals' reliance on sound quality improvement processes to evaluate and approve whatever patient safety and quality improvement practices are used (e.g., reliance on quality or efficacy standards developed by a nationally recognized body or authority). The exception should permit the use of an internal process that includes professional expertise rendered by individuals who will not be part of an incentive or efficiency program to adopt patient safety and quality improvement and efficiency practices.

Requirements for physician participation are unrealistic and counterproductive. Section 4 of the proposed exception requires a minimum of five physician participants in a program. The proposed exception is not specific about what this minimum number is intended to achieve. In many cases, a hospital will not have five practicing physicians in a particular area of focus, and having fewer than five participating physicians should not prevent a quality improvement or efficiency program from moving forward. In addition, according to the draft exception, if a program focuses on a particular department or specialty, it must be open to all physicians in that department or specialty. This is impractical and may be counterproductive. Other protections should be adequate to assure the appropriate care of patients.

Not all physicians will have a level of interest necessary to support the goals of the program. In some instances, physicians on the staff will have financial interests that conflict with the interests of the hospital. The hospital and other physicians should not be required to make them privy to business and other strategic information related to the program. The objective of the program is to achieve improved care for the most patients. The physicians on staff will vary in their use of the hospital and commitment to achieving its goals. For a combination of reasons, using the grant of privileges to secure the cooperation of physicians for many traditional activities is no longer feasible. Lifestyles, other investments, the shift of care to outpatient settings, and changes in physician payment have made a difference in what conditions can be reasonably imposed as a condition of membership on the medical staff. The use of carefully tailored incentives is necessary to achieve any improvement goal.

The proposed participation requirements, particularly in combination with required per-capita payment (see discussion below), would require a reward without regard to individual physician performance. Incentives need to be used to create, institutionalize and expand behaviors consistent with the objectives of the program. Again, it is important to keep in mind that there are other ways to protect the quality of care being provided patients. **The final exception should afford hospitals the latitude to determine which or how many physicians may participate.**

Patient Notification

Notice to individual patients and an “opt out” provision would not be useful to patients. Section 7 of the proposed exception requires prior written notice to patients affected by the program. In addition, CMS is considering whether patients should be given an opportunity to opt out of treatment under a patient safety or quality improvement measure or practice.

Prior written notice to patients and the inclusion of an opt-out provision would create the wrong impression that the use of recognized quality or effectiveness protocols would mean lesser care. Both of these notions suggest that patients need to make a risk-benefit analysis. That is not the case. **Disclosures related to treatment decisions should not be treated any differently when they are part of a quality improvement protocol or shared-savings program.** The physician would continue to have the same professional responsibility to make medically appropriate treatment decisions in consultation with the individual patient.

Appropriate Payments

Incentives should be available to encourage the achievement of quality, patient safety and efficiency goals for health care. The specific requirements in Sections 13 (per capita payments), 11 (accounting for previous payments) and 4 (permitting participation in a program only from inception) are inconsistent with the effective use of incentives.

Requiring that payments may be distributed only on a per-capita basis is too rigid a standard to allow programs to fully achieve the goals of the exception. Hospitals should be able to reduce payments to physicians whose personal contribution or effort did not meet the program’s goals, or whose effort resulted in a decrease in quality or an increase in cost. Participants also should not be rewarded if they are “free-riders.” **Payment methods should reflect the performance of individual physicians, not simply reward participation.**

Requiring that payments take into account payments previously made under an incentive program fails to recognize that it can take significant work 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.

We understand CMS’ concern that payment be made only upon demonstrated improvement. However, the prescriptive means under consideration (e.g., “rebasings”) are unreasonably burdensome and unnecessary. **The final exception should permit payments for sustaining a previous year’s achievements. The rule could require regular monitoring and reassessment of practices at least annually; and payment for**

improvement or maintenance of prior improvement, but not for the absence of any maintenance of improvements.

Permitting only those physicians on staff at the commencement of a program to participate limits a hospital's quality improvement activities. The composition of a hospital's medical staff ebbs and flows due to a variety of factors, but the need for relevant physicians to have incentives to meet quality and efficiency objectives will not. **A hospital should have the ability to include physicians who join their medical staffs at any time, subject to the expectations and rewards being adjusted to reflect the period of their participation.**

The exception should establish principles and expectations but should not micromanage programs. Specifically, we are concerned about the options under consideration in connection with Sections 12 (limiting the amount of payment) and 13 (payment to a physician organization). We also are concerned with the specific requirements in Sections 6 (disclosure of financial interest) and 11 (prohibiting payment when quality is reduced). These options and provisions inappropriately impose rigid requirements for the means to achieve the goals of the programs.

The options under consideration to limit the amounts that may be paid are unworkable and intrusive. Requiring a cap on the percentage of savings available for payment is too prescriptive and burdensome. A hospital may choose certain categories of cost as a surrogate for broader improvements, and may be willing to pay a higher percentage of savings on those items to avoid accounting for all of the costs and savings associated with a change in practice. For a multi-year program, no unique or specific payment limits are needed (e.g., "scaled limits"). It is appropriate to require that annual payments be made. Rather than focusing on the amount that is paid, it is most important that there be a clear and fixed determinant for how much may be paid. As previously discussed under "appropriate oversight," hospitals' QI processes provide additional and significant protections for patients and the Medicare program.

The final exception should not preclude payment amounts to be awarded at year-end based on the achievement of savings or improvements and a predetermined method for their calculation. Meeting the "set in advance" requirement under Section 13 of the proposal will assure that there is a predetermined method. In multi-year programs, payment should be required at least once a year.

Monitoring the pass-through of payments by a physician organization to an individual physician is impractical and unnecessary. Performance payments may be made directly to the physician or, at his or her direction, to his or her practice. If the agreement is made with a group practice for the participation of the physician, the payment will be made to the group practice. In either circumstance, there is no need to monitor the distribution of the payment by the practice to the physician. The focus should be on whether the established expectations were met and whether the physician's payment was consistent with the predetermined method for calculation. The relationship between the physician

and his or her practice should not be managed by the exception. **There is no need to regulate the pass-through of an individual physician's payment by his or her practice.**

Prohibiting payment for a reduction in quality is too ambiguous for a strict liability statute. Whether a cost-savings practice – as opposed to other unrelated factors – caused a lowering of quality may be difficult to determine. **Instead, compliance with the exception should be contingent upon implementation of a specific plan to monitor quality during the course of an incentive program. If there is a lowering of quality, appropriate action should be taken to determine if the practice needs to be changed and the related incentive adjusted. In addition, payment to an individual should be withheld in the event that known quality safeguards were not used or monitored with respect to the specific item, procedure or service.**

The burden should be on a physician to disclose to the hospital if he or she has a financial interest in an item under consideration for a shared-savings program. Section 6 prohibits payment to a physician under a shared-savings program if he or she has an ownership or investment interest in, or a compensation arrangement with, the manufacturer, distributor or group purchasing organization that arranges for the purchase of the item, supply or device. **A hospital should satisfy this requirement by creating an affirmative obligation for physicians to certify that they do not have such relationships when the program begins and to notify the hospital if they enter into such a relationship.**

CMS Consultation with the OIG

We urge CMS to consult with the Office of the Inspector General (OIG) before finalizing this exception. Section 16 of the proposal requires that the arrangement not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission. **It is essential that CMS and the OIG work together to provide companion guidance that will enable hospitals and physicians to achieve these important quality, safety and efficiency goals.** This is especially critical because of the OIG's authority to impose civil money penalties on hospitals for payments to physicians to reduce or limit services. The coordinated approach used to develop the rules for e-prescribing and electronic health records would be a good model.

We urge CMS to establish a comprehensive new exception consistent with the broad framework and specific recommendations of the AHA.

Kerry N. Weems
August 27, 2008
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If you have any questions about these comments, please feel free to contact me or Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

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Executive Vice President

cc Michael Leavitt, Secretary
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Dan Levinson, Inspector General
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