



MEMORANDUM

DATE: July 9, 2008

TO: AzHHA Compliance Task Force, CMOs and In-House Counsel

FROM: Beth Schermer and Mayan Tahan

RE: Proposed Stark Exception for Incentive Payment and Shared Savings Programs

On July 7, 2008, CMS published the 2009 Physician Fee Schedule proposed rule. 73 Fed. Reg. 38502. The proposed rule includes several proposed changes including a new Stark exception for physician incentive payment and shared savings programs. CMS recognizes that this exception is relatively narrow, and therefore solicits comments on ways to expand the exception in order to encourage health care innovation while protecting the Medicare program and beneficiaries from fraud and abuse. Comments are due to CMS by August 29, 2008. We ask that you review this summary and provide AzHHA with any comments and suggestions by August 18, 2008 so that we can provide input to AHA or provide separate comment to CMS, if needed.

CMS proposes the new exception to the Stark law because it recognizes the health care quality and efficiency benefits of incentive payment and shared savings programs. Under this exception, the Stark prohibition on referrals for designated health services would not be triggered if a hospital makes cash or cash equivalent payments to a physician on the hospital's medical staff or to a qualified physician organization (a physician organization comprised entirely of physicians participating in the same incentive payment or shared savings program) pursuant to an arrangement between the hospital and the physician or qualified physician organization *if all of the specific criteria are met* regarding the program structure, arrangement, and payments.

Although this proposed exception generally tracks the Office of Inspector General (OIG) advisory opinions regarding gainsharing programs under the Anti-Kickback Statute, it is considerably more detailed and complex. In making your comments and suggested changes, please note that CMS wants to discourage programs that directly or indirectly provide for payments in exchange for patient referrals, result in unfair competition among hospitals, or lead physicians to use the following methods:

1. stinting: limiting use of quality improving but expensive devices, tests, or treatments;

2. cherry-picking: treating only relatively healthier patients;
3. steering: avoiding relatively sicker patients; or
4. quicker-sicker discharges: discharging patients to home or post-acute care settings earlier than clinically indicated.

After reviewing this summary of the detailed requirements for the proposed exception for Incentive Payment and Shared Savings Programs, please contact Beth Schermer (bschermer@cgsblaw.com), Mayan Tahan (mtahan@cgsblaw.com) or Debbie Johnston (djohnston@azhha.org) by August 18th with comments regarding whether the proposed rule will be useful in practice and whether there are certain areas that should be addressed or revised.

Proposed Exception for Incentive Payment and Shared Savings Programs

1. Program Structure.

- 1.1. The remuneration is part of a documented incentive payment or shared savings program to achieve (i) higher quality hospital patient care services due to changes in physician clinical or administrative practices; or (ii) actual cost savings for the hospital resulting from the reduction of waste or changes in physician clinical or administrative practices, without an adverse effect on the quality of hospital patient care services.
- 1.2. Cost savings are measured by comparing the hospital's actual acquisition costs for the items and supplies or costs of providing the specified services that are subject to the shared savings program to the hospital's baseline costs for the same items, supplies, or services during the one-year period immediately preceding the commencement of the program.
- 1.3. The program identifies patient care quality measures or cost saving measures ("performance measures") that meet certain requirements, do not involve promotion of an activity that violates any law, and are reasonable and necessary for the legitimate business purposes of the arrangement.
- 1.4. The program establishes baseline and target levels for the performance measures.
- 1.5. At least five physicians participate in each performance measure.
- 1.6. There is an independent medical review of the program's impact on the quality of patient care services provided at the hospital prior to commencement of the program and annually thereafter. In addition, the program requires corrective action if the independent medical review indicates a diminution in the quality of hospital patient care services.
- 1.7. Physicians participating in a program must be on the medical staff of the hospital at the commencement of the program, and may not be selected in a manner that takes into

account the volume or value of referrals or other business generated between the parties. A hospital may elect to make a program available to physicians in a particular department or specialty, provided that the hospital offers the opportunity to participate in the program to all physicians in the department or specialty on the same terms and conditions.

1.8. Participating physicians must have access to the same selection of items, supplies or devices as prior to the commencement of the program, and must not be restricted in their ability to make medically appropriate decisions for their patients.

1.9. The hospital may not limit the availability of new technology that (i) is linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient; and (ii) meets the same Federal regulatory standards as technology available under the program.

1.10. The hospital provides prior written notice of the program and the participating physicians to patients affected by the program.

2. Arrangement. The arrangement must:

2.1. Be in writing and signed by the parties.

2.2. Specify the remuneration (or a formula for the remuneration) in detail, including the applicable baseline measures, and the targets for performance measures to be achieved by the participating physician. The remuneration must not vary during the term of the arrangement or be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

2.3. Have a term of one to three years.

2.4. Not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

3. Payments.

3.1. Payments must relate to patient care quality improvements or cost savings achieved during the current - rather than a prior - period of the arrangement ("re-basing").

3.2. In addition to the limit of the amount of remuneration paid to a physician or qualified physician organization as a result of re-basing, CMS is considering other remuneration limits:

3.2.1. a set percentage limit for savings available to the hospital as a result of the changes in clinical or administrative practices of the participating physicians (e.g. a flat 50% limit on the sharing of cost savings); and

3.2.2. a scaled limits approach – a requirement that payments to physicians decrease over the course of the performance measure.

3.3. Payments may not be made for cost savings that reduce patient care quality.

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- 3.4. The hospital may not make a payment to a participating physician or a qualified physician organization for the use of an item, supply, or device if the physician or qualified physician organization 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.
- 3.5. The remuneration must be distributed directly to the physicians in each participating physician pool or in each qualified physician organization if the qualified physician organization consists of at least five participating physicians on a *per capita* basis with respect to each performance measure.
- 3.6. The remuneration must not be based on a reduction in the length of stay for a particular patient or in the aggregate for the hospital.
- 3.7. The remuneration must not take into account the provision of a greater volume of Federal health care patient procedures or services than that provided during the period immediately preceding the commencement of the program.

We seek your comments regarding whether this exception, as proposed, is useful and whether there are changes CMS can make that would hospitals more able to utilize it in order to establish incentive payment and shared savings programs that improve health care quality and efficiency. For a copy of the proposed rule, visit: <http://edocket.access.gpo.gov/2008/pdf/E8-14949.pdf>.