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HEALTHCARE BULLETIN

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CMS PROPOSES NEW STARK EXCEPTION FOR INCENTIVE PAYMENT AND SHARED SERVICES PROGRAMS

The Centers for Medicare and Medicaid Services ("CMS") issued a proposed rule that would add a regulatory exception to the Stark law to protect incentive payment and shared savings programs between hospitals and physicians.[1]

In a proposed rule published in the July 7, 2008 Federal Register (73 Fed. Reg. 38,502), CMS issued its 2009 Physician Fee Schedule along with other proposals, including the new Stark exception. The proposed Stark exception would cover incentive payment programs, also known as "pay-for-performance" or "value-based purchasing", and shared savings programs. Shared savings programs are commonly referred to as "gainsharing" arrangements.

The new exception constitutes the first effort by CMS to directly address the parameters of acceptable pay-for-performance ("P4P") and gainsharing arrangements under the Stark Law. Although the Department of Health and Human Services, Office of Inspector General ("OIG") has issued ten advisory opinions and a Special Advisory Bulletin about gainsharing, CMS has offered little guidance on the status of gainsharing or P4P under the Stark Law. Hospitals and physicians have previously relied on incorporating gainsharing elements into arrangements protected by other Stark exceptions not specifically tailored to P4P or gainsharing, such as *bona fide* employment relationships, personal services arrangements, fair market value compensation, or indirect compensation arrangements.

Three key provisions of the proposed rule define its scope. First, the proposed exception only applies to programs offered by hospitals, and these programs cannot be offered by any other Medicare providers or suppliers. Second, the incentive payment and shared savings programs can only be offered to physicians or "qualified physician organization[s]," as defined in a proposed regulatory definition to be added to 42 C.F.R.

[1] The full text of the proposed rule is located at: http://edocket.access.gpo.gov/2008/pdf/E8-14949.pdf

§ 411.351. The proposed definition of "qualified physician organization" means "a physician organization comprised entirely of physicians participating in the same incentive payment or shared savings program." Finally, the exception would only apply to "cash or cash equivalent" forms of payment, and it would not cover non-monetary remuneration.

In formulating the exception, CMS explained the fraud, waste and abuse risks against which it intended to protect. According to CMS, P4P arrangements present the risks of disguised payments for referrals, participants cherry-picking healthy patients and steering sicker patients to other hospitals. Gainsharing arrangements, according to CMS, present the risks of: disguised payments for referrals; physicians not using quality, but more expensive, devices, tests or treatments; cherry picking healthy patients; steering sicker patients to other hospitals; and discharging patients quicker than clinically indicated.

The proposed exception contains sixteen (16) criteria, many of which contain sub-elements. In addition, CMS has solicited comments and reserved the right to add further requirements to the exception in the final rule. CMS has divided the requirements of the exception into three conceptual categories: (1) design of the program; (2) payments; and (3) arrangements between a hospital and the participating physician or qualified physician organization. A summary table of the components of the proposed exception is below.

CMS will accept comments on the proposed rule until August 29, 2008 and anticipates that the final rule will be issued by November 1, 2008.

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Proposed C.F.R. Section 42 C.F.R. § 411.357(x)...	**Requirement**	**Sub-Requirement**
(1)	Remuneration is part of a documented incentive payment or shared savings program to achieve:	---
(1)(i)	---	Quality care improvement
(1)(ii)	---	**or** actual cost savings to the hospital
(2)	Quality care or cost saving measures are identified that:	---
(2)(i)	---	Uses an objective, verifiable methodology supported by credible medical evidence that is individually tracked
(2)(ii)	---	Are reasonably related to

		the hospital's practices and population
(2)(iii)	---	With respect to quality care measures, are listed in the CMS Specification Manual for National Hospital Quality Measures, **and**
(2)(iv)	---	Are monitored throughout the term of the agreement to protect against inappropriate reductions or limitations in patient care services
(3)	The program establishes:	---
(3)(i)	---	Baseline levels for performance measures
(3)(ii)	---	Target levels for the performance measures
(3)(iii)	---	Thresholds above or below which no payments will be made to physicians
(4)	At least five physicians participate in each performance measure. Each participating physician must be on the medical staff of the hospital at the beginning of the program and may not be selected based on the value or volume of services or business generated between the parties. Payments allowed to particular hospital departments or specialties as long as all physicians in the department or specialty are offered the right to participate.	---
(5)	The program undergoes independent medical review prior to and subsequent to the establishment of the program to measure impact on quality of care.	
(6)	Under the program:	---

(6)(i)	---	Physicians must have access to the same services, supplies and tests during the program as were available prior to the program
(6)(ii)	---	Hospital may not make a payment to a physician or qualified physician organization if the physician or qualified physician organization has a financial relationship with the supplier, distributor or provider of the subject supplies, tests or services.
(6)(iii)	---	The hospital may not limit the availability of new technology that is demonstrated to improve clinical outcomes and meets the same Federal regulatory standards as the technology offered under the program.
(7)	The hospital provides effective prior written notice to patients about the program that:	---
(7)(i)	---	Identifies the participating physicians.
(7)(ii)	---	Discloses that the participating physicians receive payments for meeting performance measure targets.
(7)(iii)	---	Describes the performance measures to the patients.
(8)	The arrangement is in writing, signed by the parties, specifies the remuneration in sufficient detail to be independently verified.	---
(9)	The performance measures do not involve the counseling or	---

	promotion of an arrangement that violates the law, and are reasonable necessary for the legitimate business purposes of the arrangement.	
(10)	The term of the arrangement is at least one year and no more than three years.	---
(11)	Payments must take into account previous payments made for performance measures already achieved to prevent payments for previously achieved improvements.	---
(12)	Payments are limited in duration and amount.	---
(13)	The payment over the term (or formula) is:	---
(13)(i)	---	Set in advance, does not vary over the term of the agreement, and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
(13)(ii)	---	Not based in whole or in part on a reduction in the length of stay for a particular patient or in the aggregate for the hospital.
(13)(iii)	---	Distributed to physicians in a participating physician pool, which must consist of at least 5 physicians, on a per capita basis.
(13)(iv)	---	Paid directly to participating physicians or qualified physician organizations.
(14)	The remuneration paid may not include any amount that takes into account the provision of a greater volume of Federal health care patient procedures or services than	

	that prior to the beginning of the agreement.	
(15)	The hospital maintains accurate and contemporaneous documentation of the program and makes such documentation available to the Secretary of the Department of Health and Human Services upon request.	Types of information and documentation required are specified in proposed Sections 15(i) – (viii)
(16)	The arrangement does not violate the Federal Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission.	

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Should you have any questions, please do not hesitate to contact one of our healthcare attorneys at the offices below.

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