

# Proposed Stark Exception Covers Pay-for-Performance and Gainsharing Programs

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## Introduction

The current Medicare physician self-referral law (the “Stark Law”) is potentially implicated by any payment made to a physician under pay-for-performance (“P4P”), gainsharing and other similar quality improvement and cost saving incentive programs. Over the last several years, many hospitals and third-party payors, including Medicare, have implemented or are exploring ways to implement such programs. The Centers for Medicare and Medicaid Services (CMS) recognizes that P4P and gainsharing programs can be beneficial to providers, payors and beneficiaries. In order to encourage the development of performance improvement and cost savings programs, the proposed 2009 Medicare Physician Fee Schedule (PFS) regulation, 73 FR 38502, creates an exception to the Stark Law specifically tailored to these programs.

CMS proposes an exception that covers “incentive payment” and “shared savings” programs. “Incentive payment” programs are programs, such as P4P and quality-based purchasing programs, that create financial incentives for physicians to improve the quality of patient care. “Shared savings” programs are programs, such as gainsharing programs, that provide financial incentives to physicians to reduce the cost of patient care in the form of a share of such savings. In the proposed FY 2009 Inpatient Prospective Payment System (IPPS) rule, CMS solicited comments regarding an exception to the Stark Law that would cover gainsharing arrangements. CMS now believes that it needs to provide a broader exception that covers additional types of incentive programs.

The exception included in the proposed PFS closely resembles the model of gainsharing programs originally developed by Goodroe Consulting and approved by the Office of Inspector General (OIG) in a series of advisory opinions addressing Civil Monetary Penalty (CMP) and anti-kickback concerns. The OIG advisory opinions concluded that the gainsharing arrangements violated both the CMP and (assuming the requisite intent) the anti-kickback statutes, but that the OIG would not impose sanctions on the programs because they included specific safeguards that would limit the risk of abuses that the statutes are intended to prevent. The primary difference between the proposed rule and the OIG-approved programs is that the proposed rule covers both P4P (as “incentive payment programs”) and gainsharing arrangements (as “shared savings programs”). CMS proposes a single set of requirements that covers both types of programs since CMS believes that many programs are likely to include both quality and cost measures. However, CMS recognizes that the different types of programs present different risks of program and patient abuse. Therefore, CMS is interested in comments regarding the need for two separate sets of rules and the specific requirements that should be included for each type of program. CMS also seeks comments about whether the scope of the proposed exception is too broad or too narrow to cover the range of programs that improve quality and reduce costs without risking program integrity or patient abuse.

The inclusion of incentive payment programs is somewhat unexpected, as these have traditionally been analyzed under the personal services arrangement or other existing Stark exceptions. CMS does not indicate why it believes these exceptions to be inadequate for such programs; if the various requirements of the exception detailed below, such as independent medical review, are in fact required to structure a compliant quality bonus program, this would represent a significant development.

## Overview

The proposed “incentive payment and shared savings program” exception would apply to certain performance-based payments made by hospitals to physicians. The requirements relate to the structure of the program, the types of and limits on payments made to physicians participating in the program, and specific elements that must be included in the program participation agreements between hospitals and physicians. CMS intends the proposed requirements to address three main areas of concern: transparency, quality controls and safeguards against payments for referrals.

The proposed exception only applies to payments made by hospitals. It does not include payments by other types of providers or suppliers. In the preamble, CMS explains that it believes that providers and suppliers reimbursed on a fee schedule or other fee-for-service basis might have an incentive to create programs that result in the provision of more items and services. CMS is concerned that such programs have the potential to increase costs to the Medicare program and beneficiaries without any actual quality improvement. CMS seeks comments regarding the expansion of the exception to other DHS entities and what safeguards would be required to remove the risk of program or patient abuse. The focus in the preamble on the risks presented by non-prospective payment system (PPS) providers suggests that CMS may be receptive to comments encouraging CMS to extend the exception to other providers reimbursed under PPS methodologies. CMS also leaves open the question of whether the exception applies to hospitals that are not paid under PPS rules.

Because the Stark Law applies only to financial relationships with physicians, the proposed rule applies only to payments made to physicians. However, CMS notes that it does not intend the proposed exception to limit or prohibit participation by non-physician practitioners (NPPs) in incentive payment or shared savings programs.

Although the Stark Law applies to both monetary and non-monetary remuneration, the proposed exception only protects remuneration in the form of cash or cash equivalents. The proposed exception would not protect any program that provides non-monetary remuneration, such as new equipment or additional staff. CMS does not provide a reason for limiting the exception to cash or cash equivalent payments and does not specifically seek comments on this element of the proposed rule.

## Program Design

The proposed exception requires that performance-based payments from hospitals to physicians are a part of “a documented program intended to achieve improvement in the quality of patient care through changes in physician clinical or administrative practice or actual costs savings for the hospital from reduction in waste or changes in physician clinical or administrative practice.” In addition, programs intended to produce cost savings must not have an adverse affect on or result in a diminution of the quality of hospital patient care services.

### SELECTION OF PERFORMANCE MEASURES

The proposed rule requires programs to include patient care quality or cost savings measures, or both. CMS refers to these measures as “performance measures.” CMS is concerned that programs may incorporate sham standards that reward physicians for referrals rather than performance improvement. CMS believes that establishing performance measures that derive from already accepted criteria is the best way to prevent such abuse. The measures must reasonably relate to the hospital’s or comparable hospitals’ practices or patient populations. The hospital must monitor the measures during the term of the program to protect against “inappropriate” reductions or limitations in patient care services. In the preamble, CMS proposes that all performance measures be supported by objective, independent medical evidence indicating that the measures would not adversely affect patient care. The preamble presents two options for how programs could meet this requirement with respect to patient care quality measures: CMS could either provide a “bright-line” rule that would require all patient care quality measures to be listed in CMS’s “Specifications Manual for National Hospital Quality Measures” or it could deem such measures to meet the requirement but allow programs to use any other measures that meet the requirement. As drafted, the proposed rule requires that hospitals select measures from the CMS Manual. In addition, the text of the proposed rule requires that the measure be “supported by credible medical evidence,” but does not specifically require that the medical evidence indicate that the measures would not adversely affect patient care.

CMS does not propose to limit hospitals’ selection of cost savings measures to a particular list. While the proposed rule may provide some flexibility for programs to select cost savings measures tailored to the specific goals of the hospital, the absence of “bright-line” rules creates the potential for uncertainty about whether a particular measure will satisfy the exception. For example, the draft text of the proposed rule requires that a program use measures that “are supported by credible medical evidence.” The proposed rules do not define “credible medical evidence” or specify the degree of “support.” Therefore, a hospital desiring regulatory certainty may still need to use the OIG and/or CMS advisory opinion process to obtain assurance that its program falls within the exception. CMS seeks comments on whether programs could satisfy the performance measure requirements by including criteria deemed by the Secretary to meet the requirements and comments identifying additional performance measures or lists of performance measures. In particular, CMS is interested in identifying cost savings measures or lists of such measures.

CMS recognizes that hospitals will select products for product-standardization performance measures based on price (assuming a choice among products of equal quality and utility). However, CMS is concerned that manufacturers may attempt to influence product selection and that product standardization could limit patient access to products, particularly “breakthrough” or superior technologies. CMS is interested in comments that address the effect that product standardization measures might have on small manufacturers of medical products and patient choice of items and services.

CMS is also concerned that some programs may inappropriately incentivize reductions in length of stay and has proposed to flatly prohibit any payment based on reductions in length of stay for a particular patient or groups of patients. Nevertheless, CMS is aware that some reduction in length of stay may occur as an “incidental effect” of quality improvement programs.

## PHYSICIAN CHOICE OF TREATMENT

Programs would not qualify for protection under the proposed exception if the program limits the participating physicians' discretion to make medically appropriate decisions for their patients, including, but not limited to, decisions about tests, treatments, procedures, services, supplies or discharge. CMS proposes to allow programs to condition payments on a particular physician choice, but would also require hospitals to allow physician access to the same items, supplies and devices that were available to them before the program began. In addition, the proposed rule requires that hospitals make new technology available to participating physicians if the technology meets certain criteria. CMS does not define "new technology." Both the text of the proposed rule and the preamble require that hospitals allow participating physicians to use any new technology that meets the same regulatory requirements (for example, FDA approval and Medicare or Medicaid coverage decisions) as items or supplies included in the program. However, as drafted, the proposed rule would also require that the hospital make available new technology that "is linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient" while the preamble requires access to items and supplies that the physician deems "medically necessary for an individual patient's care." These two standards are different. For example, as drafted, the proposed rule would allow a hospital to limit access to technology that a participating physician deems medically necessary if the technology is not associated with improved outcomes. Furthermore, since this particular provision applies to new technology, there may be limited evidence of improved outcomes compared to the current technology.

Although not expressly reflected in the text of the proposed rule, in the preamble CMS notes that items, supplies and devices should not be selected for product standardization programs on the basis of a participating physician's investment interest in, or compensation arrangement with, the manufacturer or distributor of the item, supply or device, or the physician's interest in a group purchasing organization (GPO) that arranges for the purchase of the item, supply or device. The proposed rule prohibits a physician from receiving any payments under a program that involves a product in which the physician has a financial interest. In addition, CMS recommends, and may require (even though the text of the proposed rule does not), that hospitals prohibit physicians with any such interests from participating in the design or implementation of an incentive payment or shared savings program that involves a product in which the physician has a financial interest.

## INDEPENDENT MEDICAL REVIEW AND CORRECTIVE ACTION

The proposed rule requires that incentive payment and shared savings programs undergo independent medical review before implementation and at least annually after implementation. Hospitals would be required to contemporaneously document the reviews, retain all documentation related to the reviews and make the documentation available to the Secretary upon request. The purpose of the reviews is to determine whether the program is adversely affecting the quality of patient care. CMS proposes that the reviews be conducted by an individual or organization that is not affiliated with the hospital, any participating physician or any organization to which any participating physician belongs. The reviewer must also not be participating in any incentive payment or shared savings program at the hospital at the time of the review. Although not included in the proposed text of the rule, in the preamble CMS indicates that the reviewer would be required to have "relevant clinical expertise." CMS seeks comments on the appropriate frequency for and qualifications necessary to conduct the reviews.

In the preamble, CMS proposes to require that programs undertake immediate and appropriate corrective action if a review reveals an adverse impact on quality. The preamble provides several examples of possible corrective actions including termination of the program, removal of the relevant measure from the program, removal of the relevant measure from calculation of physician payments, or termination of a physician from the program. CMS is considering whether corrective action should also include modification of a performance measure. CMS would not allow a hospital to discontinue a performance measure in order to increase payment to participating physicians in the next period or because participating physicians are unable to earn a shared savings payment related to that measure. CMS is interested in comments addressing approaches to corrective actions and how to incorporate the corrective action requirement into the text of the rule.

## SELECTION OF PHYSICIANS

The proposed rule only protects payments to physicians who actually participate in the achievement of goals set under an incentive payment or shared savings program ("participating physician"). The proposed rule would not protect payments to physicians who refer patients to a hospital but do not otherwise participate in the hospital's program. CMS would not permit a hospital to determine eligibility for physician participation in a manner that takes into account the volume or value of referrals or other business generated between the parties. The proposed rule would allow a hospital to limit participation to a particular specialty or department, so long as the hospital allows all members of the medical staff in that specialty or department to participate. Neither the text of the proposed rule nor the preamble suggests other criteria that a hospital could use to limit

eligibility for participation in the program. The proposed rule does not address whether a hospital could prohibit particular physicians from participating in, or if a physician could request to participate in, a program that includes measures that are not specific to a particular specialty or department.

CMS proposes that only members of the hospital's medical staff at the commencement of the hospital's program be eligible to participate in the program. CMS is concerned that allowing physicians to join the program after it has started might serve as an inducement to attract physicians from competing hospitals, but is also aware that the normal workforce cycle may cause physicians to join the medical staff after the start of a program. Therefore, CMS seeks comments on whether the exception should permit such a physician to participate in an incentive payment or shared savings program.

#### **PARTICIPATION BY AND PAYMENTS TO PHYSICIAN ORGANIZATIONS**

The proposed rule would allow hospitals to make payments directly to participating physicians or to qualified physician organizations. "Qualified physician organizations" are physician organizations composed entirely of participating physicians. CMS is considering whether to expand the proposed definition of "qualified physician organization" to include groups of physicians who are eligible to participate in a program even if one or more of the physicians decides not to participate. CMS acknowledges that hospitals and physicians may want to develop payment arrangements in which the hospital makes payments to a "physician organization" (presumably, although not expressly stated, as defined in the Phase III Stark rule) and the physician organization passes the payments on to the physician. Although the text of the proposed rule requires that hospitals make payments directly to participating physicians or qualified physician organizations, CMS is considering revising this requirement to allow physician organizations that do not meet the definition of "qualified physician organization" to serve as pass-through entities. CMS is particularly concerned with issues such as income tax withholding, retirement plan withholding and other areas of potential manipulation of payment distributions in a manner that reflects referrals to the hospital. CMS is considering requiring that physician organizations document all incentive payment or shared savings program payments made to a physician, including any withholdings from the payment amounts. CMS would also require that such arrangements be included in the written program agreement and that the physician organization be a signatory to the agreement.

CMS believes that one benefit of allowing payments to physician organizations is that it would avoid confusion relating to the physician "stand in the shoes" provisions. CMS seeks comments regarding the relationship of the proposed exception to the "stand in the shoes" provisions.

#### **POOLING REQUIREMENT**

CMS proposes to require that hospitals establish "pools" of five or more participating physicians at the beginning of a program. The incentive payments or cost savings resulting from a particular performance measure or measures must be shared among the members of the pool on a per capita basis. CMS believes that the pools are necessary to reduce the risk of program and patient abuse. CMS seeks comments regarding the "pool" requirement and the minimum number of physicians needed in a pool in order to reduce risks. CMS is also interested in comments that address ways to pool funds for programs or measures targeted at a specific medical specialty or department in which there are fewer than five eligible physicians.

## **Payments**

#### **BASELINE PERFORMANCE LEVELS**

The proposed rule requires hospitals to set baseline levels of performance for use in calculating the payments to physicians. Hospitals must use their actual acquisition costs for items and supplies or the costs of delivering the specified services, for all patients regardless of insurance coverage, during the one-year period immediately preceding the commencement of the program.

#### **PAYMENTS CANNOT "TAKE INTO ACCOUNT" INCREASES IN REFERRAL VOLUME**

The proposed rule would not protect any payment made to a participating physician or qualified physician organization that takes into account the provision of a greater volume of federal health care patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program covered by the payment. CMS is interested in comments regarding whether, and how, to account for changes in volume due to market forces and physician practice growth.

## 50 PERCENT LIMIT ON SHARED COST SAVINGS

In the preamble, but not the draft text of the rule, CMS proposes to limit the amount of payments to 50 percent of cost savings, regardless of the length of the program. CMS does not propose a similarly rigid payment limit for incentive payment programs, but CMS is considering whether to limit the amount of payments under multi-year programs of both types to an amount that is actuarially equivalent to the amount of payments under a one-year program. CMS seeks comments on both the 50 percent limit and actuarial equivalence of payments in programs of different lengths.

## REBASING AND SCALING

CMS is considering whether to require “rebasing” or “scaling” of the performance measures used in multi-year programs based on improvements made or savings generated by the programs. The text of the proposed rule prohibits hospitals from making payments for improvements achieved in prior periods of the program, but does not set forth an approach that hospitals must use to assure that this does not occur. Because the preamble describes two possible approaches, CMS may intend to adopt one of these approaches rather than the broad requirement currently in the draft rule text. Interestingly, although the proposed rule does not expressly require rebasing, the draft text requires that hospitals retain documentation of any rebasing of performance measures.

Under a rebasing approach, CMS seeks to prevent physicians from receiving payments for improvements made in earlier periods of a multi-year program. CMS is considering an approach that would require a hospital to rebase its performance measures at the end of each year of the program and make future payments only on improvements from the rebased level. CMS proposes to apply the rebasing requirement to both incentive payments related to patient care quality and incentive payments or shared savings based on cost savings. However, CMS seeks comments on whether the rebasing is necessary to protect “quality-only” payments from program or patient abuse. CMS also requests comments regarding whether the exception should allow programs to set their own payment and rebasing periods. CMS does not intend to allow hospitals to increase the amounts available for payments to physicians as a result of rebasing.

The scaling option would require that hospitals decrease the percentage of cost savings available for payment to physicians in each year of the program. For example, the hospital could distribute 50 percent of savings in year one, 35 percent in year two and 20 percent in year three. CMS is also considering applying this approach to programs that base payments on a fixed dollar amount, rather than a percentage. Although not explicitly stated in the proposal, the scaling approach appears to apply only to cost savings programs and not to incentive payment programs. CMS seeks comments about which payment limit approach to implement, including whether CMS should implement both, or if there are other appropriate limits on the nature or amount of payments that CMS should consider.

## TARGET LEVELS

CMS proposes to require that hospitals set target levels below which the hospital would not make payments to the physicians. Although the text of the proposed rule requires only that the target levels be based on comparisons of historical data for the specific hospital with national or regional data for comparable hospitals, the preamble text proposes that the targets be set using objective historical and clinical measures related to the hospital’s practices and patient populations. The approach described in the preamble appears to allow hospitals more flexibility to set targets based on the hospital’s own goals rather than requiring that the hospital align its targets with benchmarks set by other facilities. CMS requests comments on how to develop a similar approach for measures for which a “floor” and “ceiling” are not applicable, such as product substitution and product standardization. CMS is considering whether it could address concerns about the establishment of targets by requiring an independent clinical review of a program before implementation and seeks comments regarding this question.

## Additional Requirements

### STANDARD STARK EXCEPTION REQUIREMENTS

The proposed rule includes requirements that are common in other Stark regulatory exceptions related to compensation agreements. CMS proposes to require that the programs be at least one year and, in this case, no more than three years in duration. CMS would require that the amount of compensation, or formula for compensation, be set in advance and not vary during the term of the agreement.

The proposed rule requires that programs not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission and that the selected performance measures not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law. The Civil Monetary Penalty (CMP) statute prohibits payments to a physician intended to induce the physician to reduce or limit the provision of services and, in the OIG's stated view, generally prohibits shared savings programs. Presumably, CMS does not view the CMP statute to be a "law or regulation governing billing or claims submission" given that the favorable OIG opinions uniformly conclude that gainsharing programs do violate that statute. Express clarification from CMS on this point would be welcome, however.

The proposed rule also prohibits any remuneration that "takes into account the volume or value of referrals or other business generated between the parties." In the past, some in the health law bar have argued that any payment based on a portion of cost savings generated by a referring physician would "take into account" the value of that physician's admissions to the hospital. Since CMS intends to allow such arrangements under the proposed rule, it would appear that CMS does not believe that gainsharing programs of the type approved by the OIG "take into account" the value of referrals generated by the physician.

#### WRITTEN AGREEMENTS

CMS believes that transparency is necessary to ensure that programs do not pose a risk of patient or program abuse. CMS proposes to require that the written program agreements separately and clearly describe each performance measure included in the program and the payments, or the formula for payments, that would result if the participating physicians meet specified target levels. CMS is interested in comments that address whether, and how, total savings for a particular department or service line can be included in a program and sufficiently monitored, accounted for and distributed so as not to present a risk of program or patient abuse.

#### PATIENT DISCLOSURE AND OPT-OUT

The proposed rule would require a pre-admission written disclosure to patients affected by a program. If pre-admission disclosure is not possible, CMS proposes to require disclosure before the procedure or treatment to which the program is applicable. Neither the preamble nor the draft text of the rule addresses the requirements for disclosure to patients for whom pre-admission and pre-treatment disclosure are not possible. CMS would require that the disclosure include the names of the physicians participating in the program, a description of the target measures and a statement disclosing that the physicians receive payments for meeting specific targets. CMS is considering whether to allow patients to opt out of measures that might otherwise apply to their care and is seeking comments about how such an opt-out provision might work.

#### ADDITIONAL PROPOSED REQUIREMENTS NOT INCLUDED IN DRAFT RULE TEXT

CMS proposes several additional requirements that are not included in the text of the proposed rule. CMS seeks comments on how to incorporate the following requirements into the text of the final rule:

1. CMS plans to require hospitals to track and monitor the case severity, ages and payers of patients treated by each participating physician. If the measures for a particular physician or the hospital as a whole change significantly from the hospital's historic measures, CMS would require removal of the physician from the program or termination of the program.
2. CMS intends to require that the payments eligible for distribution among the physicians in each "pool" of physicians directly relate to that pool's efforts in meeting the applicable performance measures.
3. CMS proposes to include a requirement that will prevent hospitals from developing programs with measures that apply disproportionately to procedures or treatments performed on Medicare beneficiaries. CMS suggests that may include a requirement that all measures apply uniformly to all patients.
4. CMS plans to include a requirement that hospitals audit the calculation of the cost savings and payments made under the program.

## Conclusion

The proposal to provide an exception for incentive payment and shared savings programs demonstrates that CMS recognizes the opportunities for quality improvement and cost savings that well-designed P4P and gainsharing programs create. However, the many alternative approaches presented suggest that CMS is still struggling to create an exception that balances industry concerns and program safeguards.

We recommend that affected health care organizations, including hospitals, GPOs and suppliers, carefully consider the potential effect the proposed requirements would have on any current or future performance improvement or gainsharing programs. Comments may be submitted to CMS through August 29, 2008.

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