

2. Exception for Incentive Payment and Shared Savings Programs (Proposed §411.357(x))

a. Background

The Medicare program and private industry stakeholders are increasingly exploring the benefits of various types of gainsharing, pay-for-performance ("P4P"), value-based purchasing, and similarly-styled programs that use economic incentives to foster high quality, cost-effective care. Many of these programs involve payments from hospitals to physicians. These payments potentially implicate the fraud and abuse laws, including the physician self-referral statute. Existing exceptions to the physician self-referral statute, while useful, may not be sufficiently flexible to encourage a variety of nonabusive and beneficial gainsharing, P4P, and similar programs.

For this reason, as described in greater detail below, we are proposing a new, targeted exception to the physician self-referral statute for such programs. The design of the new exception presents a particular challenge: crafting an exception that offers broad flexibility for innovative, effective programs, while at the same time protecting the Medicare program and beneficiaries from abuses. In reviewing various programs and industry suggestions, we have been struck by the considerable variety and complexity

of existing arrangements, and the likelihood of continued future innovation in the structure and method of these programs. This variety and complexity make it difficult to craft a "one-size-fits-all" set of conditions that are sufficiently "bright line" to facilitate compliance and enforceability, yet sufficiently flexible to permit innovation without undue risk of program or patient abuse.

The variety and complexity of these programs make them potential vehicles for the unscrupulous to disguise payments for referrals or compromise quality of care for patients in the interest of maximizing revenues.

Therefore, our approach to drafting a proposed exception is a cautious one. Our proposal is relatively narrow, and we acknowledge at the outset that it is unlikely to cover as many arrangements as interested stakeholders would like. As described below, we are considering various ways that we might expand the proposed exception, if we can do so without a risk to the programs and their beneficiaries. We are interested in public comments specifically addressing areas of possible expansion, the potential abuses that could occur, and the conditions necessary to ensure that such expansion does not pose a risk of program or patient abuse. It is our goal to promulgate an exception that is as broad as possible consistent with the statutory

requirement that any arrangement excepted under an exception issued using our authority in section 1877(b)(4) of the Act pose no risk of program or patient abuse. We note that section 1877 of the Act is not implicated by quality or cost savings programs that do not involve remuneration to physicians. Hospitals are free to implement quality protocols, cost savings measures, and the like without regard to section 1877 of the Act, provided that the arrangements do not involve financial relationships with referring physicians.

Although "gainsharing" is commonly used to describe certain programs that seek to align physician behavior with the goals of a hospital by rewarding physicians for reaching predetermined performance outcomes, several types of programs exist for the purpose of achieving quality standards, generating cost savings, and reducing waste. In this proposed rule, we refer to these programs as "incentive payment and shared savings programs." We describe below in more detail the characteristics of programs we consider to fall within these categories. Successful programs often result in improved quality outcomes or cost savings (or both) for the hospital sponsoring the program. To achieve these goals, hospitals make financial payments to the physicians whose efforts

contribute to the success of the program. As noted above, these payments may implicate the physician self-referral statute.

Section 1877(a)(1) of the Act states that, except as provided in section 1877(b) of the Act, if a physician (or an immediate family member of such physician) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of designated health services (DHS) for which payment otherwise may be made under title XVIII of the Act. The provision of monetary or nonmonetary remuneration by a hospital to a physician through a gainsharing arrangement or other incentive payment or shared savings program would constitute a financial relationship with an entity for purposes of the physician self-referral statute.

Incentive payment and shared savings programs also potentially implicate two additional specific fraud and abuse statutes. First, sections 1128A(b)(1) and (b)(2) of the Act, commonly referred to as the Civil Monetary Penalty (CMP) statute, prohibit a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care, and a physician from knowingly accepting such

payment. Second, these arrangements potentially implicate section 1128B(b) of the Act (the anti-kickback statute) if one purpose of the quality improvement or cost savings payment is to influence referrals of Federal health care program business.

i. Incentive Payment Programs

"Pay for performance" (P4P), also known as quality-based purchasing, is a quality improvement and reimbursement methodology aimed at moving towards payments that create stronger financial support for patient focused, high value care. There are many models for financial and non-financial incentives used in P4P and other quality-focused programs. We refer to these types of programs, which may be payer-based or provider-based, as "incentive payment programs." Through collaborative efforts with a wide range of other public agencies and private organizations that have a common goal of improving quality and avoiding unnecessary health care costs, including the National Quality Forum (NQF), The Joint Commission, the National Committee for Quality Assurance (NCQA), the Agency for Healthcare Research and Quality (AHRQ), and the American Medical Association (AMA), we are developing and implementing a set of P4P initiatives to support quality improvement in the care of Medicare beneficiaries. The

objective measures used in incentive payment programs to determine whether providers are offering high quality care are commonly referred to as "quality standards." This term is also used in many provider-based incentive payment programs. We use the term "quality standards" in this proposed rule as well.

When payer-based, P4P attempts to use reimbursement to promote quality, efficiency in providing access to needed services, and successful outcomes. In many payer-based models, payers make available to hospitals financial incentives tied to achieving certain quality or performance goals (for example, adopting health information technology, furnishing preventive care services, achieving patient satisfaction targets, or measurably improving patient health indicators). Hospitals often need physician collaboration to meet performance goals. In order to align incentives, hospitals may want to share with physicians a portion of the P4P payments they receive from the payers. In the absence of or in addition to a payer-based incentive payment program, hospitals may also sponsor quality-focused programs in which objective improvements in quality or individual patient care outcomes are rewarded with payments to physicians responsible for the improvements.

In both circumstances, payments made by a hospital to the physicians whose efforts promoted the achievement of targets (or benchmarks) for one or more performance measures create a financial relationship between the hospital and the physician that implicates the physician self-referral statute. These payments also potentially implicate the anti-kickback statute and the CMP statute. (We note that, depending on the nature of the performance measure, incentive payment programs might not implicate the CMP statute because they might not involve any reduction or limitation in patient care services.)

Although properly structured incentive payment programs can enhance health care quality and efficiency, improperly structured programs pose significant risks of program or patient abuse, including adversely affecting patient care. Moreover, such programs could be vehicles to disguise payments for referrals, including incentives to steer healthier patients to the hospital offering the incentive payment program. Programs that cannot be adequately and accurately measured for quality would also pose a high risk of program or patient abuse. We observe that payer-based programs in which the performance measures are set by a wholly independent, arms-length party with a clear financial incentive to make P4P payments prudently

may pose somewhat less risk than non-payer based programs, where there is no third-party payer that sets the performance measures and monitors compliance. We note further that payments made directly from a payer to a physician, at the payer's sole discretion, may not implicate the physician self-referral statute or other fraud and abuse statutes.

ii. Shared Savings Programs

Many programs, such as "gainsharing" and other cost savings and waste reduction programs, seek to align physician economic incentives with those of hospitals by offering physicians a share of the hospitals' variable cost savings attributable to the physicians' efforts in controlling the costs of providing patient care. For purposes of this proposed rulemaking, we refer to these types of programs as "shared savings programs." When a participating physician receives a portion of the cost savings attributable to his or her efforts in reducing waste and achieving the goals of a shared savings program, a financial relationship is created between the hospital sponsoring the shared savings program and the participating physician, and the physician self-referral statute is implicated.

The Medicare Part A DRG system of hospital reimbursement, under which a hospital receives a prospectively determined, fixed payment that covers all hospital items and services provided to a Medicare beneficiary during his or her inpatient stay or outpatient service, provides a significant incentive for hospitals to control costs. Hospitals are also motivated to reduce costs because of the growth of managed care. However, because physicians are paid separately under Medicare Part B (and by many managed care and other payers), they do not share necessarily the hospital's motivation to control patient care costs. Physicians who perform their professional services at a hospital use the hospital's equipment, supplies and services, and prescribe drugs, devices and other items and services which the hospital must provide. In short, physicians are not financially at risk for the items and services that they use and prescribe, and therefore, do not have a financial stake in controlling the hospital's patient care costs.

As part of many shared savings programs, physicians study how colleagues perform their procedures and then determine the best processes to adopt, in order to increase efficiency while ensuring quality. In other situations, outside experts are hired to analyze hospital and regional

or national data to determine appropriate opportunities for cost savings that do not jeopardize patient care. Shared savings programs are sometimes described as collaborations between physicians and hospitals to determine the best approach to providing quality patient care services.

Shared savings programs have been recognized by stakeholders as an effective means of controlling costs, improving efficiency, and promoting quality in the delivery of health care services. Government stakeholders have recognized similar potential benefits when shared savings programs are properly structured to ensure compliance with Federal health care program requirements.

Empirical evidence suggests that the goal of patient care quality maintenance or improvement can be achieved through a properly-designed shared savings program. An independent study of data from 13 separate, 1-year gainsharing programs¹ designed and administered by the organization responsible for the design of all of the gainsharing programs that, to date, have received favorable advisory opinions from OIG (see discussion below and in the FY 2009 Hospital IPPS proposed rule (73 FR 23692 through

¹ Although we refer herein to “shared savings programs,” the study cited referred to these programs as “gainsharing programs.” We retain that nomenclature for purposes of discussing the study.

23693)), found that the incentives for cost reduction in the gainsharing models studied did not result in reductions in quality and, for certain quality measures, resulted in improved quality of patient care. (See Jonathan D. Ketcham and Michael F. Furukawa "Hospital-Physician Gainsharing in Cardiology." Health Affairs, Vol. 27, No. 3 (May/June 2008), 808.) Specifically, according to the study, gainsharing slowed the growth of average in-lab cost per coronary stent patient, reducing costs relative to non-gainsharing hospitals; yet, in-lab complications did not increase during gainsharing, and three complications significantly decreased. (Id. at 808.) With respect to gainsharing's positive impact on patient care quality, the authors of the study asserted that the economic incentive for physicians participating in gainsharing programs to collaborate in defining and adopting best practices might improve the physicians' incorporation of clinical evidence into patient care decision making. This is, at least in part, because the gainsharing programs studied provided participating physicians and physician organizations with information about other physicians' practice patterns. (Id. at 809.)

Although properly structured shared savings programs may increase efficiency and reduce waste, thereby

potentially increasing a hospital's profitability and contributing to quality of care, improperly designed or implemented programs pose the same risks of program or patient abuse described above in connection with incentive payment programs. Additional risk is posed by shared savings programs that reward physicians based on overall cost savings (for example, the amount by which the total costs attributable to a particular hospital department decreased from one year to the next) without accountability for specific cost reduction measures.

We are concerned about physicians responding to a shared savings program by limiting their use of quality-improving but more costly devices, tests or treatments ("stinting"), by treating only healthier patients ("cherry picking"), by avoiding sicker patients ("steering") at the hospital, or by discharging patients earlier than clinically indicated either to home or to post acute care settings ("quicker-sicker" discharge). We are concerned also about arrangements which provide for payments in exchange for patient referrals or result in unfair competition among hospitals offering shared savings programs to foster physician loyalty and to attract more referrals. We are concerned that, because of pressures from competition or physicians, hospitals may increase the

percentage of savings shared with the physicians, manipulate hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians in order to retain them for or attract them to the hospital. (These same concerns may be present with incentive payment programs.) We are incorporating safeguards into the proposed exception that are intended to address these risks.

iii. DHHS Initiatives: Incentive Payment and Shared Savings Programs

Patient care quality improvement is a laudable goal and a priority of the Department of Health and Human Services (the Department or DHHS). Patient care should be safe, effective, efficient, patient-centered, timely and equitable. Establishing partnerships is a critical step towards achieving our goals of improving patient care quality and avoiding unnecessary costs. Incentive payment and shared savings programs, when properly structured, by design establish such partnerships.

Since 1991, we have sponsored a variety of demonstration projects and other initiatives to explore the connection between payments and the quality of care. These initiatives include the evaluation of both gainsharing (in various forms) and P4P programs affecting providers of

health care to beneficiaries in diverse care settings. Although we decline to provide detailed descriptions of individual initiatives here, gainsharing demonstrations include: (1) the Medicare Participating Heart Bypass Center Demonstration which was conducted to assess the feasibility and cost effectiveness of a negotiated all-inclusive bundled payment arrangement for coronary artery bypass graft (CABG) surgery while maintaining high quality care; (2) a 3-year demonstration under section 1866C of the Act, which has been established, but not yet implemented, to test gainsharing models involving physicians, and collaborations between hospitals working with physicians, in a single geographic area to improve the quality of inpatient hospital care; and (3) a demonstration project under section 5007 of the DRA that would involve arrangements between a hospital and physicians and practitioners under which the hospital provides remuneration (to certain physicians and to certain practitioners (as defined in 1842(b)(18)(C) of the Act)) that represents solely a share of the savings incurred directly as a result of collaborative efforts between the hospital and a particular physician (or practitioner) to improve overall quality and efficiency. In addition, we recently announced a new demonstration, the Acute Care

Episode Demonstration, for hospitals to test the use of a bundled payment for both hospital and physician services for a select set of episodes of care (orthopedic and cardiac) to improve the quality of care delivered through Medicare FFS. We note that some of the demonstration programs are proceeding under a statutory provision that waived application of section 1877 of the Act, the anti-kickback statute, and the CMP statute.

In addition to these gainsharing demonstrations, we have developed a number of P4P and other value-based purchasing initiatives across patient care settings, including: the Premier Hospital Quality Incentive Demonstration; the Medicare Care Management Performance Demonstration; the Home Health Pay-for-Performance Demonstration; and the Better Quality Information Pilots.

iv. Potential Statutory and Regulatory Applications to Incentive Payment and Shared Savings Programs

Section 1877 of the Act, also known as the physician self-referral statute: (1) prohibits a physician from making referrals for certain DHS payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or

billing another individual, entity or third party payer) for those referred services. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse.

A financial relationship is created where an incentive payment or shared savings program results in a direct or indirect payment from the hospital to a physician. Unless the arrangement satisfies the requirements of an applicable exception, the incentive payment or shared savings payment would violate the physician self-referral prohibition if the physician receiving the payment makes referrals for DHS to the hospital making the incentive payment or shared savings payment. In many cases, incentive payment and shared savings programs can be structured to satisfy the requirements of existing exceptions (for example, the exceptions for bona fide employment relationships, personal service arrangements, fair market value compensation, or indirect compensation arrangements). In some cases, no exception may be necessary (for example, incentive payments paid directly from a payer at the payer's sole discretion to a physician for the physician's efforts in improving quality). However, in other circumstances, the existing

exceptions to the physician self-referral prohibition may not be sufficiently flexible to protect payments to physicians under incentive payment and shared savings programs.

As noted above, incentive payment and shared savings programs also implicate two additional specific fraud and abuse statutes - the CMP statute and the anti-kickback statute. An incentive payment or shared savings program could run afoul of the anti-kickback statute if one purpose of the payment from the hospital to the physician is to influence referrals of Federal health care program business. In contrast, the intent of the parties does not dictate compliance with the physician self-referral statute. If an arrangement fails to satisfy all of the requirements of an exception, it would violate section 1877 of the Act.

v. Solicitation of Comments in the FY 2009 Hospital Inpatient Prospective Payment System Proposed Rule

In the FY 2009 IPPS proposed rule, we solicited comments as to whether we should issue an exception specific to gainsharing arrangements, which we stated "typically refer[] to an arrangement under which a hospital gives physicians a share of the reduction in the hospital's costs (that is, the hospital's cost savings) attributable

in part to the physicians' efforts" (73 FR 23692).

Although we noted general concerns with arrangements that involve the use of a percentage-based compensation formula (as many gainsharing arrangements involve), we solicited comments regarding a potential exception to the physician self-referral prohibition for gainsharing arrangements in recognition of "the value to the Medicare program and its beneficiaries where the alignment of hospital and physician incentives results in improvements in quality of care" (73 FR 23694). Specifically, we solicited comments on the following: (1) what types of requirements and safeguards should be included in any exception for gainsharing arrangements; and (2) whether certain services, clinical protocols, or other arrangements should not qualify for the exception (73 FR 23694).

b. Public Response to Solicitation of Comments

The following discussion describes comments received in response to the solicitation of comments on gainsharing arrangements that we have reviewed to date. In addition, we have reviewed comments received in connection with our proposal in the CY 2008 PFS proposed rule to revise §411.354(d) to permit the use of percentage-based compensation formulae (such as the type often used for making cost sharing payments) for personally performed

physician services only (72 FR 38184). In that proposal, we specifically noted that the revisions, if finalized, could potentially affect payment methodologies used in gainsharing programs. Generally, commenters strongly supported the establishment of an exception for gainsharing and other programs that compensate physicians and physician organizations for improving patient care quality and decreasing the cost of providing patient care when those achievements can be tied to the physician's or physician organization's participation in the program. Commenters urged that an exception contain safeguards to ensure patient access to necessary items and services, improve patient care quality, and avoid improper influencing of physician referral patterns due to the constraints or incentives of the program's design. One commenter suggested that the availability of the exception be contingent upon the parties obtaining a favorable advisory opinion from OIG prior to the implementation of the gainsharing program. In addition, commenters requested that an exception provide flexibility to allow an entity to design an incentive payment or shared savings program that is specific to the entity's goals and needs, as well as to modify the program as necessary. One commenter also provided recommendations regarding the types of cost

savings measures (in addition to supply cost reduction measures) that should be addressed by the exception, as well as particular services, clinical protocols, and other arrangements that we should exclude from the protection of an exception for incentive payment and shared savings programs. The commenter suggested that an exception to the physician self-referral prohibition should permit more types of arrangements (and within additional medical specialties) than thus far have been explicitly approved in OIG advisory opinions. Specifically, the commenter urged that an exception for incentive payment and shared savings programs allow a program covered by the exception to reward: (1) decreasing delays in patient care; (2) reconsidering ordering patterns for all types of testing and services (in order to reduce medically unnecessary services and reduce cost); (3) reducing consultation of other physicians when value is not added to the patient's care through the consultation; (4) establishing long-term management of chronic patient conditions; and (5) using alternative care (for example, outpatient care instead of inpatient care).

Specific recommendations for safeguards to be included in an exception for incentive payments and shared savings programs included: (1) permitting the duration of the

program to exceed 1 year (the term of the arrangements approved under the OIG advisory opinions to date); (2) requiring mechanisms to ensure that the program will not affect patient care in an adverse manner; (3) limitations on the amount of payments to participating physicians; (4) requiring periodic review of the impact of the program on clinical care; (5) a written agreement that clearly identifies the services or actions for which payment may be made to the participating physicians; (6) permitting payments only for documented and verified quality improvement and waste or cost reduction; (7) determining compensation to participating physicians (or a formula for such compensation) prior to the implementation of the program or the physician's participation in the program, and prohibiting modification to the compensation during the term of the arrangement; (8) requiring written disclosure regarding the program to all patients affected by the program to promote transparency and accountability; and (9) prohibiting payment to a physician or physician organization that is determined in any way based on a reduction in the length of stay for hospital patients.

c. Proposal

Although we solicited comments in the FY 2009 IPPS proposed rule regarding an exception to the physician

self-referral prohibition for gainsharing arrangements (73 FR 23692), we believe that a broader exception that includes incentive payment programs is needed to facilitate the full array of nonabusive, beneficial incentive payment and shared savings programs that we consider important for promoting the highest quality of care for our beneficiaries while achieving cost savings for the program. Section 1877(b)(4) of the Act authorizes the Secretary to create regulatory exceptions for financial relationships that he determines do not pose a risk of program or patient abuse. Therefore, using our authority under section 1877(b)(4) of the Act, we are proposing here an exception in new §411.357(x) for payments provided to a physician participant in an incentive payment or shared savings program that includes certain safeguards and satisfies certain conditions.

i. General Considerations with Respect to the Proposed Exception

As we described above in greater detail, we have concerns about physicians responding to incentive payment and shared savings programs by stinting, cherry picking, steering, and making quicker-sicker discharges. The criteria included in the proposed exception are focused on three aspects that we consider critical to a properly

structured, nonabusive incentive payment or shared savings program: transparency, quality controls (for example, controls to prevent reductions in resource utilization that lead to a diminution in quality), and safeguards against payments for referrals (or influencing referrals). We are proposing requirements with respect to the structure of the incentive payment and shared savings program itself, limitations and conditions regarding the payments provided to the physicians participating in the program, and requirements for the arrangement between the hospital and the physicians participating in the program. We are seeking comments on each requirement in the exception, as well as comments regarding the exception in its entirety. With respect to the latter, we are interested in comments regarding the effect of incentive payment and shared savings programs on marketplace competition, specifically with regard to whether shared savings programs that include product standardization measures disadvantage small manufacturers of items, supplies and devices due to the selection and preferred utilization of a limited number of items, supplies and devices included in the shared savings program, the ordering of which qualifies for program payments. (We note that, although we expect that the initial selection of the preferred products would be based

on clinical efficacy, safety and medical appropriateness, we recognize that the final selection of products in a product standardization program is likely to be based on price when quality and utility are comparable). We are interested in comments on how product standardization can be achieved without limiting patient access to items, supplies and devices considered beneficial to improved patient care. We are also concerned about the potential for fraud and abuse if manufacturers attempt to influence the design or implementation of hospital incentive payment or shared savings programs.

We note that, for most of the requirements and safeguards discussed in this proposal, we have proposed regulation text. However, we have not provided proposed regulation text for a limited number of the proposed requirements and safeguards described, but rather have solicited comments regarding how best to incorporate them into the regulatory text of the exception.

We are proposing a single set of requirements that would apply equally to incentive payment and shared savings programs. In many cases, programs may include both patient care quality measures and cost savings measures, or a particular performance measure may be both a quality measure and cost savings measure. We believe that one set

of requirements would ease administration and assist with hospitals' and physicians' compliance efforts. Further, similar risks of program or patient abuse exist regardless of whether a hospital pays a physician a share of its internal cost savings, a share of external funds earned by meeting quality goals (in a payer-sponsored program), or a share of its general revenues to promote quality. We are interested in comments with respect to whether separate exceptions for incentive payment programs and shared savings programs would be preferable and, if so, how they should be structured, and which requirements should appear in each.

The requirements of the proposed exception include a number of program integrity safeguards, consistent with our longstanding concern, first noted in the Phase I final rule with comment period, that a patient's choice can be affected when physicians steer patients to less convenient or lower quality items or services because the physicians are sharing profits with, or receiving remuneration from, the provider (63 FR 1659 and 1662). We are also concerned about systems that incentivize the delivery of less expensive care at the cost of patient care quality and systems that limit patient access to beneficial new technology. The proposed exception prohibits payment to

physicians 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 operating the program. However, we recognize that reduced length of stay may occur as an incidental effect of quality improvement efforts.

ii. Scope of the Proposed Exception

As noted above, we used the term "incentive payment and shared savings program" to encompass a wide variety of gainsharing and P4P programs. We do not propose to limit the exception to traditional gainsharing programs or supply cost/waste reduction programs. We are seeking comments regarding whether this approach is too limited or expansive, and whether different terminology would better describe the range of nonabusive programs we intend to cover under the proposed exception.

Our proposed exception protects only incentive payment and shared savings programs offered by hospitals. It is our understanding that these arrangements are the most common, and, as described above, are the type with which we have the most experience. We are concerned that, unlike hospitals that are reimbursed on a prospective payment basis, other types of providers and suppliers that are reimbursed on a fee schedule or other FFS basis might have an incentive to create quality measures that mandate the

furnishing of more items and services, without regard to costs to the Medicare program or its beneficiaries. In many cases, it might be relatively easy to characterize a program that offers beneficiaries more items and services as a "quality" incentive program, even in the absence of actual quality improvement. However, we are soliciting comments on whether incentive payment or shared savings programs (or similar programs) offered by other DHS entities should be protected and under what circumstances. In particular, we are interested in comments regarding the structure and design of non-hospital arrangements and the safeguards that we could include in an exception to meet the statutory standard of no risk of program or patient abuse.

We are proposing to protect remuneration only in the form of cash (or cash equivalent) payments made by a hospital. Nonmonetary remuneration, such as additional staff members or new equipment, offered to reward achievement of quality or cost savings goals would not be protected. In addition, the proposed exception would be limited to payments to physicians who actually participate ("participating physicians") in the achievement of the patient care quality measures or cost savings measures (collectively referred to in this proposal as the

"performance measures") that are the subject of the particular program. We note that the physician self-referral statute applies only to physicians. Nothing in this proposal is intended to limit or prohibit the participation of NPPs in incentive payment and shared savings programs. Moreover, the participation of NPPs in an incentive payment or shared savings program would not require the protection of an exception to the physician self-referral prohibition unless the practitioner's referrals are directed by, controlled by, or attributed to a physician with whom or for whom the practitioner works.

We are proposing that protected payments could be made to participating physicians individually or to physician organizations composed entirely of participating physicians (referred to in this proposal as "qualified physician organizations") (for example, a group practice composed entirely of cardiac surgeons participating in a cardiac surgery shared savings program could be a qualified physician organization). With respect to qualified physician organizations, we are considering whether such organizations could include physicians who are eligible to participate in the program, even if the individual physicians elect not to participate in the program (for example, a group practice composed entirely of cardiac

surgeons could be a qualified physician organization in a cardiac surgery shared savings program, even if some surgeons elect not to participate in the program). As discussed further below, qualified physician organizations would need to distribute incentive or shared savings payments received from the hospital on a per capita basis to the physicians in the physician organization who participated in the incentive payment or shared savings program. In any case, payments made to physicians who refer patients to the hospital but do not otherwise participate in the program would not be protected. For example, payments to cardiac surgeons for changing their operating room procedures would be protected (provided that all of the other requirements of the exception were satisfied), whereas payments to the cardiologists who referred the patients for cardiac surgery but did not perform the surgery or contribute to the achievement of the performance measures through their personal efforts would not be protected.

iii. Requirements Related to the Design of an Incentive Payment or Shared Savings Program

To be protected, the incentive payment or shared savings program must be a documented program that seeks to achieve the improvement of quality of hospital patient care

services through changes in physician clinical or administrative practices or actual cost savings for the hospital resulting from the reduction of waste or changes in physician clinical or administrative practices, without an adverse affect on or diminution in the quality of hospital patient care services.

We are proposing to require that, in order for payments made as part of an incentive payment or shared savings program to qualify for the protection of the exception, the program must include patient care quality or cost savings measures (or both) supported by objective, independent medical evidence indicating that the measures would not adversely affect patient care. Specifically, all performance measures must use an objective methodology, be verifiable, be supported by credible medical evidence, and be individually tracked. The measures must reasonably relate to the hospital's practices and patient population. In the interest of creating clear, bright-line rules, we are proposing specifically that patient care quality measures be listed in CMS' Specifications Manual for National Hospital Quality Measures. In the alternative, rather than require programs to include the patient care quality measures listed in CMS' Specifications Manual for

National Hospital Quality Measures, we would deem such measures to satisfy that requirement.

With respect to cost savings measures, we are proposing to require that cost savings measures included in the incentive payment or shared savings program use an objective methodology, be verifiable, be supported by credible medical evidence indicating that the measures would not adversely affect patient care, be individually tracked, and reasonably relate to the services provided. We are seeking comment regarding this approach and the described alternative for patient care quality measures in general, and we are interested specifically in comments regarding other appropriate performance measures (or lists of performance measures, particularly with respect to cost savings measures to the extent such a list might exist) that might be deemed to satisfy such a requirement if we finalize this alternative proposal, as well as whether parties could satisfy this requirement by including criteria deemed by the Secretary in an advisory opinion to meet the requirement. We are including this requirement to safeguard against programs that incorporate sham standards that are designed to reward physicians for referrals rather than the achievement of legitimate benchmarks for quality maintenance or improvement or cost savings. We believe

that appropriate performance measures should derive from broad, objective, widely-recognized criteria and not merely result from the subjective views of the parties to the arrangement. We also are proposing a specific requirement that the program ensure that the quality of patient care services is not impacted adversely as a result of the program.

We are proposing that an incentive payment or shared savings program must be reviewed prior to implementation of the program and at least annually thereafter to ascertain the program's impact on the quality of patient care services provided by the hospital. We believe that such vigilance is critical to ensure that quality of hospital patient care is not impacted adversely. Under this proposal, the reviews must be conducted by a person or organization with relevant clinical expertise, and they must be independent medical reviews. By "independent medical reviews," we mean reviews by an individual or organization that is not: (1) affiliated with the hospital operating the program under review; (2) not affiliated with any participating physician or with any physician organization with which a participating physician is affiliated; and (3) at the time of the review, not participating in any incentive payment or shared savings

program operated by the hospital. We are seeking comments specifically regarding the appropriate frequency for review of incentive payment and shared savings programs to ensure that quality of hospital patient care is not impacted adversely and to protect against program or patient abuse. We are also seeking comments addressing the circumstances, if any, under which the periodic review could be conducted by an individual or organization that does not fall within the definition of "independent medical review" outlined above.

Any reviews would need to be objective, accurate and complete and result in written findings. We are proposing that the initial and periodic reviews should be contemporaneously documented, and that all documentation related to the incentive payment or shared savings program and the reviews thereof be made available to the Secretary upon request. We are further proposing that incentive payment and shared savings programs must provide for immediate and appropriate corrective action in the event a periodic review reveals an adverse impact on quality. Corrective actions could include termination of the program, removal of the relevant measure from the program, removal of the relevant measure from the calculation of physician payments, or termination of the physician from

the program. We are considering whether corrective actions could also include modification of a performance measure and, if so, under what conditions. However, we would prohibit the discontinuation of a performance measure for the purpose of increasing the payment to the participating physicians in the next period. Also, although we do not want to encourage practice patterns that result in reduced or poor quality patient care, we do not believe it is appropriate to permit the discontinuation of a performance measure because the participating physicians are unable to earn a shared savings payment related to that measure. We are interested in comments addressing the appropriate corrective actions and how best to incorporate a corrective action requirement into the regulatory text of the exception.

We are proposing to require that participation in the program be limited to those physicians who are members of the hospital's medical staff at the commencement of the program. We believe that this would protect against abusive programs that serve as inducements to attract physicians from competing hospitals. However, we are soliciting comments on whether and, if so, how a physician who joins the medical staff at the hospital as part of the normal cycle of workforce demands for care delivery could

be permitted to participate in an incentive payment or shared savings program (either individually or as part of a qualified physician organization, as described below) that began before he or she joined the medical staff of the hospital. We are also proposing that physicians participating in an incentive payment or shared savings program, or in a particular performance measure or measures within an incentive payment or shared savings program, must do so in "pools" of five or more participating physicians among whom the aggregate incentive payment available for, or cost savings that result from, the efforts of the physicians in the "pool" with respect to a particular measure would be shared on a per capita basis. A qualified physician organization could itself constitute an eligible pool, provided that it is comprised of at least five participating physicians. Otherwise, participating physicians in the qualified physician organization would need to be grouped by the hospital into pools of at least five participating physicians.

The distribution of incentive payment and shared savings program payments must be supported by written documentation. As an additional safeguard, we are proposing to require that physician "pools" be formed at the commencement of the program. We are interested in

comments about our proposal to require hospitals to create pools for purposes of physician participation in incentive payment and shared savings programs and the minimum number of physicians needed to comprise a "pool" that adequately reduces the risk of program or patient abuse.

Specifically, we are interested in comments on whether and, if so, how we should address the "pooling" of funds for payment purposes in an incentive payment or shared savings program targeted at a specific medical specialty or hospital department in which the physicians on the medical staff in that specialty or department or in the physician organization total fewer than five physicians.

We are proposing also that a hospital may not determine eligibility for physician participation in a program based on the volume or value of referrals or other business generated between the parties. We are also considering, and soliciting comments about, conditioning protection under the exception on the hospital offering the opportunity to participate in the incentive payment or shared savings to all physicians on the medical staff who belong to the department or practice in the specialty relevant to the program (for example, the opportunity to participate in a shared savings program for cardiac surgery

would have to be offered to all cardiac surgeons on the hospital's medical staff).

To qualify for protection under the proposed exception, an incentive payment or shared savings program may not limit the discretion of physicians to make medically appropriate decisions for their patients, including, but not limited to, decisions about tests, treatments, procedures, services, supplies or discharge. Although incentive payment and shared savings programs may condition program payments on particular physician choices, to be protected under the proposed exception, such programs could not limit other choices for which physicians would not receive program payments. In particular, a hospital must not limit the availability of any specific item, supply or device, including new technology that is linked through objective evidence to improved outcomes and is clinically appropriate for a particular patient, and must permit individual physicians access to the same selection of items, supplies and devices that was available to them prior to the physician's participation in the program. We are not requiring physician access to items, supplies and devices that were not available prior to the commencement of the incentive payment or shared savings program. Rather, a hospital must make available to a participating

physician at least the same selection available to the physician prior to his or her participation in the incentive payment or shared savings program, which already may have been restricted by hospital policy, but without payment to physicians based on such situations.

We recognize that some shared savings programs are designed to channel the physician's selection of physician preference items toward a limited number of choices; however, we believe that, to safeguard the program and its beneficiaries against abuse, physicians participating in a shared savings program must have access to items or supplies that they deem medically necessary for an individual patient's care. This would include new technology, provided that it meets the same Federal regulatory standards (for example, approval by the Food and Drug Administration (FDA) and Medicare or Medicaid coverage decisions) as the items or supplies included in the program. By including this requirement, we intend that programs would ensure access to clinically appropriate new technology while, at the same time, protect patient safety. For example, if a program includes three alternative, FDA-approved devices for a particular procedure, the hospital sponsoring the program could limit access to new technology that is experimental (that is, not FDA-

approved), but could not limit access to FDA-approved alternative devices/technology. We note also that items, supplies and devices in a product standardization program (that is a cost savings action under a shared savings program) should not be selected on the basis of a participating physician's ownership or investment interest in, or compensation arrangement with, the manufacturer or distributor of the item, supply or device, or his or her interest in a group purchasing organization (GPO) that arranges for the purchase of the item, supply or device. In this regard, we would strongly recommend, and may require, that such physicians be barred from participating in any manner in the design or implementation of an incentive payment or shared savings program that involves items, supplies or devices in which the physician has a financial interest. We are proposing that a physician (or qualified physician organization) could not receive a payment under an incentive payment or shared savings program for the use of an item, supply or device if he or she (or the qualified physician organization) has an ownership or investment interest in, or a compensation arrangement with, a manufacturer or distributor of the item, supply or device, or GPO that arranges for the purchase of the item, supply or device.

iv. Requirements Related to Payments Made under an Incentive Payment or Shared Savings Program

To reduce the risk that incentive or shared savings program payments might be used to encourage or reward referrals to the hospital or provide incentives to engage in other abusive practices, such as stinting or cherry picking, we are proposing that payments made to physicians participating in the incentive payment or shared savings program be distributed on a per capita basis. We are interested in public comments that may outline alternate approaches to the per capita payment model for the distribution of incentive payments or shared savings payments, such as paying a physician more or less according to whether he or she contributed more or less to the achievement of the performance measures included in the incentive payment or shared savings program.

We believe that safeguards are necessary to ensure that incentive payment and shared savings programs do not result in altered referral patterns and to reduce the risk that programs will become vehicles used to reward referring physicians. To address this, we are proposing that remuneration paid to a participating physician or a qualified physician organization may not include any amount that takes into account the provision 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 as that covered by the payment. We are interested in comments regarding whether and, if so, how to account for volume changes due to market forces and physician practice growth.

We are also proposing that the amount of the remuneration paid to the physician or qualified physician organization be limited in duration and amount. With respect to duration, we are proposing that protected programs be no shorter than 1 year and no longer than 3 years. With respect to a limit on the amount of payments, we are proposing two types of limits, which we might adopt separately or together.

First, we are proposing a limit on payments expressed as a set percentage of the savings available to the hospital as a result of the changes in clinical or administrative practices the participating physicians. Although not incorporated into the proposed regulation text, we are specifically considering a flat 50 percent limit on the sharing of cost savings (regardless of the length of the program), and are considering whether to require "re-basing," depending on the length of the

program. We are interested in comments regarding whether this "cap" on payments is appropriate, too high, or too low. We are interested also in comments regarding whether and, if so, how we should limit payments under a multi-year incentive payment or shared savings program to an amount that would be actuarially equivalent to the amount of the payments made under a 1-year program. We are considering also "scaled" limits for programs longer than 1 year. Under the scaled limits approach, we would not require re-basing (as further described below), but would require that payments to physicians decrease over the course of the performance measure. For purposes of calculating the actual payments to the physician, we are proposing that cost savings be measured by comparing the hospital's actual acquisition costs for the items and supplies or costs of delivering the specified services that are subject to the incentive payment or shared savings program to the hospital's baseline costs for the same items, supplies or services during the 1-year period immediately preceding the commencement of the program.

Second, we are proposing a limit on payments to address the risk that physicians will continue to receive financial rewards for already implemented changes in clinical or administrative practices. This second limit

would require that payments made under an incentive payment or shared savings program must take into account any payments that have already been made for performance measures already achieved ("re-basing"). We are considering a re-basing approach under which, at the end of year one, the hospital would re-base performance measures such that available payment would be based on the difference between the hospital's then-current level for a particular performance measure and the goal established for that performance measure. This approach would apply similarly to incentive payments made exclusively for improvements in patient care quality that are unrelated to the achievement of cost savings. We are soliciting comments specifically as to whether requiring the re-basing of "quality-only" payments is a necessary safeguard against program or patient abuse, or whether a different approach for limiting such payments could be implemented that would safeguard against risk to the Medicare program or its beneficiaries. We are also soliciting comments on whether we should require re-basing at all and, if so, under what parameters and whether parties should be free to choose the frequency of the payment and re-basing periods under the incentive payment or shared savings program. In no event would a hospital be permitted to increase the incentive

payment or shared savings payment potentially available to physicians as a result of the re-basing.

By way of illustration, assume that one objective cost saving measure in the program is to decrease from 80 percent utilization of a specified item during a particular surgical procedure (the hospital's historical utilization rate for the item) to 20 percent utilization (the national average for utilization of the item). Under an approach that requires re-basing, if, after completion of the first year of the program, the hospital's utilization of the specified item decreased to 60 percent of surgical procedures, for year 2 of the arrangement, the participating physicians could receive payment only for any reduction below 60 percent utilization of the specified item, that is, the new "historical" baseline utilization rate would be 60 percent and all cost savings and waste reduction for the upcoming year would be measured against the new baseline utilization rate. If, after completion of year one, the hospital's utilization of the specified item increased to 90 percent, the hospital would be prohibited from re-basing the utilization rate higher than the initial 80 percent utilization rate determined at the commencement of the incentive payment or shared savings program. The participating physicians would, in the aggregate, be

eligible to receive as a shared savings payment the same percentage of cost savings throughout the term of the program.

Using the same figures, under an approach that requires scaling of the payments over the course of the arrangement, the physicians participating in the program would be eligible for a decreasing percentage of cost savings over the course of the arrangement. Assume, for example, we adopted an approach that permitted shared savings payments of up to 50 percent for year one, up to 35 percent for year two, and up to 20 percent for year three. If a particular cost savings measure generated savings of \$100,000 the first year, \$150,000 the second year, and \$200,000 the third year (all relative to the historical baseline utilization rate established at commencement of the program), the participating physicians would be eligible for a total of 50 percent of \$100,000 (or \$50,000) the first year, a total of 35 percent of \$150,000 (or \$52,500) the second year, and 20 percent of \$200,000 (or \$40,000) the third year. We are also considering protecting programs in which dollar limits are expressed as fixed dollar amounts rather than percentages.

Each of the approaches described above could be adopted to the exclusion of or in concert with each other.

We are interested in comments regarding whether the exception should include one or more of the payment limit alternatives, as well as comments regarding other appropriate limitations for the amount and nature of the payments made under an incentive payment or shared savings program. Regardless of which approach we adopt, we are proposing to require that payments based on cost savings be calculated on the hospital's actual acquisition costs for the items at issue, as well as the costs involved in providing the specified services and that they be calculated on the basis of all patients, regardless of insurance coverage (subject to the cap on payment for Federal health care program beneficiaries described above). We are seeking comments regarding whether these conditions are appropriate and whether we should permit modification under other or different circumstances.

We do not intend to protect arrangements in which physicians receive payments for actions taken that result in a reduction below a predetermined target. For example, in the first hypothetical (under the required re-basing approach), no payments could be made for reductions below 20 percent utilization. We intend to require that the target thresholds use objective historical and clinical measures that are reasonably related to the practices and

the patient population at the hospital. We are mindful that some performance measures may not be amendable to such utilization "floors" or "ceilings." We are considering including comparable safeguards for measures that may not be readily amenable to percentage "floors" and "ceilings", such as measures related to product substitution and product standardization. For example, the fact that the substitution of one product for another would not adversely impact quality might need to be supported by substantial objective medical evidence. We are soliciting comments on what kinds of quality controls are appropriate for performance measures that are not amendable to utilization "floors" and "ceilings." We are considering whether and, if so, how this concern can be addressed by requiring that the parties obtain a fully independent clinical review by a qualified party of the program measures prior to implementing the program. We are soliciting comments on appropriate quality safeguards in such situations.

We recognize that parties might want to structure arrangements so that payments are made by the hospital to a physician organization that would not meet our proposed definition of a qualified physician organization. This might be the case if incentive payment or shared savings payments are made by a hospital to a multi-specialty

physician practice composed of participating and non-participating physicians (for example, a group composed of cardiac surgeons and cardiologists, in the case of a cardiac surgery shared savings program). We are considering whether to extend the proposed exception to cover payments from a hospital to such physician organizations and, if so, under what conditions we could do so that would pose no risk of program or patient abuse. We are concerned that payments made to such physician organizations may become conduits to reward non-participating physicians for referrals. On the other hand, we recognize that programs structured so that hospitals make payments to physician organizations rather than to individual physicians may be administratively easier for hospitals to operate. (We note that, in some cases, payments from hospitals to physician organizations that are not qualified physician organizations might fit in the existing exception for indirect compensation arrangements, depending on the circumstances.)

We are considering several options to address this issue. First, we are considering an approach that would allow hospitals to make incentive payment or shared savings payments to individual physicians indirectly by passing the payment through the physician's physician organization.

Under this approach, the total amount of the payment earned by the physician under the incentive payment or shared savings program would need to be passed through to the physician, except amounts required for income tax and other regular withholding. Under this approach, the physician organization would simply operate as a pass-through entity. The physician organization would be prohibited from retaining any portion of the incentive payment or shared savings payment (except, potentially, for required withholdings to be paid on behalf of the participating physician). We are soliciting comments about this approach and what types of payments the physician organization could withhold (for example, whether the physician organization should be permitted to withhold required contributions to a qualified retirement plan).

We are concerned about the difficulty hospitals might encounter in ensuring that the physician organization accurately and fully passes through the full payment to the participating physician, and we are concerned about the risk of fraud and abuse if the payment mechanism were manipulated so that the physician organization retains a portion of the payments for its own benefit. Such gaming of the payment structure could result in improper remuneration from the hospital to the physician

organization for referrals (and would not fit in the proposed or any other exception to section 1877 of the Act). We are interested in comments about how to craft safeguards for the exception to prevent this type of potential abuse. In this regard, we are considering requiring that the physician organization document all amounts received and distributed to participating physicians, as well as any income tax or regular withholding payments made on behalf of the participating physician. In addition, we would require that the physician organization's obligations with respect to "pass through" payments be included in the written agreement between the parties and that the physician organization be a signatory (in addition to the hospital and the participating physician) to the agreement. We are soliciting comment on these and any other safeguards necessary to ensure that payments are appropriately passed through to participating physicians.

Second, we are considering whether, without posing a risk of program or patient abuse, we could expand the definition of a "qualified physician organization" to which protected payments can be made to include physician organizations comprised of some physicians who are not participating physicians. This approach, if implemented,

would have the effect of protecting payments made directly to such physician organizations (rather than directly to individual physicians or "passed through" the physician organization), provided that all other requirements of the exception were satisfied. We would adopt this approach only if we could do so in a manner that would not result in payments to physicians whose only contributions to the hospital's incentive payment or shared savings program are potential referrals. If we expand the definition of a qualified physician organization, we envision a requirement that would permit only participating physicians to share in the incentive or shared savings payments. Our concerns described above about the difficulty hospitals would experience in monitoring the payments and the risk of manipulation to benefit referral source physicians or the physician organization as a whole are heightened with this approach. If we were to adopt this approach, we would include the proposed safeguards described above in connection with the pass-through payments proposal. In any event, we do not intend to protect arrangements that reward passive physicians who receive payments but do not participate in the achievement of the patient care quality or cost savings measure goals.

One benefit of protecting programs that are structured so that payments are made from the hospital to a physician organization would be to avoid potential confusion that might be caused by the physician "stand in the shoes" provisions in §411.354(c)(2) (under which a physician is considered to have the same compensation arrangements with the same parties and on the same terms as his or her physician organization with respect to whether remuneration is permissible under an exception). We are interested in comments on the relationship of the proposed exception to the "stand in the shoes" provisions. We are also interested in comments regarding whether the new exception, if adopted, should be included in §411.357, or whether it would be preferable to include it in §411.355 or elsewhere in the physician self-referral regulatory scheme.

v. Requirements Related to the Arrangement Between a Hospital and the Participating Physician or Qualified Physician Organization

We are proposing to include in the exception certain criteria that are common to most of the exceptions to the physician self-referral prohibition for compensation arrangements, namely, that the arrangement be set out in writing, signed by the parties, have a minimum term of 1 year and a maximum term of 3 years, and specify

compensation that 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. We are proposing to require that the written agreement between the hospital offering the program and the physicians participating in the program document the performance measures against which the performance of the participating physicians will be measured. In addition, we are proposing that each performance measure (including, for example, specific cost savings measures) and the payments resulting from the achievement of established targets must be delineated separately and clearly. We believe transparency is crucial to ensure that the incentive payment or shared savings program does not pose a risk of program or patient abuse. However, we are interested in comments regarding whether and, if so, how total (or "global") savings for a particular department or service line can be included in the program and sufficiently monitored, accounted for, and distributed so as not to pose a risk of program or patient abuse and to permit transparency of the program.

As in all exceptions issued using our authority under section 1877(b)(4) of the Act, we are proposing to include

a requirement that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. This is necessary to ensure that the arrangement does not pose a risk of program or patient abuse, the standard for all exceptions issued using this authority.

In order to promote transparency and foster accountability, we are proposing to require that the arrangement between the parties require written disclosure to patients affected by the program regarding the nature of the program and the physician's or qualified physician organization's participation in the program prior to admission to the hospital, or, if pre-admission disclosure is not feasible, prior to the procedure or other treatment to which the program is applicable. Affected patients include those patients whose patient care at the hospital relates to any of the measures that are part of the program. For example, a patient being admitted to a hospital for cardiac surgery should receive a disclosure if the hospital operates an incentive payment or shared savings program related to cardiac surgery and his or her physician participates in that program. We are considering whether patients should be permitted to opt out of a measure that might otherwise apply to their care and are

seeking comments regarding whether and how this would work in practice.

Finally, we are proposing the following additional safeguards. We are interested in comments regarding how to incorporate these requirements into the regulation text. First, to guard against cherry picking or other abuse, the case severity, and the ages and payers of the patient population treated by the participating physician under the arrangement must be monitored using generally-accepted standards. The monitoring could be conducted by an independent outside party or by a committee composed of representatives of the hospital and participating physicians. If there are significant changes from the hospital's historical measures, the physician at issue must be terminated from participation in the arrangement. The monitor should also assess these characteristics in the aggregate across all participating physicians; if there are significant changes, the program should be terminated. Second, physicians are only eligible for payments that are related to their own efforts, combined with the efforts of the other physicians in their pool, at meeting cost savings measures or achieving patient care quality measures; that is, a physician is eligible to receive only a per capita share of that portion of an available incentive payment or

shared savings payment attributable to the efforts of his or her pool. Third, all measures should be uniformly applied to all patients including Medicare beneficiaries (that is, the measures should not be applied disproportionately to Medicare beneficiaries). Procedures or treatments subject to the incentive payment or shared savings program should not be performed disproportionately on Federal health care program beneficiaries. We are also considering and interested in comments regarding a requirement that the hospital offering an incentive payment or shared savings program audit the calculation of cost savings and payments made under the program. To this end, we are interested in comments regarding the formality of such an audit; that is, should we permit the hospital to complete the audit internally, or should we require an independent financial audit of the books and records related to the incentive payment or shared savings program.

We would also require that incentive payment and shared savings programs must not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law. In addition, we are proposing that the full range of documentation developed and maintained in connection with compliance with the new