

## **Physician Self-Referral Update for PPAC**

In 2008 thus far, CMS has proposed some changes, and finalized other changes to the Physician Self-Referral Regulations, which appear at 42 CFR, Part 411, Subpart J. These are discussed below. Also discussed are the proposed revisions to the anti-markup rules and the Disclosure of Financial Relationships Report, an information collection instrument.

### **I. Proposed changes appearing in the CY 2009 Physician Fee Schedule Proposed Rule (73 FR 38502, 38544-38558)**

#### **A. Proposed exception for Incentive Payment and Reward Sharing Programs (Proposed §411.357(x))**

- Although “gainsharing” is the most common term used to describe programs that seek to align physician behavior with the goals of a hospital or reward the achievement of predetermined performance outcomes, several types of programs exist for achieving quality standards and waste reduction. In our proposal, we referred to these programs as “incentive payment and reward sharing programs.” Successful programs often result in improved quality outcomes or cost savings (or both) for the hospital or other entity sponsoring the program, as well as financial payments to the physicians whose efforts contribute to the success of the program. These payments may implicate the physician self-referral law.
- Gainsharing and waste reduction programs seek to align physician economic incentives with those of hospitals and other entities by offering physicians a share of the entity’s variable cost savings attributable to the physicians’ efforts in controlling the cost of providing patient care. Following the institution of the Medicare Part A DRG system of hospital reimbursement and with the growth of managed care, hospitals have experienced significant financial pressure to reduce costs. (Similar pressures have been realized by other providers as corresponding prospective payment systems have been implemented.) However, because physicians are paid separately under Medicare Part B and Medicaid, physicians do not share necessarily an entity’s incentive to control its patient care costs. Gainsharing and waste reduction programs have been recognized by industry stakeholders as an effective means of controlling costs and improving efficiency in the delivery of health care services. Many gainsharing and waste reduction programs also include requirements regarding the improvement or maintenance of patient care quality.
- “Pay for performance” (P4P), also known as value-based purchasing, is a quality improvement and reimbursement methodology that is aimed at moving toward payments that create much 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. When payor-based, P4P attempts to promote reimbursement for quality, access efficiency, and successful outcomes. Through collaborative efforts with a wide range of other public agencies and private organizations who have a common goal of improving quality and avoiding unnecessary health care costs, including the National Quality Forum (NQF), the Joint Commission of the Accreditation of Health Care Organizations (JCAHO), the National Committee for Quality Assurance (NCQA), the Agency for Health Care Research and Quality (AHRQ), the American Medical Association (AMA), CMS is developing and implementing a set of P4P initiatives to support quality improvement in the care of Medicare beneficiaries.

- In addition to payor-based P4P, health care providers also sponsor similar quality-focused programs in which objective improvements in quality or individual patient care outcomes are rewarded with payments to physicians and other health care practitioners responsible for the improvements. The objective measures used to determine whether providers are offering high quality care are commonly referred to as “quality standards.” When payments are made by an entity to a physician under this type of P4P or quality-focused program, the physician self-referral statute is implicated.
- In the FY 2009 Hospital Inpatient Prospective Payment System (IPPS) proposed rule, published in the Federal Register on April 30, 2008, 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, a portion of the hospital’s cost savings) attributable in part to the physicians’ efforts” (73 FR 23528, 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: (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).
- Using our authority under section 1877(b)(4) of the Act, we proposed an exception in §411.357(x) for remuneration provided to a physician (or his or her immediate family member) or to a physician organization under an incentive payment or reward sharing program that includes certain safeguards and satisfies certain conditions. Many of the conditions mirror those found important by the OIG in the 10 favorable advisory opinions it has issued for gainsharing programs.

- We proposed an exception in §411.357(x) for remuneration provided to a physician (or his or her immediate family member) or to a physician organization under an incentive payment or shared savings program that includes certain safeguards and satisfies certain conditions, that would rely on our authority under section 1877(b)(4) of the Act. Many of the conditions mirror those found important by the OIG in the 10 favorable advisory opinions it has issued for gainsharing programs; and
- We proposed excluding from the protection of the exception any incentive payment or reward sharing program that compensates physicians and physician organizations based on reduced lengths of stay.

#### B. Revisions to anti-markup provisions (§414.50)

Note: the anti-markup provisions are not a physician self-referral rule, as they do not prohibit or limit physician self-referral, but are closely linked to the rules on physician self-referral because the TC and PC arrangements affected involve physician self-referral

- In the CY 2008 PFS final rule, we revised §414.50 to impose anti-markup provisions on the technical component (TC) and professional component (PC) of diagnostic tests (other than clinical diagnostic laboratory tests) that are either purchased from an outside supplier or performed in a place other than the office of the billing supplier. The effect of the anti-markup provisions is to limit the amount that the billing supplier can bill Medicare to the lesser of what it paid the performing supplier or the fee schedule amount. The primary impetus for the provisions was our concern regarding overutilization that occurs when a single-specialty physician group practice refers patients to a pathologist or other specialist who (with a technician) performs the TC and PC and the single-specialty group practice bills for the TC and the PC. These offsite locations where the pathology work is performed are sometimes known as pod labs.
- Following publication of the CY 2008 PFS final rule (November 27, 2007), we received comments and questions regarding the revisions, including questions regarding what constituted the “office of the billing supplier.” For example, commenters wished to know whether the anti-markup provisions applied to diagnostic testing conducted in the “same building” (as defined in the physician self-referral regulations) in which the billing supplier has an office in which it treats patients, but on a different floor. Large multi-specialty groups, including non-profit groups, were concerned that the provisions would cause patient access problems and lost revenue, and alleged that their arrangements were not abusive and far different from the typical “pod lab” arrangement.
- Based on these informal comments, we determined that the definition of “office of the billing physician or other supplier” may not have been entirely clear. Therefore, on January 3, 2008, we published a final rule that delayed until January 1, 2009 much of the application of the anti-markup provisions. In the delay

notice, we indicated that, within the next 12 months, we planned to issue clarifying guidance as to what constitutes the “office of the billing physician or other supplier” or propose additional rulemaking, or both. We note that we did not delay application of the provisions to anatomic pathology diagnostic testing services that are performed in space that (1) is utilized as a “centralized building” for purposes of meeting the physician self-referral rules, and (2) does not qualify as a “same building” in which the billing supplier sees patients.

- A lawsuit was filed on January 24, 2008 (by “Uropath”) that challenged the January 3, 2008 rule that delayed the date of applicability of the anti-markup provision from the CY 2008 PFS final rule except for certain claims involving anatomic pathology diagnostic testing services. On May 5, 2008, the court granted the Secretary’s motion to dismiss Uropath’s complaint and vacated the preliminary injunction preventing the Secretary from enforcing the anti-markup provisions.
- In the proposed rule we proposed
  - + clarifying what would constitute the “office of the billing physician or other supplier;”
  - + an exception to the application of the anti-markup provisions for diagnostic tests ordered by a physician owner or a physician organization that does not have the right to receive profit distributions; and
  - + Solicited comments on: (1) defining “net charge”; (2) whether, in addition to, or in lieu of the anti-markup provision, we should prohibit reassignment in certain situations and require the physician supervising the technical component or performing the professional component to bill Medicare directly; and (3) whether we should delay the application of the revisions made by the November 27, 2007 final rule with comment period, or the proposed revisions (to the extent they are finalized), or both, beyond January 1, 2009.

## **I. Final changes appearing in the FY 2009 Inpatient Prospective Payment System Final Rule (73 FR 48688-745)**

The IPPS final rule finalized several proposed changes to our physician self-referral regulations. These proposals, for the most part, appeared in the CY 2008 PFS proposed rule, but two of them, stand in the shoes and period of disallowance, appeared in this year’s IPPS proposed rule. With three exceptions, noted below, the effective date for the provisions is October 1, 2008, the same as for the IPPS rule generally.

### **A. Stand in the shoes**

- In the final rule, we finalized revisions to the physician “stand in the shoes” provisions to deem a physician who has an ownership or investment interest in a physician organization to stand in the shoes of that physician organization. Physicians with only a titular ownership interest (that is, physicians without the ability or right to receive the financial benefits of ownership or investment,

including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment) are not required to stand in the shoes of their physician organizations. In addition, we are permitting nonowner physicians (and titular owners) to stand in the shoes of their physician organizations and we are also clarifying that the physician “stand in the shoes” provisions in §411.354(c) do not apply to an arrangement that satisfies the requirements of the exception in §411.355(e) for AMCs. We did not finalize our proposal regarding compensation arrangements between physician organizations and AMC components for the provision of services required to satisfy the AMC’s obligations under the Medicare GME rules, because we did not think it was necessary to do so, and nor did we want to protect only AMCs. Rather, we believe that a properly structured formula for the compensation to the community physician organization could meet an applicable “set in advance” requirement if it is determined at the commencement of the compensation arrangement, does not take into account the volume or value of referrals or other business generated between the parties, and satisfies the other requirements in §411.354(d)(1).

- We also did not finalize proposal to deem a DHS entity to stand in the shoes of an organization in which it has a 100 percent ownership interest.
- We finalized the revisions to the definitions of “physician” and “physician organization” as proposed in the FY 2009 IPPS proposed rule (73 FR 23690) in order to clarify that (1) a physician and the PC of which he or she is the sole owner are always treated the same for purposes of applying the physician “stand in the shoes” rules; and (2) a physician who stands in the shoes of his or her wholly-owned PC also stands in the shoes of his or her physician organization in accordance with revised §§411.354(c)(1)(ii)

#### **B. Period of Disallowance**

- where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;
- (2) where the noncompliance is due to the payment of excess compensation, the date on which the excess compensation is returned to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception;
- (3) where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which the additional required compensation is paid to the party to which it is owed such that the financial relationship would satisfy all of the requirements of the exception as of its date of inception. We continue to believe that it is possible that a financial relationship may end prior to the arrangement being brought into compliance.

#### **C. Alternative method for compliance**

- Under new paragraph (g) of §411.353, payment may be made to an entity that submits a claim or bill for DHS if the financial relationship between

the entity and the referring physician fully complied with an applicable exception under §411.357, except with respect to a signature requirement, and the following conditions are met: (1) if the failure to comply with the signature requirement was inadvertent, the entity rectifies the failure to comply with the signature requirement within 90 days after the commencement of the financial relationship (without regard to whether any referrals have occurred or compensation has been paid during such 90-day period); or (2) if the failure to comply with the signature requirement was not inadvertent, the entity rectifies the failure to comply with the signature requirement within 30 days after the commencement of the financial relationship (without regard to whether any referrals have occurred or compensation has been paid during such 30-day period). In order to take advantage of the alternative method for compliance in §411.353(g), the financial relationship at issue must, at the commencement of the financial relationship, satisfy all of the requirements (except the signature requirement) of an applicable exception.

**D. Percentage-based compensation formulae**

- Although we proposed to revise §411.354(d) to specify that compensation determined using a percentage-based formula may be used for paying for personally performed physician services only, at this time, we are finalizing a targeted approach for addressing our primary concerns regarding percentage-based compensation formulae that are used to determine compensation outside the context of personally performed physician services. Specifically, we revised our regulations to prohibit the use of percentage-based compensation formulae in the determination of rental charges for the lease of office space or equipment. We continue to believe that the use of percentage-based compensation formulae to determine rental charges for office space or equipment poses a heightened risk of program and patient abuse. This provision is effective for lease payments made on or after October 1, 2009.

**E. Per-click leases**

- The final rule revises the regulations to provide that per unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. The prohibition on per-click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician applies regardless of whether the physician himself or herself is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. The prohibition also applies where the lessor is a DHS entity that refers patients to a physician lessee or a

physician organization lessee. This provision is effective for lease payments made on or after October 1, 2009.

**F. Services furnished under arrangements**

- The final rule revises the definition of “entity” to provide that a DHS entity includes not only the person or entity billing for the DHS, but also the person or entity that performs the service that is then billed as DHS. This means that were a physician owner of a service provider refers a patient to his or her service provider which performs services and then sells those services to a hospital or other provider that then bills them under arrangements, the physician will need to satisfy an ownership exception (which really means the rural provider exception). This provision is effective for referrals made on or after October 1, 2009.

**G. Obstetrical malpractice subsidies**

- We revised our current exception to (1) retain the provisions of the current exception (renumbered as §411.357(r)(1)); and (2) provide an alternative set of requirements under which hospitals, federally qualified health centers, and rural health clinics (but not other entities) may provide obstetrical malpractice insurance subsidies (new §411.357(r)(2)). We believe that the provisions in new §411.357(r)(2) will reduce perceived obstacles to maintaining or improving patient access to needed obstetrical services by providing flexibility for the provision to qualifying physicians of obstetrical malpractice insurance subsidies. New §411.357(r)(2) allows hospitals, federally qualified health centers, and rural health clinics to provide an obstetrical malpractice insurance subsidy to a physician who regularly engages in obstetrical practice as a routine part of a medical practice that is: (1) located in a primary care HPSA, rural area, or area with a demonstrated need, as determined by the Secretary in an advisory opinion; or (2) is comprised of patients at least 75 percent of whom reside in a medically underserved area (MUA) or are part of a medically underserved population (MUP).

**H. Physician ownership in retirement plans**

- We proposed to revise our regulations to clarify that the exclusion from the definition of “ownership or investment interest” of an interest in a retirement plan pertains only to an interest in an entity arising from a retirement plan offered by that entity to the physician (or the physician’s immediate family member) through the physician’s (or immediate family member’s) employment with that entity (72 FR 38224). That is, where a physician has an interest in a retirement plan offered by Entity A, through the physician’s (or immediate family member’s) employment with Entity A, we intended to except from the definition of “ownership or investment

interest” any interest the physician would have in Entity A by virtue of his or her interest in the retirement plan; we did not intend to exclude from the definition of “ownership or investment interest” any interest the physician may have in Entity B through the retirement plan’s purchase of an interest in Entity B.

**I. Burden of proof**

- After consideration of the public comments, we are adopting our proposal as final and clarifying that the burden of proof (otherwise known as the burden of persuasion) is on the claimant throughout the course of the appellate proceeding (and at each level of appeal), whereas the burden of production initially is on the claimant but may shift to us or our contractor during the course of the proceeding.

**J. Disclosure of Financial Relationships Report (DFRR)**

- This is an information collection request and not a change to the regulations. Designed to collect information concerning the ownership and investment interests and compensation arrangements between hospitals and physicians. An information collection request was previously submitted to OMB for approval 60-day notice May 18, 2007 and a 30-day notice Sept. 14, 2007. Information collection request was withdrawn on April 10, 2008
- Announced and sought public comment on the information collection request in the FY 2009 IPPS proposed rule (60-day notice). We proposed to send the DFRR to 500 hospitals (both general acute care hospitals and specialty hospitals). (1) to identify arrangements that potentially may not be in compliance with the physician self-referral statute and implementing regulations; and (2) to identify practices that may assist CMS in any future rulemaking concerning the reporting requirements and other physician self-referral provisions (73 FR 23697)
- In FY 2009 IPPS final rule we discussed comments received in response to proposed rule’s solicitation of comments. We stated that we were proceeding with collection. We revised burden estimate to 100 hours and we signaled that we may send the DFRR to less than 500 hospitals
  - Upcoming publication of the 30-day Paperwork Reduction Act notice in the Federal Register. Comments should be sent directly to OMB. We will respond to comments received and revise DFRR as necessary. The collection of information process is complete when approval received from OMB.