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OIG issues green light to hospital "Pay for Quality" arrangement

By Janice A. Anderson, Richard K. Rifenbark, and Anil Shankar

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This is the fourth in a series of articles by Foley & Lardner LLP published in* Compliance Today *designed to address the compliance risks associated with quality of care in the hospital setting.

In Advisory Opinion 08-16, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services approved, for the first time, a hospital program to pay physicians for achieving quality of care by sharing the financial benefits received by the hospital through pay-for-performance (P4P) programs offered by third-party payers. This P4P arrangement allows hospitals to align financially with their medical staffs to drive quality of care improvements at the hospital.

The approved arrangement consists of a Quality Enhancement Professional Services Agreement (Agreement) between a hospital and a physician-owned professional limited liability corporation (PLLC), which all active staff members in relevant departments can join after they have worked at the hospital for more than one year. Under the Agreement, physicians who participate in the PLLC will commit to practice in compliance with hospital quality targets and will provide specific quality-related services to the hospital in order to improve the quality of care provided to the hospital's patients. These services include:

- developing policies and procedures,
- reviewing and monitoring quality of care in the hospital,
- providing care in accordance with hospital quality targets,
- ensuring adequate peer review if quality targets are not achieved, and
- auditing medical records to track compliance with quality activities.

In exchange for these services, the hospital will pay the PLLC (which then distributes the payment(s) to the member physicians on a per capita basis) a percentage of the P4P award received by the hospital for achieving specific quality targets established by the payer under a P4P incentive plan. This arrangement permits the physicians to participate in the proceeds received by the hospital for providing high quality care, which benefits the hospital, physicians, and patients.

The importance of alignment

The approved P4P arrangement comes at a time when trends in health care reimbursement and regulation underscore the need for new business models that align the financial incentives of hospitals and physicians. Today, the relationship between hospitals and physicians is often marked by distrust, conflicts of interest, and the erosion of the belief in mutual dependence. Historically, hospitals and physicians operated symbiotically, with physicians relying on hospitals as a place to provide services to their patients, and hospitals relying on physicians to refer and care for patients. Declining reimbursement and increasing costs, however, have led many physicians to compete directly with the hospital for business, for example, by owning and operating ambulatory surgery centers or imaging centers. These efforts by physicians to bolster income often increase the financial strain on hospitals and can place the hospital and its physicians in direct competition.

The advent of P4P as a dominant trend in health care reimbursement makes alignment with physicians a business necessity for hospitals. P4P programs reward hospitals that meet target quality metrics, and high scores on these metrics are necessary for hospitals to remain competitive in markets where P4P dominates. High scores, however, are almost impossible to achieve without the full cooperation of the medical staff. Physicians must cooperate with the hospital by providing care in accordance with the targets for the hospital to succeed. The misalignment occurs because hospitals receive the P4P payment, yet physicians must be the ones to earn it.

Medicare has announced its intent to move to a P4P payment methodology called Value Based Purchasing (VBP). The Centers for Medicare and Medicaid Services (CMS) was charged by Congress to reform its payment methodology when the Deficit Reduction Act was passed in 2005.[1] CMS spent 2007 developing its VBP model by holding industry listening sessions, and CMS submitted to Congress a final report describing the program on November 21, 2007.[2] On September 25, 2008, the Quality FIRST Act[3] was introduced for the purpose of implementing many of the principles of VBP recommended by CMS. Notably, the Act would begin paying hospitals for their performance on quality targets in four specified conditions currently reported to CMS (i.e., acute myocardial infarction, heart failure, pneumonia, and surgical care improvement and infection prevention) in 2011 based on the hospital's 2010 data. This means that hospitals will be paid based on performance beginning with data generated on or after October 1, 2009, the beginning of the government's 2010 fiscal year. The Act further phases in the amount at risk based on performance. For 2011, the amount is 0.5% of Medicare payments, with graduated increases until a full 2% of Medicare payments are based on performance.

As the government focuses on quality to drive its payment policies, regulators are more willing to hold providers accountable for unnecessary or poor quality care. As a result, quality has become a top compliance issue for hospitals and other health care providers. Today, quality-of-care violations are often enforced under the False Claims Act, resulting in multi-million dollar payments to the government for alleged substandard quality of care and unnecessary procedures.[4] The 2009 OIG Work Plan highlights the fraud and abuse risks associated with quality and has identified two specific enforcement initiatives focused on quality of care: a review of the reliability of hospital reported quality measurement data and a review of incidence of, and payments for, serious medical errors or "never events." The serious compliance risk based on quality of care cannot be managed appropriately by hospitals unless the medical staff is engaged to develop and implement quality improvement for the care delivered at hospitals.

Advisory Opinion 08-16 describes a business model that addresses these adverse trends by creating an opportunity for the hospitals and a broad group of physicians on the medical staff to align financial incentives to achieve common interests around quality. Unlike other physician/hospital alignment strategies of the past, the "Pay for Quality" structure creates a win/win for hospitals and the physicians. For hospitals, the active alignment of physicians around quality allows hospitals to perform better under P4P methodologies, thus maximizing payment for care delivered to patients. For physicians, sharing in the P4P awards with hospitals allows physicians to supplement declining reimbursement by cooperating, instead of competing, with the hospital.

The approved P4P arrangement successfully aligns the interests of the hospital and participating physicians. By sharing the financial rewards for achieving quality metrics with physicians, the hospital shares the incentive to maintain high levels of compliance with specific quality standards. Moreover, the structure encourages physicians to take the lead in developing and policing the methods to be used to ensure quality compliance. Although physicians are under no obligation to join the arrangement, the physicians who *do* have strong incentives for encouraging non-participating physicians to meet the quality metrics, because P4P awards are tied to the hospital's overall performance outcomes, not the participating physicians'. Participating physicians thus have a vested interest in encouraging the recommended medical practices and in engaging in meaningful peer review. These incentives place physicians in the lead in ensuring quality of care.

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Hospitals that have a structure in place to align physician performance around quality will have a marked advantage in seeking out additional P4P programs from payers and attracting business to the hospital. The Medicare demonstration projects focusing on P4P have proven that the programs can generate significant savings, creating a large pool of dollars to share with providers.[5] Hospitals that have a structure in place to achieve top performance under P4P will be significantly advantaged, because they can seek out P4P contracts with third-party payers and know that they can perform well under them. Thus, both physicians and hospitals are likely to perform well under the arrangement, increasing revenue while maintaining focus on their respective core business.

For the same reasons, the arrangement provides the added bonus of minimizing the compliance risks for both hospitals and physicians now associated with quality of care. By providing a structure in which hospitals can engage physicians proactively to improve quality, hospitals can avoid costly public enforcement actions based on quality failures.

Structuring the P4P arrangement

Although there are clear benefits to structures that align the incentives of physicians and hospitals to improve the quality of patient care, such as the P4P arrangement reviewed in Advisory Opinion 08-16, these structures must comply with federal health care fraud and abuse laws, including the Civil Monetary Penalty Law (CMPL),[6] federal Anti-kickback Statute,[7] and federal Physician Self Referral law (commonly referred to as the Stark laws).[8]

The CMPL prohibits hospitals from knowingly making payments directly or indirectly to physicians as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Violations of the CMPL are punishable by monetary penalties of $2,000 per patient.

The federal Anti-kickback Statute prohibits any person from "knowingly and willfully" paying, offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service covered by a federal health care program, or in exchange for arranging for or recommending purchasing, leasing or ordering any good, facility, service or item covered by a federal health care program, including Medicare and Medicaid. Violation of the Anti-kickback Statute is punishable by a $25,000 fine or imprisonment for up to five years, or both; may subject a violator to civil monetary penalties; and results in exclusion from participation in the Medicare and Medicaid programs.

Stark prohibits a physician from referring Medicare beneficiaries for designated health services, including inpatient and outpatient hospital services, to entities with which the physician has a financial relationship (and prohibits billing for services provided pursuant to such a referral), unless an exception applies. Violations of Stark may result in penalties that include denial of payment, civil monetary penalties of up to $15,000 per service (and $100,000 for schemes that are designed to circumvent Stark), and exclusion from the Medicare and Medicaid programs.

Although OIG found that the Agreement does raise issues under the CMPL and the Anti-kickback Statute,[9] the parties included several safeguards designed to reduce the risk of federal health care program abuse:

- First, only physicians who have been members of the hospital's active medical staff for at least one year are eligible to become owners of the PLLC; a requirement intended to reduce the risk of physicians joining the medical staff of the hospital (and moving their patients there) in order to join the PLLC and participate in the potential quality-bonus payments.
- Second, the physician owners of the PLLC receive distributions on a per capita basis; no payments are made to induce patient referrals to the hospital.
- Third, the payments by the hospital to the PLLC are capped, based on historical activity levels of the payer(s) at the hospital (adjusted for inflation) to ensure that physicians are not provided a financial incentive to refer additional patients to the hospital.
- Fourth, the hospital will provide written disclosure of its arrangement with the PLLC to its patients.
- Fifth, the hospital will monitor both the quality of care provided and the volume and case mix of its patients to ensure that the financial rewards of the program do not reduce quality or inappropriately change referral patterns of the physician participants.
- Finally, the quality targets that can be incentivized under the program without raising the need for further analysis by the OIG are limited to those listed by CMS and the Joint Commission in the Specifications Manual for National Hospital Quality Measures, which represents the consensus of the medical community as to the appropriate standard of care.

The OIG deemed these safeguards sufficient to approve the P4P arrangement, and they can serve as a guide for future arrangements as well. The OIG's approval of the P4P arrangement demonstrates a willingness to allow hospitals to pursue this promising method of aligning hospitals and physicians so that they can better work together to drive quality of care improvements.

As to Stark compliance, there presently exist Stark exceptions that can be utilized when

structuring a Pay for Quality arrangement. The fair market value, personal services, and indirect compensation exceptions all can be considered when structuring this type of physician alignment strategy. When CMS finalizes its proposed new Stark exception for shared savings and incentive programs, another more detailed exception also may be available to allow Stark compliance for this type of arrangement.

Although the OIG approved the P4P arrangement in Advisory Opinion 08-16, there are limitations on the reach of the OIG's Advisory Opinion. First, the OIG's approval extends only to those parties who submitted the OIG Advisory Opinion request, and, technically, only they may rely on it. This means that parties seeking to replicate the P4P arrangement should consider whether to pursue their own Advisory Opinion. Legal counsel should be consulted to assist in making that determination.

Second, the OIG Advisory Opinion does not analyze the P4P arrangement under Stark or under state fraud and abuse laws, which must also be considered when entering into financial relationships with physicians. As a result of these limitations, manifestations of this model must be structured carefully with the advice of legal counsel to survive regulatory scrutiny.

Conclusion

The primary benefit of the P4P arrangement is that it will likely improve quality of patient care by sharing the rewards for high quality care with the medical staff that are primarily responsible for delivering it, and who are better suited to initiate, innovate, or carry out required actions. The OIG Advisory Opinion recognized that some of the actions proposed by the P4P arrangement could conceivably violate fraud and abuse laws; its decision not to seek enforcement of these literal violations expresses an understanding of the importance of hospital/physician alignment around quality in the modern health care industry. By providing a structure that financially rewards hospitals and physicians for working together to raise the quality of care at a hospital, the P4P arrangement should benefit hospitals, physicians, and patients alike. ■

1 Pub. L. 109-171 § 5001(b) (Feb 8, 2006).
2 Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program, at http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf.
3 Quality FIRST (From Incentives, Reporting, Standards, and Technology) Act of 2008, H.R. 7067, introduced by Jason Altmire (D – PA).
4 See, e.g.,U.S. v. Rogan, 459 F. Supp. 2d 692 (N.D. Ill. 2006).
5 See Medicare Demonstration Shows Hospital Quality of Care Improves with Payments Tied to Quality, (CMS press release) at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1729; Physician Group Practice Demonstration Bonus Methodology Specifications, (project report) at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PGP_Payment.pdf.
6 42 U.S.C. § 1320-7a(b).
7 42 U.S.C. § 1320a-7b(b).
8 42 U.S.C. § 1395nn.
9 The OIG did not review P4P arrangement for compliance with Stark, since Stark is under the purview of CMS. However, many of the protections approved by the OIG are similar to requirements that CMS proposed when it issued its proposed new Stark exception on shared savings and quality incentive programs on July 7, 2008 (73 F.R. 38502).