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Pay For Performance and Medicare Compliance; The Irresistible Force Meets the Immovable Object

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Since the Institute of Medicine's (IOM's) 2001 report entitled *Crossing the Quality Chasm, A New Health System for the 21st Century,* there has been a concerted effort to create financial incentives for physicians to improve the quality of care delivered through the healthcare system. These efforts have become known as "pay for performance" or "P4P" programs. The IOM report has been the impetus for nearly a dozen Centers for Medicare and Medicaid Services (CMS)-sponsored demonstration projects that include pay for performance provisions, and many commercial health plans have implemented their own programs. Most of these programs, however, are implemented at the payor level; government or commercial insurers awarding additional payments to providers who meet designated quality standards. The employer-sponsored "Bridges to Excellence" and the CMS large physician group practice demonstration program (BIPA 2000) are two such examples.

Hospitals and health systems seeking to improve quality and reduce unnecessary care at their individual institutions have been groping for effective P4P strategies that could be implemented with their medical staffs. Unfortunately, when hospitals engage in P4P activities they are often characterized as "gainsharing" and run into major legal hurdles. The problem is that the compliance laws—the anti-kickback statute, the Stark law, and the civil monetary penalties law—are designed largely to permit hospitals to pay physicians based only on volume, and often impede efforts to pay based on quality. Hospitals seeking to pay more for better care, which in some cases equates to less care, are often stymied by the compliance problems. This article examines the compliance-related restrictions on P4P initiatives and explores what regulatory room is left for hospitals to incentivize quality of care by describing some types of P4P activities that may be permissible.

LAWS IMPEDING PAY FOR PERFORMANCE

Hospitals seeking to implement P4P initiatives are faced with a number of legal hurdles. One category of P4P initiatives often considered by hospitals are those designed to eliminate unnecessary care or reduce costs related to clinical preference items selected by physicians. The chief compliance hurdle for these programs is often the "gainsharing" prohibition contained in the civil monetary penalties (CMP) statute. This prohibition authorizes the Office of Inspector General (OIG) to impose financial penalties upon a hospital whenever it "knowingly makes a payment, directly or indirectly, to a physician as an inducement to *reduce* or *limit* services provided with respect to individuals who are entitled to benefits under the Medicare or Medicaid programs and who are under the direct care of the physician."[1] The prohibition contains three key elements: (1) the payments are made knowingly; (2) they are an inducement to *reduce* or *limit* services; and (3) they are paid with respect to patients under the *direct* care of the physician receiving the payment.

The OIG has interpreted the gainsharing prohibition very broadly, stating that it prohibits any payment that may influence a physician to reduce or limit services to his or her patients. "There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute."[2] The OIG stated that even payments for reducing unnecessary lengths of stay could violate the statute.[3]

Notwithstanding the OIG's broad interpretation of the gainsharing prohibition, a key requirement of the statute remains that the payment must be an inducement to reduce or limit services provided with respect to individuals who "are under the direct care of the physician."[4]

The OIG has construed the direct care requirement as meaning patients under a physician's "clinical care": "the plain language of section 1128A(b)(1) of the Act prohibits tying the physicians' compensation for such services to reductions or limitations in items or services provided to patients under the *physicians' clinical care.*"[5]

Another category of P4P initiatives are those designed to encourage the provision of "effective care."[6] For these categories the compliance hurdles are more likely to come from the Stark and anti-kickback laws. Both laws are intended to prohibit physicians from profiting from their own referrals. In doing so, however, they make it difficult for hospitals to pay physicians in ways other than based on the volume of services rendered (whether measured in hours or other units of service). For example, the Stark Law exceptions relevant to physician services are the employment, fair market value, personal services, and indirect compensation arrangements exceptions. The key provisions of all these exceptions are very similar: a physician's compensation must be consistent with fair market value and may not take into account the volume or value of referrals by the referring physician, and in the case of independent contractors, other business generated by the physician for the hospital (such as private pay business).[7] While the government states that it will accept any method of valuation that is commercially reasonable, its suggested methodologies focus on hourly rates.[8] The idea of paying a premium for better care, rather than more care, may not be well received by enforcement agents who, like Representative Pete Stark (D-CA), might view P4P initiatives as "offensive."[9]

Similarly, those same enforcement agents might view P4P payments from a hospital as an inducement for additional referrals by those physicians, rather than compensation for a job well done. The OIG has expressed concern that P4P payments, such as in gainsharing arrangements, create an opportunity for physicians to earn significant additional income not available at other institutions, which can serve as an inducement for referrals.[10]

So what can a hospital do to align financial incentives with quality care? Unfortunately the list is short and constricted, but here are some activities that may still be permissible:

A. Implement an OIG-Approved Gainsharing Program

Most readers will be familiar with the gainsharing model that has been approved by the OIG in six different advisory opinions. These programs have been limited to cardiac surgery and cardiology procedures. They have focused on generating and sharing cost savings resulting from practice pattern changes that involve activities such as "use only as needed," product substitution (for lower cost products with no clinical significance), and product standardization (for clinical preference items). The OIG-approved plans utilize a base year formula for calculating savings that imposes a ceiling on the number of procedures that can be measured and the historic costs from which savings can be measured. Each year the program continues, the cost ceiling is lowered to reflect savings captured in the previous year, while the procedures ceiling is held constant, so that the net effect is a continuous reduction in the amount of gain that can be shared with participating physicians.

While the shelf life for the OIG-approved gainsharing model is short, the ramp up to implement such a program can be lengthy and expensive. All of the OIG-approved programs have involved the use of an outside consultant to develop the program and monitor performance. Further, those hospitals that have obtained OIG-approval for their programs have also incurred significant time and expense in connection with the advisory opinion process. Thus, the high start-up costs and short lifespan of the OIG-approved gainsharing model make it unlikely that it will be widely implemented.

B. Develop a Hospitalist Program

The use of hospitalists to improve inpatient care is becoming increasingly common.[11] Over the past decade, a considerable body of evidence has developed indicating that the presence of hospitalist physicians on a 24/7 basis improved the quality of care provided at a hospital.[12] The hospitalist specialty is premised on the assumption that inpatient care provided by a small number of physicians who practice exclusively in the hospital and are available throughout their shifts is less costly, of higher quality, and less variable than the care provided by many primary care physicians, who see patients only briefly once a day.

The use of hospitalists has increased rapidly in recent years, partly in response to the expectations of third-party payors that hospitals will improve patient safety and quality of care rendered by physicians in their facilities. Hospitals contracting with hospitalists often need to supplement their income from professional fees[13] and wish to include P4P provisions in their compensation arrangements. Before even addressing the P4P issue, however, a hospital must consider the threshold question of whether it can provide any subsidy to a hospitalist without violating the compliance laws.

Typically, hospitalists do not maintain private practices outside the hospital; rather, they treat patients who are admitted by other physicians or who self-present through the hospital's emergency department. Therefore, hospitalists generally are not considered referral sources to hospitals. Nevertheless, subsidy arrangements between hospitals and hospitalists implicate the Stark, anti-kickback, and other compliance laws because hospitalists often admit patients from the emergency department and order hospital services for their patients. The safest compliance strategy for implementing a hospitalist program is for a hospital to employ the hospitalists and bill for their services. The employment exception is clearly

the broadest and strongest exception to the anti-kickback statute and Stark laws, with one federal court describing the exception as protecting any compensation arrangement with an employee that is not directly related to referrals.[14]

Many hospitals, however, are reluctant to employ physicians and assume responsibility for physician billing; they prefer to contract with existing hospitalists or groups of hospitalists on an independent contractor basis. To provide a payment to a hospitalist group, the hospital must be careful to document that it is paying for services the hospitalists will provide to the hospital, not merely subsidizing the payments the hospitalists will receive from third-party payors for services provided to patients. Examples of services for which a hospital can pay a hospitalist include:

- 24/7 coverage of the inpatient departments;
- 24/7 on-call coverage for the emergency department;
- admission and management of unassigned patients (e.g., uninsured patients who present to the emergency department without an attending physician); and
- medical director services.

Once a hospital has identified what it can pay for, the next hurdle is to structure a compensation system that includes P4P features. The Stark law exceptions for both employment and independent contractor arrangements generally permit a hospital to pay compensation that is consistent with fair market value so long as it does not vary based on the volume or value of the physician's referrals; that is, referrals he or she controls or has the ability to influence. Further, in the preamble to the Stark II Final Rule, CMS stated that nothing in the employment exception prohibits payments based on quality measures, as long as the overall compensation is consistent with fair market value and not based directly or indirectly on the volume or value of DHS referrals.[15] Two examples of permissible P4P arrangements cited by CMS include payments based on achieving certain benchmarks related to the provision of appropriate preventive healthcare services or patient satisfaction. Hospitals can use other types of quality measures as well, such as absolute and relative performance standards tied to achieving designated clinical outcomes or adopting preferred practice patterns, or both.[16] The keys to using any of these P4P standards are to impose a fair market value cap on total compensation and avoid financial incentives to reduce or limit services. Presumably, the fair market value of the services rendered to or for the hospital will increase as the quality increases, although the government has not confirmed this truism in any of its guidance. These rules should also apply to hospitalists retained as independent contractors. While the Stark compliance strategy will rely on exceptions other than employment, (e.g., personal service contract exception, FMV exception, or indirect compensation arrangements exception in the case of group arrangements) the Stark rule does not prohibit payments based on quality measures such as those described above.

Under the anti-kickback statute, the P4P compliance issues are easier to address in the context of an employment arrangement than they are for hospitalists retained as independent contractors because the employment exception provides much greater flexibility for P4P compensation provisions than the personal services contract safe harbor, which is the only exception available for independent contractor arrangements. That safe harbor permits only arrangements where the aggregate compensation is fixed in advance; P4P bonuses with independent contractor hospitalists could not qualify for safe harbor protection. Therefore, hospitals seeking to contract with hospitalists on an independent contractor basis need to proceed more cautiously with a careful "facts and circumstances" analysis of any compensation plan they might develop.

While hospitalist programs are an important tool for improving quality and initiating P4P strategies, they also have the potential to adversely impact a hospital's relationship with other physicians on the medical staff. A recent study noted that hospitalists have decreased the presence of both primary care physicians and specialists in the hospital, which can threaten physician's long-standing orientation towards supporting hospital's social missions, including care for the uninsured.[17] This breakdown in the alignment of interests between hospitals and their medical staff can lead to greater competition and reduced availability of physicians for ED call. Therefore, hospitals may wish to look for other strategies to improve quality.

C. Medical Director Compensation Arrangements

Another strategy used by some hospitals to align financial incentives with quality care is to include P4P bonuses in their medical director agreements. Most hospitals contract with or employ physicians to serve as medical directors of the hospitals' various departments. These positions are administrative rather than clinical in nature, and include activities such as performing functions required by The Joint Commission and other external review bodies; participating in patient care quality and peer review activities; strategic planning for the department; physician recruiting; community education and outreach; and medical staff relations. A hospital may include incentive P4P provisions in its compensation plans used with medical directors to achieve goals such as reduction in departmental costs, lowering length of stay, and improving quality of patient outcomes if they are careful in structuring how the department's performance is measured. Often, the key is

to exclude any referrals of the medical director or any physician under his or her control from the calculation of a department's performance.

As noted previously, the CMP statute prohibits payments that might serve as an inducement to reduce or withhold services to patients under the *direct* care of a physician. Similarly, the proscription on referrals contained in the Stark law applies with respect to the referrals for DHS of the physician who is being compensated. In the case of a medical director, these referrals would include referrals by a physician under the control or influence of the medical director, such as another physician in the same group practice, physicians who are supervised by the medical director, and non-physician personnel under the medical director's control in either setting. Under ordinary circumstances, however, the medical director is unlikely to have control or influence over other members of the medical staff who are in private practice or who are also employed by the hospital but do not report to the medical director in any clinical capacity.

Therefore, these laws should permit a hospital to pay a medical director a P4P bonus based on the performance of the department that he or she manages—including measures of departmental production or departmental costs—so long as the hospital excludes from the calculation any patient activity generated by the medical director and those under his or her control or influence. The medical director's status as an employee or independent contractor would not change this requirement. In either case, the formula used to measure departmental performance should exclude any referral or admission activity of the medical director, or any physician or non-physician under his or her control. If the measurement of departmental performance does not include any admissions, tests, procedures, or other types of referrals generated by the medical director or any physician under his or her control or influence, the P4P bonus should not implicate the Stark law or the CMP statute.

Unfortunately, however, the analysis of a medical director P4P bonus cannot stop with the Stark law and CMP statute. The federal anti-kickback statute also is potentially applicable to such a plan. If the P4P bonus formula is tied even in part to departmental productivity, it may be construed as a form of inducement for referrals, and the use of any type of variable compensation precludes the arrangement from qualifying for the personal services contract safe harbor. Nevertheless, a hospital may have strong arguments as to why a P4P bonus is permissible under the anti-kickback statute. If the medical director's referrals, and those of any other physician under his or her control or influence, are excluded from the calculation of the P4P bonus, then the bonus should not be construed as an inducement for referrals from the medical director. Instead, at most, the arrangement might be construed as a type of marketing agreement unrelated to the physician's provision of healthcare services. Importantly, even if the medical director is being paid for promoting the department, he or she will not be taking advantage of any fiduciary position or exceptional influence in those activities.[18] To the extent that the medical director engages in promotion activities, they are likely to be focused on the medical staff, who are financially independent from the medical director and sophisticated decision-makers when it comes to the selection of a hospital for their patients. These medical staff members will be aware of the medical director's position with the hospital and will be able to take that relationship into account when evaluating his or her recommendations. Under these circumstances, a P4P bonus payable to a medical director is unlikely to constitute an "inducement" under the anti-kickback statute for referrals by physicians on the medical staff who are not under the medical director's control with respect to their private practice.

The net effect of excluding any patient activity generated by a medical director from his or her P4P bonus calculation is to insulate patient care decisions from being influenced by financial incentives (either to provide more or less care). Thus, the medical director is rewarded only for his ability to influence the patient care decisions of his colleagues through education and demonstration of the process improvements advocated by the hospital. The government should not object to a hospital's use of this type of incentive.

D. Medical Staff Participation in Computerized Physician Order Entry

Another strategy that holds significant promise for improving care for hospital inpatients is the implementation of computerized physician ordering systems that prompt the admitting physician to follow the best demonstrated care plan for the patient's diagnosis. A number of hospitals have implemented these systems with their hospitalist physicians. The ordering systems are computer-generated decision trees that prompt the admitting physician to map out the patient's plan of care, using on-screen prompts to trigger quality indicators and suggest appropriate ordering patterns based on the patient's diagnosis. An open question is whether hospitals can pay members of their medical staff, who are not employed by the hospital, to use the ordering systems when admitting patients. While hospitals are permitted to pay physicians a fair market fee for services rendered, these arrangements raise issues as to whether a physician is actually providing any service to the hospital by completing the care plan; how to calculate a fair market value fee for completing a form; and whether such a fee will be sufficient to influence physicians to change their

traditional ordering patterns.

A hospital can make a good argument that when a physician uses a hospital's computerized ordering system he or she is providing an important service to the hospital for which the physician can be paid. The system potentially improves the quality of care that a hospital is able to render to its patients; improves the hospital's ability to demonstrate its compliance with quality performance standards applied by payors; improves the hospital's medical records documentation; and improves the performance of the hospital's nurses and allied health professionals by clarifying and standardizing patient orders and treatment plans. It may be difficult, however, for a hospital to determine a fair market payment to compensate physicians for their additional time and inconvenience associated with using a computerized ordering system. Basing the fee solely on an estimate of the additional time required of the physician may not capture the true value of the service to the hospital and may be insufficient to encourage physicians to adopt the system. On the other hand, if a substantial payment is offered the potential for it to be viewed as an inducement for patient admissions is likely to be high. Therefore, any hospital considering such an arrangement for other than its employed physicians would be wise to seek an advisory opinion from the OIG.

CONCLUSION

In summary, the feasibility of P4P systems at hospitals, particularly community hospitals where the medical staff is comprised predominantly of independent practitioners, is greatly limited by the restrictions imposed by the various federal fraud and abuse laws. While many healthcare policy analysts view P4P as a significant tool for improving the quality of healthcare delivered in this country, unless Congress changes how the fraud and abuse laws apply in the P4P setting, the ability of hospitals to implement these program will continue to be very limited.

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END NOTES

1 42 U.S.C. § 1320a-7(a)(b)(1).
2 Department of Health and Human Services Office of Inspector General, Special Advisory Bulletin, *Gainsharing Arrangements,* July 1999, *available at* oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.
3 *Id.*
4 42 U.S.C. § 1320a-7a(b)(1)(B).
5 OIG Special Advisory Bulletin, *supra* note 2, at 3 (emphasis added).
6 "Effective Care" is defined broadly as care where "the benefits are thought to so outweigh the risks that virtually all patients with a specific medical need should receive the service." John E. Wennberg, *Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers,* Commonwealth Fund Pub. No. 874 at 2 (Dec, 2005).
7 *See, e.g.,* 42 C.F.R. § 411.357(c) (employment exception); 42 C.F.R. §§ 411.357(d) (personal service arrangement) 411.357(l) (fair market value compensation). The personal service arrangements and fair market value compensation exceptions also require that the compensation be "set in advance," which means that the aggregate compensation, or a specific formula for calculating the compensation, must be set forth in an agreement between the parties before the furnishing of services for which the compensation is to be paid. *See* Special Rules on Compensation, 42 C.F.R. § 411.354(d).
8 *See* Stark II Final Rule, 42 C.F.R. § 411.351, definition of "Fair market Value."
9 *Stark Describes P4P as "Offensive,"* MODERN HEALTHCARE (Dec. 5, 2006).
10 OIG Special Advisory Bulletin, *supra* note 2, at 4 .
11 Hospitalists are a relatively new form of medical specialty that involves internal medicine and family practice specialists who treat patients only in the inpatient hospital setting.
12 *See, e.g., Hospitalists: Leading the Way To More Effective, Higher Quality Healthcare,* Society of Hospital Medicine (Jan. 2007), *available at* www.hospitalmedicine.org/AM/Template.cfm?Section=Advocacy_Policy&Template=/CM/ContentDisplay.cfm&ContentID=11835.
13 *Id.* at p. 5. The Society of Hospital Medicine reports that the average hospitalist requires about $50,000 - $60,000 of annual salary support.
14 *United States ex rel. Obert-Hong v. Advocate Healthcare,* 211 F.Supp.2d 1045 (N.D. Ill. 2002) (holding that there is nothing in either the Stark or anti-kickback statutes that prohibits hospitals from requiring that employee physicians refer patients to the hospital, and that employee compensation is exempt unless directly related to referrals).
15 Stark II Final Rule, 69 Fed. Reg. 16054 at 16088 (Mar. 26, 2004).
16 An absolute standard would reward physicians for achieving a specific goal (e.g., giving aspirin to patients with acute myocardial infarction) while a relative standard would reward improvement related to peer performance (e.g., moving from the third quartile to the second).
17 Robert A. Berenson, Paul B. Ginsburg and Jessica H. May, *Hospital-Physician Relations: Cooperation, Competition, or Separation?* Health Affairs—Web Exclusive, W 31, 37 (Dec. 5, 2006), *available at* www.healthaffairs.org.
18 *See* OIG Commentary to Initial Safe Harbor Regulations, 56 Fed. Reg. 35984 at 35974 (1991) (commenting that marketing arrangements that do not involve individuals in a position of public trust marketing products or services to patients pose less risk).