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HOSPITAL-PHYSICIAN COLLABORATIONS: ANTITRUST AND HEALTH CARE FRAUD AND ABUSE CONSIDERATIONS

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"Accepted for publication in the Health Law Handbook, 2009 Edition. Alice G. Gosfield, Editor, ©Thomson Reuters. A complete copy of the handbook is available from West by calling 1-800-382-9252 or online at www.west.thomson.com."

Part III

ACCOUNTABILITY AND ENFORCEMENT

Chapter 7

Hospital-Physician Collaborations: Antitrust and Health Care Fraud and Abuse Considerations

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§ 7:1 Introduction

It is becoming increasingly clear that prevailing structures for delivering hospital and physician services in the United States often frustrate efforts to improve quality and enhance efficiency, and that greater clinical collaboration is a prerequisite for achieving both. However, federal and parallel state laws present hurdles, some real and some perceived, to restructuring delivery models for improving quality and efficiency through collaboration among physicians and hospitals. This article addresses two sets of these legal constraints governing antitrust and health care fraud and abuse laws and examines the extent to which they can limit effective collaboration, and how some of these obstacles can be overcome.

Historically, most physicians have practiced in small groups, and they continue to do so—currently over 50% of all physicians are in groups of five or less.¹ These small practices lack the scale and infrastructure that can optimally

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¹Hing E. Burt CW, Characteristics of Office-Based Physicians and their Medical Practices: United States 2005–2006, National Center for

support health information technology, interface efficiently with third-party payors, and develop and maintain specialized expertise. Hospitals, too, are constrained in how they can improve the quality of care provided in their facilities. With the exception of the oversight hospitals exercise over radiologists, anesthesiologists, pathologists, and other hospital-based physicians, they typically do not employ nor exercise extensive control over the physicians who practice in their facilities. In fact, hospitals are habitually reluctant to impose restrictions on their voluntary medical staff physicians upon whom they depend for admissions. Thus, hospitals rarely turn to the blunt instrument of withholding privileges to discipline "independent" physicians who resist initiatives to enhance quality and efficiency.

The impact of these constraints on quality and cost has been widely chronicled.² Moreover, the need for more coordinated care among physicians, and between physicians and hospitals, is only intensifying as payment systems are increasingly rewarding care that can most efficiently be provided through collaborations. Thus, for example, Medicare and other payors are turning to "pay-for-performance" (P4P) programs to incentivize providers to improve quality. These programs, which are focused primarily on hospital outcomes measures, reward hospitals for improvements that largely depend on the hospitals' ability to change the behavior and clinical practices of their medical staff over whom they have limited control. While physicians in individual or small group practices can participate in P4P programs, larger groups are often better equipped to monitor data and implement organized processes that will enable them to fully implement the desired changes and take advantage of P4P incentives.³ The importance of collaborations will be even greater if certain payment reforms are instituted that rely on paying

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Health Statistics, Vital Health Stat. 13 (166), at 4 (2008), available at <u>htt</u> p://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf.

²See generally Institute of Medicine, Crossing the Quality Chasm: A New Health System for the 21st Century (2001) [hereinafter, Crossing Quality Chasm].

³Jon Christianson, Sheila Leatherman, & Kim Sutherland, Robert Wood Johnson Foundation, Paying for Quality: Understanding and Assessing Physicians Pay-for-Performance Initiatives, at 4 (2007).

bundled payments for an entire episode of care furnished by a hospital along with its physicians and other providers.⁴

These trends may result in an increase in the number of physicians who are employed by hospitals, as well as the growth in both single and multispecialty group practices. However, history suggests that this increase will be gradual as many physicians resist change, wishing to retain their autonomy and continue to practice independently in individual or small group practices. Thus, the question arises whether there is a practical way in which physicians can continue in their independent practices, but collaborate with each other, and with hospitals, to achieve significant quality and cost improvements.

Collaborations among independent economic entities are common throughout the economy. When they involve agreements among competitors, particularly if these include price or price-related terms, they can raise serious antitrust issues. As described in more detail below, a crucial element in addressing these antitrust issues is to establish that the agreement is reasonably necessary or "ancillary" to an "efficiency-enhancing integration of economic activity." Much attention has been focused on what should be considered in evaluating the extent of such an integration among health care providers, particularly where the providers are not contracting with health plans on the basis of capitation or some other form of shared financial risk, which is typically the case today. The federal antitrust enforcers have stated that such "clinical integration" programs typically will involve: (1) mechanisms to monitor and control health care utilization to control costs and assure quality; (2) selectively choosing participating providers; and (3) significant investment of capital, both financial and human, in the necessary

⁴See, e.g., S.M. Shortell and L.P. Casalino, *Health Care Reform Requires Accountable Organizations*, 300 J.A.M.A. 95 (2008); Gosfield, The Prometheus[™] Payment Program: A Legal Blueprint, Health Law Handbook (Gosfield, ed. 2007) (proposing new payment systems using "Evidence-informed Case Rates[™]" that would compensate all of the providers who furnish services for a specific clinical condition); Harold S. Luft, Total Cure, The Antidote to the Health Care Crisis, at 91–92 (2008) (describing a model of payments for episodes of care to "care delivery teams").

infrastructure.⁵ Moreover, some believe that financial incentives are especially important to provide the mechanisms in (1), above, needed for a successful clinical integration program.⁶

However, collaborations that involve payments from hospitals to physicians directly implicate federal health care fraud and abuse laws. These laws generally are designed to guard *against* the influence financial incentives may have on physician referral patterns and clinical judgment. The criteria for selecting participating physicians, and how a hospital might provide infrastructure support to the physicians, also can raise fraud and abuse issues. In short, clinical integration that involves hospital/physician arrangements could be viewed with favor under the antitrust laws while heightening concerns under the fraud and abuse laws.

The task for providers who wish to navigate these issues is made more difficult by the fact that there is little relevant case law, and both the antitrust enforcers as well as the government officials responsible for applying the fraud and abuse statutes have not always given either clear guidance or encouragement. In their defense, the enforcers themselves have a difficult challenge. The antitrust law is very broadly written, and of general applicability to all industries, so it is crucial that whatever guidance the antitrust enforcers provide is consistent with their approach in other settings. The fraud and abuse laws, in contrast, are very specific to the health care industry, but in some respects their lack of flexibility may make it harder to accommodate productive collaborations. Both sets of enforcers are also concerned that whatever guidance they adopt not "straitjacket" providers and deter innovation, yet at the same time they do not wish to foreclose their ability to prosecute egregious arrangements that few would argue constitute acceptable conduct.

⁵Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care (1996), *available at* <u>http://www.usdoj.g</u> <u>ov/atr/public/guidelines/0000.pdf</u> [hereinafter, *Health Care Policy Statements*].

⁶FTC Commissioner Thomas Rosch has said, "Those incentives are what makes financial integration work. If a clinical integration program includes a very strong system of rewards and punishment, . . . it could be successful." J. Thomas Rosch, Commissioner, FTC, Remarks at the 2007 Antitrust in Health Care Conference, Clinical Integration in Antitrust: Prospects for the Future, at 17 (Sept. 17, 2007), *available at* <u>http://www.ft</u> <u>c.gov/speeches/rosch/070917clinic.pdf</u> [hereinafter, Rosch Remarks].

This article takes a close look at these issues, and examines how several key aspects of clinical integration programs are analyzed under both the antitrust and fraud and abuse laws. It identifies where hospitals and physicians retain some latitude to pursue carefully crafted collaborative efforts under existing law and government enforcement policy.' That said, we also identify some of those areas where more flexible guidance and permissive structures would be instrumental in helping achieve the Institute of Medicine's recommendation to transform health care quality through, among other things, aligning payment policies and quality improvement.⁸

We begin with some "basics" for those who are not experts in both antitrust and fraud and abuse law.

§ 7:2 Analytical framework under antitrust laws

The primary antitrust concern raised by a collaboration among competing providers is whether it might violate the prohibition in section 1 of the Sherman Act against "[e]very contract, combination . . . or conspiracy, in restraint of trade."¹ In decisions spanning more than a century, courts have identified certain agreements that are viewed as so likely to have an anticompetitive effect that they can be condemned without any inquiry into the relevant markets

¹15 U.S.C.A. § 1.

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⁷Of course, entities considering hospital-physician collaboration will need to consider a number of additional laws that are outside the scope of this paper. For example, tax-exempt organizations such as nonprofit hospitals would need to evaluate—under the Internal Revenue Code and applicable Internal Revenue Service guidance—any incentive program that might arguably result in private inurement of net earnings to "insiders" or confer impermissible benefit on private parties. The IRS uses a variety of factors to assess whether incentive compensation could jeopardize a hospital's tax-exempt status. *See, e.g.*, I.R.S. Info. Ltr. 2002-0021 (Jan. 9, 2002), *available at* <u>http://www.irs.gov/pub/irs-wd/02-0021.pdf</u>, which details factors that will be considered in determining whether incentivebased compensation arrangements result in private inurement or impermissible private benefit.

⁸Crossing the Quality Chasm, at 18 (recommending that "all purchasers, both public and private, should carefully reexamine their payment policies . . . to remove barriers that currently impede quality improvement, and to build in stronger incentives for quality enhancement").

[[]Section 7:2]

that might be affected by the agreement, and whether the agreement might have procompetitive aspects that, on balance, could redeem the conduct. When agreements are deemed per se unlawful, the parties are not given an opportunity to defend their conduct by claiming that their prices are "reasonable" or that their conduct causes good effects. Examples of per se conduct include price fixing and market allocation agreements (*e.g.*, competitors agreeing with each other to divide up a market so that they do not compete with each other in certain geographic areas or with respect to certain products or services).

In contrast, the federal antitrust agencies have observed that if otherwise competing entities join together in an "efficiency-enhancing integration of economic activity" and "enter into an agreement that is reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits," the agreement is analyzed under the socalled "rule of reason."² Analysis under the rule of reason requires a much more extensive inquiry into the actual competitive effects of the venture, including market power, and antitrust plaintiffs find it much more difficult to prevail in a challenge under the rule of reason.³

Thus, the key antitrust issues raised by a joint venture among health care providers essentially involve addressing the following four questions.⁴

²U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors (2000), at 8, *available at* <u>http://ww</u> <u>w.ftc.gov/os/2000/04/ftcdojguidelines.pdf</u> [hereinafter *Collaboration Guidelines*]. This article refers often to the *Collaboration Guidelines*, and to the industry-specific *Health Care Policy Statements*, because they reflect how the federal antitrust agencies interpret and intend to apply the antitrust laws. While not binding on the courts, conduct that is consistent with these guidelines will likely be difficult to challenge successfully.

³This is a somewhat simplified summary of the relevant law that is evolving and rather complex. For example, recent decisions suggest a departure from a simple dichotomy between per se and rule of reason conduct, and there have been various formulations regarding how these issues should be addressed by the courts. The two-step framework should suffice, however, for purposes of the analysis herein.

 $^{^{4}}$ A full discussion of all the antitrust issues raised by joint ventures is beyond the scope of this article. To simplify matters, this discussion focuses only on the antitrust issues that arise under Sherman Act § 1 regarding agreements that competitors may enter into with each other

§ 7:3 Analytical framework under antitrust laws— Does the venture involve agreements which might be construed as per se offenses?

If the venture does not involve an agreement among competitors relating to the prices they will charge, the customers they will serve, or other matters that arguably could be condemned as per se illegal, then the venture will be analyzed under the rule of reason. While this does not mean there are no potential antitrust concerns, the antitrust risks are much less serious, as a challenge will depend on the ability of a complainant to demonstrate that the parties

§ 7:3

through the formation and operation of a joint venture. The formation of a joint venture under certain circumstances also may be subject to analysis under Clayton Act § 7 which governs mergers and acquisitions. That analysis is essentially the same, however, as the analysis described here of an integrated competitor collaboration under the rule of reason. Thus, a joint venture that survives antitrust scrutiny under Sherman Act § 1 will likely also pass muster under Clayton Act § 7 review. Joint ventures that do not involve competitors also can raise antitrust issues, but these will almost always be evaluated under the rule of reason and, unless they involve providers who have substantial market shares (*i.e.*, more than 35%-40%), are unlikely to be problematic. If such ventures do involve a dominant provider, they are not necessarily illegal, but a more extensive antitrust analysis would be required to address potential issues such as monopolization and tying.

have market power¹ and that their conduct, on balance, will have an anticompetitive effect.²

§ 7:4 Analytical framework under antitrust laws—Is there sufficient integration to avoid per se condemnation so that the joint venture can be analyzed under the rule of reason, *i.e.*, does the venture have the potential to achieve substantial efficiencies?

Assuming that the venture does involve agreements that, standing alone, might be per se illegal, the next question is whether such agreements are not "naked" restraints, but rather are related to what the federal antitrust agencies have called "an efficiency-enhancing integration of economic activity." The agencies comment that in such arrangements,

participants collaborate to perform or cause to be performed (by a joint venture entity . . .) one or more business functions, such as production, distribution, marketing, purchasing or R&D, and thereby benefit or potentially benefit, consumers by expanding output, reducing price, or enhancing quality, service or innovation. Participants in an efficiency-enhancing integration typically combine, by contract or otherwise, signif-

[Section 7:3]

 ^{2}See § 7:6 for the analysis with respect to anticompetitive effect of a joint venture.

¹There is no bright-line market power test. The federal antitrust agencies have established a "safety zone" for joint ventures generally where they have indicated that "absent extraordinary circumstances" they "will not challenge a competitor collaboration when the market shares of the collaboration and its participants collectively account for no more than twenty percent of each relevant market in which competition may be affected." Collaboration Guidelines, at § 4.2. The federal agencies have established a safety zone for financially integrated physician networks of 30% share for nonexclusive networks and 20% share for exclusive networks. Health Care Policy Statements, at 79–80. However, these are "safety zones" and therefore conservatively drawn, and parties may have greater market shares (particularly if the venture is nonexclusive) without necessarily having market power. Moreover, even if the collaboration and its participants have a substantially larger market share, it is possible that they may lack market power because entry into the market by competitors is relatively easy. Unfortunately, defining the relevant product and geographic markets and assigning market shares can be a difficult and complex task, even if reliable data are available, which often may not be the case.

icant capital, technology or other complementary assets to achieve procompetitive benefits that the participants could not achieve separately. The mere coordination of decisions on price, output, customers, territories, and the like is not integration, and cost savings without integration are not a basis for avoiding per se condemnation.¹

In the context of health care collaborations, the federal Health Care Policy Statements focus on whether the collaboration involves sufficient "financial" or "clinical integration." Joint price negotiations that are ancillary to financially or clinically integrated physician organizations, therefore, will not be condemned as per se unlawful horizontal price-fixing agreements, but rather should be considered under a rule of reason analysis.² The Health Care Policy Statements recognize that there are many different arrangements that have the potential to achieve substantial efficiencies. On one end, there are group practices that are fully integrated where, among other things, doctors share revenues and losses, contribute to salaries of support staff and administrative personnel, develop practice protocols, and maintain joint insurance coverage. On the other end of the spectrum are ventures that have little or no financial risk sharing, but instead implement clinical programs that integrate physician and hospital care to improve quality and efficiency across a broad network of providers. The determination of whether a venture is either financially or clinically integrated is a critical step in assessing a venture's legality under the antitrust laws.

Guidance from the antitrust agencies is fairly straightforward with respect to the elements necessary to meet the safe harbors of financial integration because the agencies are more confident that such arrangements have the potential to achieve significant efficiencies. Financial integration exists if providers provide services at a shared capitated rate, or where payment is subject to a substantial financial withholding depending on whether group performance goals are met. In financially integrated ventures, participants are clearly incentivized to cooperate in controlling costs and improving quality by managing the provision of services

[Section 7:4]

¹Collaboration Guidelines, at § 3.2. ²Health Care Policy Statements, at 3 n.27. because a failure to achieve the goals across the venture results in lost revenue for all participants.

The available guidance from the agencies with respect to clinical integration is not as simple. In 2002, the FTC issued an Advisory Opinion to address the proposed clinical integration program of MedSouth, an independent practice association (IPA) in south Denver, Colorado.³ The FTC ultimately concluded that MedSouth's proposed clinical integration of physician practices had the potential to generate substantial fiscal, administrative and guality-related efficiencies and thus, as long as MedSouth was able to implement the programs and achieve the efficiency goals laid out in its proposal, the program would be analyzed under a rule of reason analysis.⁴ Nearly five years after the initial MedSouth opinion,⁵ the FTC issued an Advisory Opinion to the Greater Rochester Independent Physician Association (GRIPA) stating that it had no intention to issue a challenge with respect to GRIPA's nonexclusive physician network joint venture. The FTC recognized some key elements of GRIPA's program, including: in-network referrals; monitoring and measuring individual and group performance against benchmarks; a Web-based network that allows physicians to share patient information and order lab tests and prescriptions electronically; a peer review system to identify underperforming members; and substantial investment by physicians of time

³Letter from Jeffrey W. Brennan, Assistant Dir. Health Care Servs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290 (Feb. 19, 2002), *available at* <u>http://www.ftc.gov/bc/adops/medsouth.htm</u> [hereinafter MedSouth Opinion].

⁴MedSouth Opinion at *8. Some of the specific indicia of integration in the MedSouth proposal included: a single clinical resource management tool, computer and data systems, that facilitates increased communications and cooperation among physicians regarding treatment and practice patterns; required financial investment by member physicians in the hardware necessary to participate in the Web-based clinical computer system; and clinical practice protocols and ongoing monitoring of physician performance.

⁵In June 2007, the FTC staff issued a second opinion with respect to MedSouth. Letter from Markus Meier, Assistant Dir. Health Care Servs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler (June 18, 2007), *available at* <u>http://www.ftc.gov/bc/adops/070618medsouth.pdf</u>. In this follow-up letter, the FTC staff concluded that MedSouth's responses to requests from the FTC for up-to-date information on the status of its clinical integration program supported its 2002 opinion.

and effort to collaborate to develop and oversee implementation of program practice guidelines.

In 2007, the American Hospital Association (AHA), in an effort to provide more complete guidance to its member hospitals and health care providers, released its *Proposed Guidance on Establishing Clinical Integration Programs.*⁶ The document addresses practical considerations in developing a clinical integration program and also expands on the legal analysis provided in the *Health Care Statements* and FTC Advisory Opinions.

§ 7:5 Analytical framework under antitrust laws— Even if there is substantial integration, are the competitive restraints "ancillary" to the venture's procompetitive goals?

If a joint venture involves substantial integration, the next step is to examine the agreements made in connection with the joint venture to determine whether they are "ancillary," that is, related and reasonably necessary to achieve the procompetitive goals of the venture. For example, two hospitals might decide to form a joint venture to buy a mobile lithotripsy unit that would provide services at each of the hospitals half the time. Agreements regarding the purchase, operation, and sale of the technical component of the lithotripsy services (including the price for such services) are all likely to be viewed as ancillary to the joint venture. However, an agreement regarding the prices for services that are not furnished through the joint venture, for example the daily hospital room charge, prices for cardiac services, or the prices that independent urologists would charge for their professional services,¹ are likely to be viewed as not ancillary to the joint venture and will be condemned as per se illegal.

Thus, this step of the analysis requires consideration of the subject of any agreements that the parties make with

⁶Thomas B. Leary et al., Guidance for Clinical Integration Working Paper (Hogan & Hartson LLP for the American Hospital Association) (2007), *available at* <u>http://www.aha.org/aha/content/2007/pdf/070417clinic</u> <u>alintegration.pdf</u>.

[[]Section 7:5]

¹Decision and Order, Matter of Urological Stone Surgeons, Inc., 125 F.T.C. 513, 1998 WL 34077361 (1998), *available at* <u>http://www.ftc.gov/os/c</u> <u>aselist/c3791.shtm</u>.

each other to ensure that they are related and reasonably necessary to achieving the legitimate goals of the joint venture.²

§ 7:6 Analytical framework under antitrust laws— Will the joint venture, on balance, have anticompetitive effects?

If the competitive restraints are ancillary to the joint venture's procompetitive goals, then it is necessary to determine under the rule of reason whether, on balance, the venture will be anticompetitive. This assessment involves (1) a further examination of the nature of the relevant agreements and the type of competitive harm and benefits that may result; and (2) an assessment of competitive conditions in the market, including whether the parties to the joint venture will have market power. These two inquiries may be somewhat interrelated. For example, if an agreement on its face looks as if it very likely will have significant anticompetitive effects and few procompetitive benefits, it might be challenged without a detailed analysis of the market. Conversely, in other situations, it may be possible to conclude that the agreement is unlikely to have substantial anticompetitive effects, whether or not the parties have market power, and therefore the antitrust review also could be concluded without an extensive market power assessment.

In analyzing the effect of the agreement, consideration will be given to the rationale for the restraint and whether its goals could be accomplished by less restrictive alternatives. For example, are the joint venture parties permitted to compete with the collaboration and are they allowed to independently set prices for the output of the joint venture? Similarly, is the venture nonexclusive so that the parties can compete with each other with respect to services that are not furnished through the venture? The extent to which members of the venture may impact the efficiencies generated through the venture but may also reduce the venture's market power, thereby balancing the possibility of greater anticompetitive harm. Other anticompetitive con-

²For a discussion of ancillarity in the context of clinical integration, *see* Robert F. Leibenluft & Theresa E. Weir, Clinical Integration: Assessing the Antitrust Issues, Health Law Handbook 32 (Gosfield, ed. 2004).

cerns include whether the collaboration can facilitate collusion among members of the venture, for example, through sharing competitively sensitive information and whether the duration of the venture is reasonably related to the time required to achieve and sustain the efficiency-enhancing goals of the venture.

§ 7:7 Analytical framework under federal health care fraud and abuse laws¹

Several federal health care fraud and abuse laws have a significant impact on the ability of hospitals to form financial relationships with physicians. These laws creates additional hurdles to be overcome in order for hospitals and physicians to achieve the bona fide integration that can be essential to surviving the antitrust scrutiny outlined above. The three federal fraud and abuse laws that are most likely implicated in relation to financial incentives under clinical integration models are the federal civil monetary penalty (CMP) for a hospital's payment to a physician to induce reductions or limitations of services,² the Anti-kickback statute (AKS),³ and the physician self-referral (Stark) law.⁴

These laws attempt, in different ways, to address a concern

[Section 7:7]

¹There are other laws that would need to be considered in addition to the federal health care program fraud and abuse laws discussed here. For example, many states have fraud and abuse laws, such as antikickback and self-referral prohibitions, which apply only in connection with items or services paid for through the state's medical assistance benefit. In addition, other state laws, often referred to as "all-payor" laws, apply regardless of whether federal health care program patients are involved. Finally, a number of states have what are known as "fee split" laws which generally prohibit a licensed health care provider from dividing professional fees with another person or entity, especially when that other person or entity has referred a patient. Although these laws differ from state to state regarding the types of providers and payors that are covered, with distinctions among the laws as to the scope of the general prohibition and relevant exceptions, the principles underlying these prohibitions are generally the same as the federal health care program fraud and abuse laws, so this analysis of these three laws provides a good framework for discussion.

²42 U.S.C.A. § 1320a-7a(b)(1).

³42 U.S.C.A. § 1320a-7b(b)(2)(D), (E).

⁴42 U.S.C.A. § 1395nn; 42 C.F.R. § 411, Subpart J.

that financial incentives to physicians can, among other things, induce referrals that are not based on what is best for the patient, encourage unnecessary medical procedures, influence physicians to reduce or limit services, subsidize marginal providers, or undercut "honest competition."⁵ Each law is implemented largely independently by different agencies and, by design or effect, each of these statutes can create significant tensions around financial incentives paid through hospital-physician clinical integration models. As discussed below, other aspects that are important to a clinical integration program, such as criteria for excluding providers or funding for infrastructure, also can raise concerns under the fraud and abuse laws.

§ 7:8 Analytical framework under federal health care fraud and abuse laws—The civil monetary penalty for the reduction or limitation of services

Of the fraud and abuse laws we will review, the CMP law is probably the most straightforward, and the one that presents the most obvious obstacle to creating patient- or procedure-specific financial incentives for physicians to reduce hospital costs. The law simply provides that a civil monetary penalty may be imposed against a hospital that "knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services" and against a physician who "knowingly accepts receipt of [such] payment."¹ Penalties for violation of the statute, which is enforced by the Department of Health and Human Services Office of Inspector General (OIG), include a civil money penalty of not more than \$2,000 for each violation, additional

⁵See, e.g., Issues Related to Physician "Self-Referrals": Hearings before the Subcommittee on Health and the Subcommittee on Oversight of the House Committee on Ways and Means, 101st Cong., 1st Sess. 27–28 (1989) (Statement of Rep. Stark, House Comm. on Ways & Means). As Rep. Stark explains in his statement to the subcommittee, one of the concerns from physician self-referrals is that "[h]onest competition, is undercut. To maintain market share, suppliers are being forced to compete — not on price or quality — but on the 'cut' they give physicians."

[[]Section 7:8]

¹42 U.S.C.A. § 1320a-7a(b)(1), (2).

assessments, and/or exclusion from participation in federal health care programs.²

The prohibition is very broad. The CMP law is violated whenever the hospital intends that the payment induce the physician to "reduce or limit" services and need not be tied to an actual reduction in the care provided to the patient. The OIG in a 1999 Special Advisory Bulletin addressed the application of the CMP law to "gainsharing" arrangements, where hospitals share a percentage of cost-savings realized when physicians adopt hospital-prescribed protocols that require them to standardize the use of certain products or the approach to treating certain conditions in ways that are intended to reduce the hospitals' costs. In its Special Advisory Bulletin, the OIG made clear its view that gainsharing arrangements "appropriately structured . . . may offer significant benefits where there is no adverse impact on the quality of care received by patients" but are nonetheless prohibited by the CMP law, *irrespective of medical necessity*.³ That proof of actual adverse effects on particular patients is not required under the CMP law was emphasized in an open letter by the OIG in response to criticism of its Special Advisory Bulletin.⁴

The impetus for the CMP law makes somewhat under-

²42 U.S.C.A. § 1320a-7a. "Federal health care programs" include Medicare, Medicaid, Tricare, and other payments (with the exception of the Federal Employees Health benefit Program) arising out of federal funds. *See* 42 U.S.C.A. § 1320a-7b(f) (defining "federal health care programs").

³Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37985, 37985 (July 14, 1999) [hereinafter Gainsharing SAB] ("[A]ny hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute); *see also* OIG Advisory Op. 07-21 (Dec. 28, 2007) ("[W]hether current medical practice reflects necessity or prudence is irrelevant for the purpose of the CMP").

⁴D. McCarty Thornton & Kevin G. McAnaney, Dep't of Health & Human Servs., Recent Commentary Distorts HHS IG's Gainsharing Bulletin (1999), *available at* <u>http://oig.hhs.gov/fraud/docs/alertsandbulletin</u> <u>s/bnagain.htm</u> ("The authors of the commentary contend that the 'plain language' of the statute requires *both* that a violator have the specific intent to induce treating physicians to withhold *medically necessary* services from their patients and that the incentive plan *actually cause* a reduction or limitation of medically necessary services. In our view, this interpretation is plainly wrong. Simply put, the language of the statute

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standable, if not more acceptable, its sweeping impact on financial incentives under clinical integration programs: policymakers were concerned that the Medicare diagnostic related group (DRG) prospective payment system (PPS) that was adopted in 1983 had drastically changed the financial incentives for hospitals.⁵ Thus, the General Accounting Office (GAO) commented that where under the prior system cost reimbursement-hospitals had incentives to encourage physicians to "admit more patients, leave them in the hospital longer, and use more services while they were there," under PPS, the incentives could lead hospitals to, among other things, "underprovide services [and] discharge patients too early."⁶ Although hospitals have an incentive to reduce cost under PPS, physicians are paid separately under Medicare Part B (on a fee-for-service basis) and have no incentive to either save hospital costs or reduce the utilization of their services. Therefore, some hospitals had designed physician incentive plans to align the physician interests with those of the hospital. At Congress' request, the GAO reviewed the incentive plans. In its report, the GAO concluded that, despite including some features designed to reduce financial incentives to give substandard care, "no combination of features can guarantee that a plan will not be subject to abuse."⁷ In short, the CMP law was enacted in response to these physician incentive plans which, in the eyes of Congress, "may create a conflict of interests that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients."8

The CMP law gives rise to the most direct constraints on financial and clinical integration between physicians and

refers to 'services,' not 'medically necessary services,' and requires a showing of an intent to induce a reduction of services, not an actual reduction") (emphasis in original).

⁵The prospective payment system was enacted as part of the Social Security Amendments of 1983, Pub. L. No. 98-21, 51 U.S.L.W. 203 (1983), and was phased in during fiscal years 1984–1987.

⁶U.S. General Accounting Office, Physician Incentive Payments by Hospitals Could Lead to Abuse, GAO/HRD-86-103, at 9 (July 22, 1986).

⁷U.S. General Accounting Office, Physician Incentive Payments by Hospitals Could Lead to Abuse, GAO/HRD-86-103, at 23.

⁸Gainsharing SAB, at 37986 (quoting H.R. Rep. No. 99-727, at 441 (1986)).

hospital where the goal of integration is efficiency. That said, through the OIG's advisory opinion process,⁹ gainsharing programs have emerged that, although the programs would constitute an inducement to reduce or limit services to federal health care program beneficiaries in violation of the CMP law, the OIG has been persuaded that the programs contained sufficient safeguards intended to protect against inappropriate reduction in services such that the OIG would decline to impose sanctions. As a result, the CMP law hurdle, while a high one, is not insurmountable for those pursuing enhanced provider collaboration.

§ 7:9 Analytical framework under federal health care fraud and abuse laws—Anti-kickback statute

The AKS prohibits, among other things, giving or receiving any benefit or "remuneration" in exchange for, or to induce, the referral of any patients for, or the purchase, lease, order, or recommendation of, any facility, item, or service for which payment may be made under Medicare, Medicaid, and most other federal health care programs.¹ The AKS covers "any remuneration" whether "in cash or in kind."² The OIG is responsible for interpreting the AKS and, along with the Department of Justice (DOJ), enforcing it. Penalties for violation of this felony statute can include substantial criminal fines and imprisonment, possible exclusion from participation in federal health care programs, and civil monetary penalties.³

The OIG and a majority of courts have adopted the posi-

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⁹The OIG, in consultation with the DOJ, issues written advisory opinions with regard to the application of the AKS and other OIG health care fraud and abuse sanctions, including the CMP law. However, the advisory opinions may legally be relied upon only by the requestor. *See* 42 U.S.C.A. § 1320a-7d(b); 42 C.F.R. Part 1008.

¹42 U.S.C.A. § 1320a-7b(b)(2)(D), (E).

²42 U.S.C.A. § 1320a-7b(b)(1), (2).

 $^{^{3}42}$ U.S.C.A. § 1320a-7 (exclusion from federal health care programs); § 1320a-7a (civil monetary penalties of up to \$50,000 per act plus three times the remuneration); 42 U.S.C.A. § 1320a-7b(b) (imprisonment of up to five years or criminal fines of \$25,000 or both); 18 U.S.C.A. § 3571 (augmenting penalties: \$250,000 per violation for individuals and \$500,000 per violation for entities).

tion that conduct can violate the AKS if "one purpose" (as opposed to a sole or primary purpose) of the remuneration is to induce a recommendation or referral for covered items or services reimbursable under a federal health care program, though it can be a defense if the purpose is "incidental" or not "material."⁴ A number of courts have also held that mere "encouragement" to obtain, or the "hope or expectation" of obtaining, program-related business does not, in and of itself, constitute an "inducement."⁵

The statute is quite broad and "encompass[es] many harmless or efficient arrangements."⁶ Accordingly, Congress and the OIG have created a series of statutory "exceptions"⁷ and regulatory "safe harbors."⁸ These exceptions and safe harbors identify the criteria of specific payment practices that do not violate the AKS and could protect, for example, paying physicians as employees (under the safe harbor for employment)⁹ or for a physician's medical directorship position (under the personal services and management contracts safe harbors).¹⁰ According to the OIG, one function of these safe harbors is "to permit physicians to freely engage in business practices and arrangements that encourage competition, innovation, and economy."¹¹ Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the AKS. but certainly may be subject to scrutiny and challenge.¹²

The OIG's general approach to arrangements that might technically violate the AKS is to assess them on a case-bycase basis under "the many factors which are part of the decision-making process regarding case selection for investi-

⁴See 56 Fed. Reg. 35952, 35958 (July 29, 1991); see also U.S. v. Greber, 760 F.2d 68, 72 (3d Cir. 1985).

⁵See Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995); U.S. v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000).

⁶54 Fed. Reg. 3088, 3088 (Jan. 23, 1989).

⁷See 42 U.S.C.A. § 1320a-7b(b)(3).

⁸See 42 C.F.R. § 1001.952.

⁹42 C.F.R. § 1001.952(i).

¹⁰42 C.F.R.§ 1001.952(d).

¹¹54 Fed. Reg. 3088 (Jan. 23, 1989); 42 C.F.R. § 1001.952.

¹²42 U.S.C.A. § 1320a-7b(b)(3)(E); 56 Fed. Reg. at 35954.

gation and prosecution."¹³ The OIG frequently identifies these factors as increased risk of overutilization, increased program costs, adverse impacts on patient freedom of choice, and unfair competition.¹⁴

Clinical integration models implicate the AKS in at least two respects. First, the structure of the clinically integrated venture implicates the AKS whenever anything of value flows from a person or entity that receives referrals to a person or entity in a position to make such referrals. Integration ranging from the formation a physician-hospital organization or similar joint venture, or a hospital employment of a physician to help design a clinical integration program, must be analyzed under the AKS to determine whether their structure provides payment or other remuneration to the physician to induce or reward his or her referrals. Second, the payments themselves made under an otherwise innocuous structure implicate the AKS where one purpose of those payments is to induce or reward referrals of health care items or services. Incentive payment and shared saving arrangements often cannot satisfy a safe harbor. The personal services and management contracts safe harbor, for one, will not protect such payments because hospital payments to the physicians are often not set in advance and do not fit the existing paradigm of fair market value fees being measured in terms of hours of service provided.¹⁵

§ 7:10 Analytical framework under federal health care fraud and abuse laws—The Stark law

Subject to certain exceptions, the Stark law prohibits physician referrals for certain "designated health services" to an entity with which the physician or the physician's immediate family member has financial relationship (either an ownership or investment interest or compensation arrange-

¹³56 Fed. Reg. at 35954. An advisory opinion process is available for the AKS. *See* Gainsharing SAB, at 37986 (quoting H.R. Rep. No. 99-727, at 441 (1986)).

¹⁴See 56 Fed. Reg. at 35954.

¹⁵See 73 Fed. Reg. 69726, 69798 (Nov. 19, 2008) ("[P]roperly structured arrangements involving physician participation in an incentive payment or shared savings program may meet the requirements of one or more of the existing [Stark] exceptions for compensation arrangements").

ment), if such services may be reimbursed by Medicare.¹ "Designated health services" (DHS) under the Stark law include inpatient and outpatient hospital services and certain ancillary services for which physicians may refer patients to hospitals.² Unlike the safe harbors under the AKS—which are sufficient, but not necessary, to protect against an alleged violation—if a physician has a financial relationship that falls within the Stark law, that financial relationship *must* meet one of the exceptions for any referrals to be lawful. A physician is subject to a civil monetary penalty if he or she knowingly makes a noncompliant referral, as is the entity, such as a hospital, that knowingly makes a Medicare claim for services provided pursuant to a noncompliant referral. In addition, a hospital is liable for any reimbursement related to services ordered by the selfreferring physician, regardless of whether the hospital knew that the referral was noncompliant. If the government can show that a hospital knew or should have known that the claim should not have been billed, then additional penalties may be available under the civil False Claims Act.³

As with the AKS, the Stark law presents a challenge for hospital-physician clinical integration with respect to any arrangement that will result in a financial relationship be-

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²42 C.F.R. § 411.351. "Designated health services" are defined as clinical laboratory services; physical therapy services; occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 U.S.C.A. § 1395nn.

³31 U.S.C.A. § 3729 (providing for \$5,500 to \$11,000 per claim plus three times the amount of the claim). The applicability of the FCA to Stark law violations adds another twist to enforcement in this area because the FCA can be enforced by whistleblowers in addition or as an alternative to government enforcement. *See, e.g.,* U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998).

¹42 U.S.C.A. § 1395nn; 42 C.F.R. § 411, Subpart J. Although the Stark law does not apply to Medicaid referrals and billing directly, under the Medicaid statute arrangements that would violate this law may prevent a state Medicaid program from receiving federal matching funds for services furnished to Medicaid patients pursuant to such arrangements. *See* 42 U.S.C.A. § 1396b(s).

tween the hospital and the physician either through ownership (with joint physician-hospital owners) or through compensation (from incentive payments or shared savings). Although a number of the relevant Stark law exceptions (e.g., those for fair market value services,⁴ personal services,⁵ employment compensation,⁶ or indirect compensation arrangements)⁷ might be applicable to purchases of physician services, the elements of those exceptions are difficult to apply in the context of hospital-physician collaborations that offer incentive payments to encourage hospital savings, that may then be shared with the physicians, or which reward quality of care.

The analysis of any clinical integration model between hospitals and physicians under the Stark law requires a careful consideration of the specific type of financial relationship that is created. The analysis may vary depending on whether it is a financial relationship created through ownership (*e.g.*, with hospital or physician owners of a PHO entity), through compensation (*e.g.*, bonus payments), or some combination thereof. Likewise, it may vary depending on whether the financial relationship is a direct one between the parties or an indirect one with some entity interposed between the hospital and physician. To understand the obstacle that the Stark law presents, however, we can look generally at some of the elements that appear in some, but not all, of the potential exceptions noted above.

Fair market value for services. Establishing whether payments for services are "fair market value" is a challenge where the "services" are not easily translated into an hourly wage (the typical analytical framework for what constitutes fair market value). For example, what is the fair market value for the effort required to meet a clinically based performance outcome measure required under a clinical integration incentive payment program? Likewise, under a shared saving program, what should be the share of the savings in order to reflect the fair market value of the effort needed to achieve those savings? Where the savings result from prod-

⁴42 C.F.R. § 411.357(l).

⁵42 C.F.R. § 411.357(d).

⁶42 C.F.R. § 411.357(c).

⁷42 C.F.R. § 411.357(p).

uct substitution of a lower cost item for a higher cost item, does the fact of a greater differential between the high and low cost items justify the higher payment to the physician? Often in shared savings programs every physician that participates is paid an equal, or per-capita, amount of the savings. As a result, those who did not contribute the same level of effort may be getting the same payment.

Set in advance. Several Stark law exceptions require that compensation be "set in advance." Under the Stark law, compensation can be considered "set in advance" if the aggregate compensation, a time-based or per-unit of servicebased (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid.⁸ In 2007, responding in part to perceived abuses regarding lease payments based on a percentage of the revenues generated by use of the space or equipment, CMS had proposed that percentage-based compensation arrangements could only be (1) used to pay for "personally performed physician services"; and (2) based on the revenues directly resulting from the physician services rather than based on some other factor "such as a percentage of the savings by a hospital department."9 Were CMS to have adopted such an interpretation, compensation paid under shared savings program would not have met an exception that required compensation to be "set in advance." However, CMS ultimately prohibited the use of percentage-based compensation formulae only in the determination of rental charges for space and equipment leases. As a result, CMS's current position on whether percentage-based compensation for other than personally performed physician services is somewhat unclear. CMS has noted that its regulations do not prohibit percentage-based compensation arrangements for nonprofessional services like management or billing services but, in doing so, CMS referenced a proposed new exception for incen-

⁸42 C.F.R. § 411.354(d)(1). "The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician." 42 C.F.R. § 411.354(d)(1).

⁹72 Fed. Reg. 38122, 38184 (July 12, 2007).

tive payment and shared savings programs.¹⁰ As discussed further in § 7:19 below, as of the date of this writing, such an exception has not been promulgated.

Payment not based on volume or value of referrals. A number of the potentially applicable exceptions include the requirement that payments are not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician to the DHS entity (e.g., the hospital). It may be possible to structure a program that arguably does not "take into account" the volume or value of any referrals or other business generated to the physician where the program includes the safeguards that have been included in arrangements already blessed by the OIG through its advisory opinion process.¹¹ For example. the payments could be distributed on a per-capita basis to all participating physicians and not be directly related to the savings attributed to the individual physician or, in the case of an incentive payment program, to his or her compliance with the performance criteria. In such a case, an argument could be made that the referrals made by an individual physician are not related to the cost savings achieved in a shared savings program (e.g., because that particular physician might not have used the lower cost products) or the payments made pursuant to an incentive payment program (e.g., because that particular physician might not have achieved the clinical outcome targets). On the other hand, every time there is a referral there is at least an *opportunity* to earn a payment. The larger the pool of physicians in the program, the more attenuated is the link between each individual physician's actions and the payment achieved under the program.

§ 7:11 Application of antitrust and fraud and abuse laws to hospital/physician collaborations

There are substantial differences in the nature of the antitrust and fraud and abuse laws as they apply to hospitalphysician collaborations. As noted above, in the context of provider collaborations, the principal antitrust law is the

¹⁰73 Fed. Reg. 48434, 48711 (Aug. 19, 2008) (referring to 73 Fed. Reg. 38502, 38548 (July 7, 2008)).

¹¹See § 7:17.

simple Sherman Act § 1 prohibition against unreasonable restraints of trade that applies to joint ventures of all kinds and in all industries. Although the federal antitrust agencies have issued guidelines from time to time explaining how they interpret the antitrust laws, they emphasize that they are not "regulators" and are reluctant to be too specific in their guidance out of concern that it would deter entities from trying innovative solutions. In contrast, the fraud and abuse laws were passed to address specific concerns regarding arrangements among health care providers who are reimbursed under certain federal programs. The laws themselves are more detailed and are enforced by individuals at CMS and OIG who do view themselves as regulators and are accustomed to drawing more "bright lines" in regulations regarding what conduct is or is not lawful. In both cases, of course, the courts are the ultimate arbiter as to whether conduct is unlawful, but there have been very few court decisions on provider collaborations. For this reason, the guidance and actions taken by the antitrust and fraud and abuse enforcers (through advisory opinions, consents, and speeches) is given particular weight.

As outlined in the preceding sections, antitrust law requires that competitor agreements be ancillary to an integrated venture's procompetitive goals, subject to a rule of reason analysis. To the antitrust enforcers, the extent of a venture's infrastructure and its funding, its rules concerning who can participate in the venture and the size of the venture, and the existence and nature of financial incentives are key features in assessing the extent of clinical integration, and whether a venture is likely to raise serious antitrust concerns. Such factors are also closely scrutinized for compliance with the fraud and abuse laws, but with different goals in mind. Under these laws, the government is concerned that the arrangement may disguise an inducement in return for referral, or in the case of the CMP law, involve a payment that could be attributed to a reduction in items or services made to federal health care program beneficiaries.

This section discusses the extent to which the antitrust and fraud and abuse laws, as reflected in the actions taken by the government enforcers, may create tensions with respect to the venture's infrastructure, and in decisions regarding participation criteria and the breadth of the provider panel. Section 7:14, below, presents a comparable analysis with respect to the venture's financial incentives.

§ 7:12 Application of antitrust and fraud and abuse laws to hospital/physician collaborations— Infrastructure and return on investment

Clinical integration programs often require substantial investment in infrastructure. Costly infrastructure may include, for example, an interconnected electronic health records (EHR) system, including the hardware and software necessary to deploy such a system and the contracts or staff necessary to program and maintain it. EHR programs provide physicians and hospitals with real-time access to patient records, as well as up-to-date clinical software, which can improve health outcomes.¹ Another example of infrastructure is nursing staff to implement clinical programs, including data and chart reviews.

Under the antitrust analysis, a substantial infrastructure can help establish that the venture is real and may have the potential for significant efficiencies—that is, it is not a sham. The source of funds to pay for infrastructure costs can be relevant to the antitrust analysis because such funding may reflect elements of financial integration. Physician investment in both startup and maintenance costs for infrastructure evidences actual financial integration across physicians, although a collaboration could be economically integrated even without such contributions. For example, a venture may utilize, expand, or improve a participating hospital's existing EHR system, and staff could find this to be more practical and efficient than seeking investments from its physicians for an entirely new system.

The source of infrastructure financing, in particular the relative return and "return on investment," may have implications under the fraud and abuse laws. Fraud and abuse laws look at these types of ventures to determine whether the structure is aimed at improving quality and ef-

[[]Section 7:12]

¹See eHealthInitiative, eHealth Initiative Blueprint, Building Consensus for Common Action, 11 (2007), *available at* <u>http://www.ehealth</u> <u>initiative.org/blueprint/eHiBlueprint-BuildingConsensusForCommonActio</u> <u>n.pdf</u>.

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ficiency, or is merely a vehicle through which hospital money flows to participating physicians, directly or as a means of reducing the cost of operating a physician practice, as a reward for past referrals, and/or an incentive to maintain those referrals. In this respect, the fraud and abuse analysis-like the threshold antitrust analysis-is focused on considering whether the venture is no more than a sham. However, consistent with their more regulatory approach. the fraud and abuse enforcers have been more specific in outlining particular requirements in connection with infrastructure. For example, in its Special Fraud Alert on Joint Venture Arrangements, the OIG outlined some of the characteristics of suspect joint ventures, many of which are not intended "to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals."² The OIG identified a nonexhaustive list of examples of questionable features, "which separately or taken together may result in a business arrangement that violates the [AKS]."

A number of these questionable features are relevant considerations when structuring a clinical integrated entity or arrangement that comports with the antitrust laws. For example, the OIG expresses concerns over business structures that are best characterized as only a "shell"; in other words, is the structure indicative of a legitimate joint venture or merely a way to disguise kickbacks? The OIG also scrutinizes closely the terms of financing and profit distributions and questions joint venture situations where the amount of capital invested by the physicians are "disproportionately small and the returns on investment . . . disproportionately large when compared to a typical investment in a new business enterprise." Other considerations are whether physicians are investing only a nominal amount or are paid "extraordinary returns on the investment in comparison with the risk involved."

In achieving clinical integration, some types of disproportionate investment on the part of one entity would not be unexpected. As noted above, it may be more practical and economically efficient for the hospital to expand its existing

²See Special Fraud Alert: Joint Venture Arrangements, 59 Fed. Reg. 65373, 65374 (Dec. 19, 1994).

EHR infrastructure to physician offices—a feature that would be looked upon favorably under the antitrust analysis if it facilitated ways in which the physicians could work interdependently with each other. However, the OIG has a longstanding concern that the provision of free or reduced price goods or services to an existing or potential referral source may be used as a vehicle to disguise or confer an unlawful payment for referrals of federal health care program business, and the provision of free technology has been no exception. In a 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Lab Services, the OIG identified as among the examples of inducements offered by clinical laboratories to providers which may implicate the AKS the "provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work."3

Recent developments indicate that the enforcers may be applying somewhat more flexibility to their fraud and abuse analysis of unequal contributions to mutually beneficial infrastructure investments. In 2006, CMS and the OIG promulgated exceptions to the Stark law and AKS prohibitions to permit certain donations of software and equipment from hospitals to physicians for establishing electronic prescribing and EHR capabilities. The OIG drafted an AKS safe harbor for the donation of interoperable electronic health records software or information technology and training services to "protect beneficial arrangements that would eliminate perceived barriers to the adoption of electronic health records without creating undue risk that the arrangements might be used to induce or reward the generation of Federal health care program business."4 CMS created a parallel Stark law exception at the same time.⁵ Most important for this discussion is the recognition on the part of the OIG and CMS that "certain transfers of health information technology between parties with actual or potential referral relationships may further the important national policy of promoting widespread adoption of health informa-

³See 59 Fed. Reg. at 65374.

 $^{^{4}}See$ 71 Fed. Reg. 45110 (Aug. 8, 2006) (codified at 42 C.F.R. 1001.952(y)).

 $^{^5}See~71$ Fed. Reg. 45140 (Aug. 8, 2006) (codified at 42 C.F.R. $\,$ $\,$ $\,$ 411.257(w)).

tion technology to improve patient safety, quality of care, and efficiency in the delivery of health care."⁶ The agencies have since abandoned their earlier "exclusivity" requirement, and instead have adopted an approach that allows for the donation of EHR software packages that are "necessary and used predominantly" to create, maintain, transmit, or receive EHR but may include other software that is functionally directly related to care and treatment of individual patients (*e.g.*, patient administration, scheduling functions, billing, and clinical support software).⁷ Among the types of donations that would not be protected are those for personal, nonmedical purposes or to office staff.

Although the breadth of the Stark law and AKS EHR exceptions suggests that the law *can* be applied so as to adapt to changes in health care delivery in the interest of quality care and efficiency, the specificity of those exceptions and the steps required to develop them also demonstrate that the fraud and abuse laws have been far more rigid in application than the analysis of venture integration under the antitrust laws. Thus, it was only after years of discussion, a GAO study of barriers to the development and deployment of EHR systems,⁸ and the appointment of a White House EHR "czar," that regulatory change came about, and then only as the result of a congressional mandate that the agencies remove barriers to electronic prescribing.

⁶71 Fed. Reg. at 45113. Note that the agencies also created a Stark law exception (42 C.F.R. § 411.357(v)) and AKS safe harbor (42 C.F.R. § 1001.952(x)) for the provision of items and services that are necessary and used solely to transmit and receive electronic prescription information including hardware, software, Internet connectivity, and training and support services. The electronic prescribing exception and safe harbor were mandated by Congress in section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The electronic health records exception and safe harbor were promulgated by CMS and the OIG under the authority of sections 1877(b)(4) (Stark law) and 1128B(b) (3)(E) (AKS) of the Social Security Act.

⁷Interestingly, the congressionally mandated electronic prescribing exception and safe harbor were limited to those items and services that were necessary and "used solely" to transmit and receive electronic prescribing information.

⁸See U.S. General Accounting Office, "HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption," GAO-04–991R (Aug. 13, 2004).

§ 7:13 Application of antitrust and fraud and abuse laws to hospital/physician collaborations— Selection, breadth, and removal of physicians

Selection and removal criteria for membership in a provider network is relevant to the antitrust analysis of a clinically integrated network because it can shed light on whether a network is likely to achieve substantial efficiencies. The use of strict membership participation criteria can be a very useful tool for first limiting the provider panel to individuals who meet certain minimum standards, and then as an ultimate "enforcement mechanism" to ensure adherence to the venture's program. However, as with many other aspects of clinically integrated networks, there may be variations in approach, and some ventures may choose, particularly at the outset, to be less strict in their membership criteria in order to offer a wider breadth of services or to improve the quality of care across a wider spectrum of providers through the clinical program itself.¹

The relative size of a venture's provider panel can be an important element of the antitrust analysis under the rule of reason because generally networks with a high share of the relevant market are more likely to have market power. A full market power analysis requires defining the relevant product market (*i.e.* which types of physician specialties provide services that are substitutes for each other) and relevant geographic market (*i.e.*, from what geographic area can substitute providers be found), and considering what barriers to entry into the market exist. Also, market power concerns will be reduced if a network is truly nonexclusive, that is, its members are free to contract directly with health plans outside of the network. The federal antitrust agencies in their *Health Care Policy Statements* include a "safety zone" for nonexclusive financially integrated networks with

[[]Section 7:13]

¹Note that exclusion or expulsion of specific providers from a venture could prompt an antitrust lawsuit from that provider. Such challenges, however, are similar to challenges to a denial of hospital privileges and are rarely successful because, among other things, the plaintiff typically has difficulty showing that competition has been actually harmed as opposed to simply harming competing providers. *See* American Bar Assoc., Antitrust Law Developments 122 (6th ed., 2007) (citing case law in the area of antitrust challenges to denial of hospital privileges).

market shares of less than 30%, and for exclusive networks with market shares of less than 20%.² These are just safety zones, however, and networks with substantially higher market shares may still not have market power. However, clearly the extent to which a network has a high market share in one or more specialty will increase the potential for antitrust scrutiny.

From the fraud and abuse perspective, the selection of physicians to participate in a venture should be based on the number and specialty of physicians necessary to successfully achieve the cost savings or the quality or patient safety goals for which the collaboration is formed—*i.e.*, each willing participant, or at a minimum a critical mass of physicians if not all are willing, whose effort and contribution is required to achieve the goals of the clinically integrated venture. In this regard, the antitrust consideration is similar in that a key issue is whether the venture has the minimum scale needed to achieve its goals and whether adding more members would make it even more efficient. As noted above, however, where the venture might have so many participants that it may have market power, antitrust concerns arise and the increased efficiencies will need to be weighed against the greater potential for anticompetitive effects.

In contrast, fraud and abuse regulators look most favorably on ventures that offer the entire group of relevant physicians the opportunity to participate. The OIG would view the selection of any subgroup of relevant physicians as suspect, potentially indicating that the opportunity had been offered only to those expected to generate large numbers of referrals (or as a reward for having done so). In this context, the OIG does not view the absence of referral requirements, or even explicit acknowledgement that referrals are not a condition of collaboration, as dispositive of whether the opportunity is in fact tied to the referral of patients among participants in a venture. Experience has taught the OIG to look beyond the form and controlling documents of a transaction to examine whether its putative structure reflects the reality of its implementation.

That said, the OIG (in an AKS context) and CMS (in a Stark law context) have each recognized that participation

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²Health Care Policy Statements, Statement 8.

in certain hospital-related activities can, and in some cases must, be conditioned on performing a minimum number of procedures, and thus admitting a certain number of patients, to the hospital. For example, a hospital that is recruiting a physician to work at the hospital may require a practitioner to have and maintain staff privileges, but may not condition recruitment payments on aggregate admissions by the physician.³ Moreover, in the context of staff privileges generally, CMS recognizes that a "hospital may impose conditions" intended to ensure quality of patient care such as requiring that a physician have [sic] performed a minimum number of a particular type of care before performing the procedure at the hospital."4 In the shared savings programs that the OIG has reviewed through the advisory opinion process, hospitals' limited program participation (and thus payment) to physicians already on the hospitals' medical staff for at least one year at the time the program began. In the OIG's view, that limitation actually reduced the likelihood that the arrangements would be used to attract referring physicians or to increase referrals from existing practices.

Like selection criteria, the bases for disciplining and eliminating nonproductive or low-quality physicians from a collaborative venture can be viewed somewhat differently depending on whether the analysis is under an antitrust or fraud and abuse context. As noted above, antitrust enforcers have found that clinical integration programs that utilize enforcement mechanisms to maintain a provider group that is actively engaged and integrated in the clinical protocols tends to demonstrate real indicia of integration.⁵ Ventures that discipline or eliminate repeatedly poor performers demonstrate that the program is not a mere sham through which competitors are coordinating their activities. The fraud and abuse laws, in contrast, view skeptically efforts to separate out "non-productive" physicians-at least to the extent "nonproductive" is interpreted as physicians who fail to have a high volume of patients. Clearly, physicians investors should not be actively encouraged to make referrals to the joint

³64 Fed. Reg. 63518, 63543 (Nov. 19, 1999).

⁴64 Fed. Reg. at 63543-44.

⁵See MedSouth Opinion.

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venture nor encouraged to divest their ownership interest if they fail to sustain an "acceptable" level of referrals.⁶

In summary, selection criteria and panel size can be important considerations for both the antitrust and fraud and abuse analyses. Under both assessments, it is important that whatever criteria are used be carefully and objectively based and are developed and applied with the goal of achieving the legitimate aims of the venture. Under the antitrust laws, selectivity with respect to membership and enforcement of selection criteria through expulsion of noncompliant members are important to establishing that the venture is more than a vehicle for competitor collaborations. Under the fraud and abuse laws, a particular focus is on ensuring that participants are not chosen or excluded based on their potential or history for making referrals. Given that concern, very broad participation by an existing medical staff is actually favored under the fraud and abuse analysis, while offering participation to individuals not currently on staff is disfavored. In contrast, under the antitrust laws, very broad participation so that a high share of the physicians in one or more specialties in the geographic market could raise market power concerns. Note that with respect to this last issue, the focus is the share within a properly defined relevant market. Thus, a venture that included a very large share of all of the physicians on a hospital's medical staff is unlikely to have market power if there are other nearby physicians who are not on the medical staff and who do not participate in the collaboration.

§7:14 Incentives

In order to achieve the level of commitment among physicians necessary to achieve real efficiencies, many programs, in addition to providing feedback to members on their performance, implement financial incentives to reward providers for meeting or exceeding performance benchmarks or penalize those with poor performance. Indeed, some observers believe that financial incentives are essential to a suc-

⁶See Gainsharing SAB.

cessful clinical integration program.¹ However, financial incentives paid to physicians can raise some of the most serious questions under the fraud and abuse laws. In this section, we first address the antitrust issued raised by financial incentives, and then turn to the fraud and abuse considerations.

§ 7:15 Incentives—Establishing appropriate incentives under antitrust law—Basis and amount of the financial incentives

Many clinically integrated programs choose to provide financial incentives to reward and penalize physicians for their performance. The first step in developing such an incentive program is to determine what will be measured, what will be the targeted benchmarks for evaluation, and what adjustments will be made periodically to reflect performance improvements or shortfalls. There are various approaches to determining what will be measured. Some programs may concentrate on the process of care-to what extent do providers follow certain protocols that have been linked to better outcomes or lower costs. Other programs may focus on actual outcomes in the form of actual cost savings or clinical outcomes. Both approaches have benefits and drawbacks. Although outcome-based measures have the advantage of going directly to the core goals of the program, it is often difficult to tease out how much of the ultimate outcome should be attributed to a provider's efforts, and how much is due to other variables which are beyond a provider's control. Under either approach, a physician's performance can be measured against a variety of benchmarks including his own historical achievements, those of others in the collaboration, or local or national performance levels.

In an antitrust analysis of a clinical integration arrangement, enforcers will be interested in whether and how the venture enables the providers to achieve significant efficiencies. Such efficiencies may be reflected in improved scores relative to certain objective criteria, and the financial incentives typically will be structured around those criteria. The enforcers are likely to consider several questions: Are

¹See Rosch Remarks.

[[]Section 7:14]

the goals the venture is seeking to accomplish meaningful in terms of seeking to achieve substantial quality improvements and/or cost savings? Is the venture able to measure reliably whether the providers are making progress in reaching these goals, and is such progress greater than they would like have achieved without the venture? Are the rewards and penalties in the program sufficient in size to adequately motivate the participating providers? Are the financial incentives structured in a way that rewards may be earned by providers if they improve their performance, but those who did not improve will not be rewarded or might even be penalized?

When third-party payors establish financial incentive arrangements such as P4P and similar programs to reward or punish providers based on their performance, it is reasonable to presume that the goals, measurements, and structure of the program have been designed by the payor to accomplish goals that it believes are important. Presumably the payor would have little reason to develop the program if that was not the case. Of course, that does not mean that the program will succeed, but absent extraordinary circumstances there would be little reason to assume that the effort was not a genuine attempt to achieve meaningful results. In assessing a clinically integrated arrangement, however, the antitrust enforcers may be more skeptical about the substance of a program because it is developed not at arm's length by a payor, but rather by the providers themselves.

One way a venture can address this issue is by trying to work with health plans and employers (essentially the venture's "customers") to determine what kinds of improved performance they believe is most important, and which would they value most. In some situations, it may be difficult for a provider venture to work with health plans in such a way. In such cases, the venture should be able to explain why it chose the goals, targets, benchmarks, and incentive structure that it did. For example, if the collaboration seeks to improve its performance on a set of clinical measures that have been broadly viewed as important, and can show that its approach is objectively sound and reliable, this should satisfy enforcers that there is a genuine effort to obtain significant efficiencies.
§ 7:16 Incentives—Establishing appropriate incentives under antitrust law—Individual vs. group performance

Financial incentives can be based on individual or group performance, or a combination of the two. Individual-based incentives provide a reward (or assess a penalty) to a provider based on his or own individual performance. In contrast, group-based incentives depend on how well an entire group of providers perform. Whether a participating physician prefers an individual or group-based incentive may depend on the level of his performance and his commitment to the program. High-scoring individuals, or those who are very committed to improving their own scores, may favor individual-based performance incentives because they may believe they have more control over their scores and are more likely to be rewarded. On the other hand, group-based performance incentives encourage the kind of interdependence that is the hallmark of an integrated joint venture. If Dr. Jones knows that his potential incentive payments is based on how well Dr. Smith, Dr. Green, and his other colleagues perform, he will do more to work with them to improve their scores.

Closely related to the question of individual or group performance is where the source of the reward money comes from and to whom any penalty amounts are forfeited. For example, one alternative is for the group to withhold a certain amount, and to distribute the withholding so that essentially the poor performers are penalized by paying bonuses to the high performers. While this approach has the advantage of simplicity, it may actually provide a disincentive for participants to work together to improve their collective performance: Dr. Jones may believe he is more likely to earn a bonus if Dr. Smith does poorly. An alternative is to have a shared risk pool, so that if the group as a whole does poorly, it essentially forfeits money collectively to a third party. This is the kind of arrangement that was more common in the 1990s when payors entered into various risk arrangements with IPAs and other provider groups. Currently, fewer payors are interested in such arrangements, so provider ventures need to be more creative if they wish to emulate a shared-risk situation. Some ventures have decided to donate "forfeited" funds to charities. Others keep the money in escrow for distribution at a future time. Some

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health systems that include multiple hospitals have some of the forfeited funds from one PHO put into a common fund so that they might be distributed to another PHO the following year.

From an antitrust perspective, rewards and penalties that are based on shared-risk and group performance are favored since they provide the greatest incentive for the kind of interdependence and efficiencies that a joint venture might achieve compared to that of individual efforts. Indeed, this is the basis in the *Health Care Policy Statements* for recognizing that entities that have financial risk-sharing through capitation or substantial withholds warrant rule of reason treatment. But individual-based incentive programs also can be a means by which a group can encourage desired performance and achieve significant efficiencies and thus are also relevant to the antitrust analysis.

§ 7:17 Incentives—Establishing appropriate incentives under fraud and abuse laws— Shared savings ("gainsharing") advisory opinions

At the time of this writing, there is a great deal of uncertainty under fraud and abuse laws regarding what types of shared savings or incentive payment arrangements (flowing from hospitals to physicians) may be utilized as part of a clinically integrated model. This uncertainty stems, in large part, from a tortured regulatory history in this area.

In 2001, only a few years after the OIG released its *Special Advisory Bulletin* concerning hospital-physician gainsharing, the OIG began issuing advisory opinions, exercising its enforcement discretion and permitting certain arrangements to go forward. In those opinions, the OIG concluded that the proposed arrangements incorporated sufficient safeguards such that, while the arrangements implicated the CMP law and could potentially generate prohibited remuneration under the AKS (if the requisite intent was present), the OIG would not impose administrative sanctions because, as structured, the arrangements posed a low risk of program abuse.

The first opinion involved a gainsharing arrangement through which a group of cardiovascular surgeons could share a percentage of the hospital's cost savings arising from the group's implementation of a number of separate cost saving procedures. These procedures, designed to "curb the inappropriate use or waste of medical supplies," involved: (1) not opening surgical packs until needed; (2) standardize use with respect to certain high cost, clinical preference devices, and substituting less costly items to be used by the surgeons; and (3) limited use of an antihemorrhaging drug to only high-risk patients as recommended by independent, objective clinical standards.1 "Properly structured, cost sharing arrangements can serve legitimate business and medical purposes," the OIG wrote. However, the OIG stated that, the same arrangements can "potentially influence physician judgment to the detriment of patient care" and said that it is concerned about: "(i) stinting on patient care; (ii) 'cherry picking' healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a 'race to the bottom') among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals."²

Similar programs were proposed in 2005,³ in 2006,⁴ and in 2007.⁵ Of the first 10 programs, six involved cardiac surgery, three involved cardiology, and one involved anesthesiology services provided during cardiac surgery. Unfortunately, these programs are all fairly similar,⁶ and so the opinions have provided only a limited, and somewhat formulaic, approach aligning hospital and physician incentives.

In general, the opinions consistently identify eight primary features as contributing to its decision not to impose civil monetary penalties:

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¹OIG Advisory Op. 01-1, at 3 (Jan. 18, 2001).

²OIG Advisory Op. 01-1, at 6.

³OIG Advisory Op. 05-01 (Jan. 28, 2005); OIG Advisory Op. 05-02 (Feb. 10, 2005); OIG Advisory Op. 05-03 (Feb. 10, 2005); OIG Advisory Op. 05-04 (Feb 10, 2005); OIG Advisory Op. 05-05 (Feb. 18, 2005); OIG Advisory Op. 05-06 (Feb. 18, 2005).

⁴OIG Advisory Op. 06-22 (Nov. 9, 2006).

⁵OIG Advisory Op. 07-21 (Dec. 28, 2008).

⁶This is likely due, in no small measure, to the fact that all the programs were developed, and submitted for Advisory Opinion approval, by the same health care consulting company.

- 1. The arrangements are transparent, which allow for "public scrutiny and individual physician accountability for any adverse effects of the arrangement," including difference in treatment based on nonclinical indicators.
- 2. There is "credible medical support for the position that implementation of the recommendations [to reduce costs] will not adversely affect patient care" and the arrangements are "periodically reviewed . . . to confirm that the arrangement was not having an adverse impact on clinical care."
- 3. The amount to be paid is "calculated based on all surgeries regardless of the patients' insurance coverage," with a cap on payment for federal health care procedures. Procedures subject to the arrangement are not "disproportionately performed on federal health care" beneficiaries. These cost savings are "calculated from the hospital's actual out-of-pocket acquisition costs."
- 4. The arrangements utilize "objective historical and clinical measures to establish" a floor beyond which no savings accrued to the group. Baseline measures are related to "comparable hospitals' practices and patient populations."
- 5. Inappropriate reductions in services are prevented in product standardization recommendations by "ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the arrangement as before."
- 6. Patients possibly affected by the arrangements are given written disclosures of physicians' involvement in the arrangement with an opportunity to review the arrangement prior to admission (or, where preadmission consent is impracticable, prior to consenting to surgery). The OIG notes that disclosure is insufficient standing alone, but this practice helps prevent abuses of patient trust.
- 7. The financial incentives under the arrangement are reasonably limited in duration and amount.
- 8. Profits from arrangements are distributed to individual physicians on a "per capita basis" (thereby reducing the incentive for an individual physician to generate disproportionate cost savings).

Similarly, the OIG found that sufficient safeguards existed to mitigate kickback risks.⁷ Among the safeguards identified by the OIG were that the arrangements contained provisions that reduced the likelihood that they were being used to attract referring physicians or to increase referrals from existing physicians and were structured to eliminate the risk of rewards for referrals to the group practices.

Finally, the OIG identifies certain factors it believes would "heighten" the risk that payments will lead to inappropriate reductions of services. The risk would be heightened where:

- 1. There is no demonstrable direct connection between a physician's activity and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- 2. The performance that would give rise to the savings is not identified with specificity.
- 3. There are not sufficient safeguards to protect against the risk that other unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- 4. The quality of care indicators are of questionable validity and statistical significance.
- 5. There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

More recently, the OIG has approved arrangements involving an anesthesiology group,⁸ an arrangement between a hospital and orthopedic surgeons and neurosurgeons,⁹ as well as arrangements that are three years¹⁰ and two years¹¹ instead of the one year that had been in place for the previous proposals.

⁷The OIG noted that the arrangements potentially met the AKS safe harbor for personal services and management, but that they ultimately did not fit because the payments under the arrangements to the group practices were calculated on a percentage basis, and as such were not set in advance, as required to meet the safe harbor.

⁸OIG Advisory Op. 07-22 (Dec. 28, 2007).

⁹OIG Advisory Op. 08-09 (July 31, 2008).

¹⁰OIG Advisory Op. 08-15 (Oct. 6, 2008). For purposes of calculating the payment to each cardiology group, the actual costs incurred for the items specified in the recommendations when used by cardiologists in the particular cardiology group during the specified procedures (the "current year costs") are subtracted from the costs for the same items when used

§ 7:18 Incentives—Establishing appropriate incentives under fraud and abuse laws— Incentive payment advisory opinion

The most significant change for the OIG, however, is an advisory opinion from October 2008 that addressed not a gainsharing/shared saving program but an incentive payment proposal wherein a hospital proposed to share with a physician-owned entity certain performance-based compensation available to the hospital under a quality and efficiency agreement with a private insurer.¹ As in the advisory opinions that address shared saving programs, the OIG determined that this incentive payment proposal could violate the CMP law as well as the AKS; however, the OIG further determined that it would not penalize the hospital in connection with the arrangement because of safeguards against fraud and abuse in the proposed arrangement.

Under the arrangement, a hospital participated in a P4P program implemented by a private insurer. The program dictated that, in addition to the amount the private insurer would pay the hospital for the care of patients in a given year, the insurer would also pay the hospital a percentage based on the extent to which the hospital met certain quality and efficiency standards. These quality of care standards required data reporting and the achievement of quality targets described in the Specifications Manual for National Hospital Quality Measures published by the Joint Commission; these are quality measures that have been derived from a joint effort of CMS and the Joint Commission.² The incentive payment arrangement between the insurance company and the hospital would require that the hospital track quality measures and outcomes for all patients, not just enrollees of the insurer's plans. The efforts of the hospital and its staff to achieve the quality care standards would thus affect

¹¹OIG Advisory Op. 08-21 (Nov. 25, 2008).

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¹OIG Advisory Op. 08-16 (Oct. 7, 2008).

²See The Joint Commission, Specifications Manual for National Hospital Quality Measures (2008), at <u>http://www.jointcommission.org/Perf</u>ormanceMeasurement/Current+NHOM+Manual.html.

during comparable procedures in the respective base year (the "base year costs").

Medicare and Medicaid beneficiaries. As such, the arrangement could violate the CMP law and could violate the AKS if it were used by the hospital to induce doctors for referrals. According to the requestor of the advisory opinion, the hospital could not achieve these quality targets without the assistance and cooperation of its medical staff.

The physician entity in the arrangement would be composed of physician members of the hospital's active medical staff. Each physician who joined the entity would make an equal capital contribution which, in the aggregate, would provide for working capital needed for the entity. The entity would need at least 10 participating physicians before going forward. Under a three-year quality enhancement professional services agreement between the hospital and the physician entity, the entity would require its members to undertake various tasks to ensure that the quality targets were achieved, including developing policies and procedures, conducting peer review, and auditing medical records. The hospital would pay the physician entity as much as 50% of its incentive payments to the doctors for their efforts in helping the hospital meet quality targets established by the insurer. The entity would then distribute the payouts to the member doctors on a per-capita basis.

Although the CMP law would apply, the OIG identified the safeguards in the proposed arrangement, including: (1) credible medical support for the likelihood the proposed arrangement would improve patient care and was unlikely to have adverse effects on patient care; accordingly, the "physicians are to be compensated for specific actions which have been recognized as improving patient care"; (2) the lack of an incentive (*i.e.*, no reduction in compensation) for a physician to apply a specific standard in medically inappropriate circumstances; (3) a reasonable relationship between the quality targets to the practice and patient population of the hospital; (4) transparency, through notification to patients affected by any of the performance measures; and (5) monitoring of the quality targets "to protect against inappropriate or limitations in patient care or services."

The safeguards that helped mitigate the OIG's AKSrelated concerns were: (1) the structure of the program (*e.g.*, limiting it to physicians who have been on active medical staff for at least a year and a cap on compensation) would not likely attract referring physicians to the hospital or HOSPITAL-PHYSICIAN COLLABORATIONS

increase referrals from doctors already on the hospital's staff; (2) per-capita distributions which would reduce the risk that the arrangement would be used to reward individual physicians who refer patients to the hospital; and that participation would not be limited to any particular group of highreferring physicians, but could include all physicians, subject to the requirement that they have been on the active medical staff for at least a year; (3) transparency, which would ensure that the purpose of the program would be to improve quality rather than to reward referrals; and (4) the oversight role of the private insurer, whom the OIG viewed as having no incentive to overcompensate either the hospital directly or the physicians indirectly and having "every incentive" to pay the portion of the bonus only as earned through the achievement of the quality targets. Acknowledging that achieving the quality targets is an important part of the program, a final mitigating factor noted by the OIG is that the hospital had "certified that it is not feasible to achieve them without the assistance of its medical staff."

§ 7:19 Incentives—Establishing appropriate incentives under fraud and abuse laws—Stark law exception for hospital shared savings and incentive payments

In 2004, CMS published a discussion of the application of the Stark law to payments hospitals might make to create incentives for physicians to assist the hospital in achieving certain quality and efficiency goals. Specifically, in the preamble to the Stark II, Phase II, Interim Final Rules, CMS addressed comments requesting that the Stark law's employment exception be extended to permit hospitals to pay such incentives to employed physicians. The comments argued that such incentive payments should not be construed as being based on the volume or value of referrals for purposes of the Stark law. CMS replied:

There is no exception in the statute or in these regulations that would permit payments to physicians based on their utilization of DHS, except as specifically permitted by the risksharing arrangements, prepaid plans, and personal service arrangements exceptions. None of those exceptions permit those payments other than in the context of services provided to enrollees of certain health plans. We believe that the Congress intended to limit these kinds of incentives consistent with the

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civil monetary penalty provision at section 1128A(b)(1) of the Act that prohibits a hospital from paying physicians to reduce or limit care to hospital patients. Given that prohibition, we cannot say that payments based on lowering utilization present no risk of fraud or abuse.¹

However, then in April 2008, CMS advised providers that it was considering adding a specific Stark law exception for certain gainsharing arrangements and sought comments on how to circumscribe the exception to avoid abuse.² CMS then issued a proposed regulatory exception to the physician selfreferral law that would allow hospitals to pay incentive payments to physicians who participate in quality improvement and shared savings programs.³ CMS ultimately declined to finalize its proposed exception to the Stark law that would have expressly permitted either incentive payment programs, such as pay-for-performance arrangements, or that allowed physicians to share in the cost savings attributed to their efforts (i.e., "shared savings programs," such as gainsharing). This exception arguably was needed to ensure that such programs did not run afoul of the self-referral restrictions of the Stark law.

Rather than finalize its proposal, however, CMS extended the comment period for 90 days and requested additional input from the industry on a number of topics relevant to such an exception. In doing so, CMS conceded that it has "had limited opportunity to review incentive payment and shared savings programs for compliance with the physician self-referral law, and [it] lacked familiarity with the specifics of measuring achievements and calculating payments under such programs." Through the solicitation of comments, CMS hopes to obtain the information it needs to finalize a new Stark law exception that will achieve transparency and accountability and ensure quality of care, while guarding against the risks of disguised payments for referrals, participants cherry-picking healthy patients and steering sicker patients to other hospitals, and, for shared savings arrangements, physicians not using cheaper devices, tests, or

[[]Section 7:19]

¹69 Fed. Reg. 16054, 16088 (Mar. 26, 2004).

²73 Fed. Reg. 23528, 23692 (April 30, 2008).

³73 Fed. Reg. at 38502.

treatments but which are of inferior quality and discharging patients quicker than clinically appropriate.

The best that can be said of recent fraud and abuse pronouncements on gainsharing and incentive payments is that CMS and the OIG recognize that the health care marketplace is developing faster and in more directions than the current regulatory scheme can accommodate and that some of those developments are at risk of being unnecessarily constrained. The history of the OIG's treatment of the CMP law and AKS, through the advisory opinion process, and of CMS's evolving position on these types of clinically integrated structures, reveals a growing consensus both on the value of these programs and a recognition that the law should allow arrangements that, while establishing some safeguards against sham arrangements, provide the flexibility to deal with innovative ways of achieving clinical integration through hospital-physician models. That said, other than a few tightly crafted advisory opinions, fraud and abuse guidance offers only uncertain comfort to those who would develop innovative collaborations. Again, the flexibility of the antitrust rule of reason analysis—an analysis that recognizes value in innovation itself-if properly applied, has been shown to be better suited to accommodating new forms of clinical integration than the regulatory approach under the fraud and abuse statutes.

§ 7:20 Incentives—Putting it all together

As discussed above, there are several aspects of financial incentives for which the antitrust considerations will be aligned with those assessed under the fraud and abuse laws. For example, both favor (a) incentives that encourage clinical protocols or practice patterns based on credible medical support that they will reduce costs without adversely affecting care or which might improve quality; (b) the use of appropriate benchmarks involving appropriate comparables; (c) the use of quality of care indicators that are valid and statistically significant; and (d) independent verification of cost savings, quality of care indicators and other essential aspects of the arrangement.

A number of factors that fraud and abuse regulators consider favorably in assessing incentives generally would be viewed neutrally under the antitrust laws. These factors include:

- payments calculated based on all performance regardless of insurance coverage;
- limits on the duration and amount of incentives;
- distribution of funds on a per-capita basis;
- ensuring provider access to devices and supplies that are available outside of the program; and
- transparency of arrangements so that there can be public scrutiny and individual accountability for any possible adverse effects.

While the existence of these latter factors would not weigh against an arrangement in an antitrust assessment, they could have the effect of restricting the tools that a collaboration has available to it to most effectively achieve its goals. For example, under the antitrust laws, there generally would not be strict limits set on the amount or duration of incentives if the collaboration thought it would best drive optimum provider conduct. Similarly, a collaboration might determine that sharply limiting access by providers to nonapproved suppliers would best achieve cost-savings, and barring extraordinary circumstances, it would be free to do so under the antitrust laws. Although transparency is often desirable, some ventures may consider some of their arrangements proprietary and not wish to share them with competitors. Perhaps the most serious limitation might be the apparent preference under the CMP statute for the distribution of funds on a per-capita basis; that might be viewed as substantially less effective at incentivizing desired behavior than would be the distribution of funds based on individual performance or the amount of services provided by the physician.

In summary, it does not appear that hospital/physician collaborations face inconsistent requirements under the antitrust laws and the fraud and abuse laws when they consider a financial incentive program. There are areas, however, where the fraud and abuse laws, at least as reflected in the guidance available so far, may restrict the range and structure of some incentives, perhaps limiting their overall effectiveness.

§ 7:21 Conclusion

The question remains, what is the best strategy for

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hospitals and physicians that wish to collaborate on improving quality or reducing costs to assure compliance with both the antitrust laws and the fraud and abuse statutes?

The starting point should be a clear understanding by everyone involved in the collaboration about what the venture legitimately can—and cannot—seek to accomplish. For example, if members of a PHO believe that their goal is to simply develop some way in which they can collectively negotiate with health plans to "level the playing field" and achieve the reimbursement levels to which they believe they are entitled, the collaboration is likely to create ongoing antitrust concerns—particularly if it is successful in achieving its goal absent any quality improvement. The same applies to a venture, for example, which is viewed by hospital administrators as a means of rewarding referring physicians and increasing their admissions. In such circumstances, the venture is bound to raise serious fraud and abuse questions.

Once the legitimate goals are clear, the organizers of the collaboration should then consider, given their particular needs and circumstances, what are the best ways to structure their arrangement. This will include addressing such issues as the criteria for participation, what specific kinds of conduct should be encouraged (or discouraged), how to structure the incentive payments, and how the necessary infrastructure will be funded. Although it may be helpful to examine successful arrangements that others have developed elsewhere or to consider those that have been favorably reviewed by regulators, these examples should not be viewed as the entire universe of acceptable approaches. Rather, if there are compelling reasons for fashioning a collaboration in a novel way that will best achieve legitimate goals, those potential arrangements should be fully considered.

We emphasize always keeping an eye on how best to accomplish the collaboration's legitimate goals for several reasons. Doing so will maximize the chance that the venture will succeed from a practical standpoint because it will be able to provide higher-quality or less costly services that are valued by patients and payors. However, it will also help increase the chances that the venture will survive legal scrutiny. As we have discussed above, both the antitrust and the fraud and abuse enforcers have a threshold concern that a venture may be a "sham" designed simply as a cover to obtain market power or induce referrals. By documenting the rationale for each of the steps it has taken and demonstrating that these were all carefully considered to achieve real results, an entity can help minimize the risk that enforcers will find it to be a sham. What is more, the venture likely will run more smoothly if the collaboration is taking steps that seem to "make sense" to its own participants so as to achieve its own particular goals, as opposed to trying to follow an approach designed simply to pass regulatory review even though it may poorly fit the situation at hand.

Notwithstanding the above, the collaboration may face difficult legal questions. For example, the venture may conclude that in order to maximize the commitment and focus of its participants, and thereby increase efficiencies, it wishes to limit participation to only those physicians whose practice is predominantly centered at the hospital. For the same reasons, it may wish to pay members not the same percapita, but rather based on individual performance or how many services each physician provides through the venture. Likewise, it may decide that performance will not be measured across all payment sources, but only those who are providing increased P4P bonuses.

These, and similar questions, can be challenging. However, as we have explained, fundamentally there should be ways to structure a core hospital/physician arrangement that can meet both antitrust and fraud and abuse considerations. Most of the open questions relate to the extent to which the venture can take steps that are intended to increase efficiencies, but which lack some of the safeguards regarding fraud and abuse issues that the OIG or CMS have identified. On these issues, the venture, guided by its counsel, will need to carefully consider the importance of the proposed steps, the potential for abuse, and whether there are alternative approaches that could produce similar results. In some cases, the collaboration may wish to proceed further only after obtaining feedback from the enforcers.

As noted above, both the OIG and CMS have been considering an increasing number of physician/hospital collaborations. Health care reform may increase the push for such collaborations, and with it, the pressure for greater guidance and flexibility from the enforcers on such arrangements. If this occurs, we will be able to determine more conclusively whether such efforts truly hold the promise for significant advances in health care quality and HOSPITAL-PHYSICIAN COLLABORATIONS efficiency.

§ 7:21