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Health Law and Compliance Update - Steiner, §4.01, OVERVIEW

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Finding a legal way to promote and encourage collaboration between a hospital and its medical staff has been an elusive goal for many years. In theory, a hospital and its medical staff constitute one health care delivery system with the principal goal of delivery of efficient, high-quality care to its patients. However, usually the hospital and the physician members of its medical staff are or work for separate legal entities. Therefore, many legal obstacles, some specific to health care, and others part of the general legal restrictions applicable to business operations, have combined to make such collaborations difficult. Examples of health-law specific constraints include the Civil Monetary Penalties Law, as amended (CMP Act), [1] the Medicare and Medicaid Patient Protection Act of 1987, as amended (Anti-Kickback Act and, together with the applicable regulations, the Anti-Kickback Law) [2] and Section 1877 of the Social Security Act, as amended (Stark Act and, together with the applicable regulations, the Stark Law). [3] General legal constraints include the laws pertaining to antitrust, tax exemption, and public contracting. While not every legal impediment is implicated in any one particular collaborative proposal, all such restraints must be considered when examining a proposed course of collaborative action, as any of them can create obstacles to successful implementation of collaborative arrangements.

The recently emerging concept of Clinical Co-Management Arrangements (CCMAs) may offer a structure that may, in some cases, help reduce the legal risks of such collaboration. Recent guidance from the Office of Inspector General, U.S. Department of Health and Human Services (OIG) [4] suggests, along with other recent developments, [5] that, in some situations, such arrangements may be a permissible means of collaboration. By understanding the concept of clinical co-management and the legal risks attendant with such arrangements, the legal or compliance professional may be better able to assist management in considering these types of relationships. However, there are many potential areas of concern. This chapter explores CCMAs along with their existing legal risks and practical constraints in order to assist the legal and compliance practitioner.

Simply stated, a CCMA is a means of collaboration between a hospital and a segment of its medical staff to achieve certain, usually non-monetary, goals. The CCMA usually is limited to a particular program or service line and is for a limited duration. The building block for a CCMA is the concept of medical direction. Health care institutions long have recognized the need for (and value of) having one or more physicians oversee the clinical operations of their various departments. While such arrangements can present the potential for abuse,

[6] medical direction performs a significant function of provision of physician expertise and insight to the overall operations of a hospital program or department. Moreover, in many instances, such physician oversight is required for licensure or accreditation purposes. [7] The health care laws provide safe harbors and exceptions for certain personal service and management contracts that can make certain properly developed medical director agreements legally permissible, usually as a personal service contract or as part of employment. Thus, so long as the medical director arrangement is at fair market value and meets all the other personal service or employment exception or safe harbor requirements, it may be legal, at least under the Anti-Kickback Law and Stark Law. [8] However, most of these arrangements pay a set predetermined amount of compensation for a specified service with no incentive for good performance. For purposes of this chapter, we assume that CCMAs (unlike typical medical director agreements) will have a bonus or performance component. If not, compliance with the legal requirements we discuss may be simpler.

The CCMA is typically viewed as an enhanced version of medical direction. Unlike medical direction, it does not limit its total potential compensation to a set fee for service, but provides incentives if certain predetermined goals are met. The CCMA has some of the same features as a medical director arrangement. For one, it is typically department or program specific. Moreover, its goals typically include efficient, compliant and safe operation of the department or service line. However, unlike the standard medical direction arrangement, a CCMA typically provides predetermined goals and potential incentives for achieving those goals. Thus, the participating physicians have the ability to earn more remuneration for exemplary performance. The regulatory basis for its legal existence is, to a significant extent, rooted in the safe harbors or exceptions under the Anti-Kickback Law or Stark Law. However, unlike many medical director arrangements, CCMAs typically involve or typically seek to involve multiple members of the medical staff, perhaps all who practice in the department or service line, incorporate predetermined performance goals and include the incentive component.

Depending on the model utilized, the CCMA may also involve use of a management company and have other distinguishing factors. However, the common components of CCMAs typically are as follows: (1) a baseline management function; (2) objectively developed metrics based upon benchmarks other than direct financial performance; (3) incentives for meeting goals tied to such metrics; and (4) broad participation within the service line or program. Each will be discussed in turn.

The foundation for each CCMA is typically a baseline management function within the service line or program. This is usually all or part of the function of the standard medical director agreement. With this function, the participating physicians will assume joint contractual responsibility for the management and operation of the service line or program. This function may include standard responsibilities such as assurance of regulatory and accreditation compliance, but it may also include quality, safety, patient satisfaction, and efficiency responsibilities. These responsibilities may become the basis of the performance metrics.

Performance metrics are predetermined goals for a service line or department. Unlike gainsharing, which will be discussed, *infra*, these goals or metrics traditionally have not been directly tied to financial performance of the department or service line. Rather, these performance metrics are based upon relatively objective and measurable standards related to the overall performance of the service line or department. The specific goals will vary depending upon the precise needs for the program. However, the types of goals commonly recognized include such matters as program development, general medical direction, budgetary improvements, strategic business planning, community relations, patient satisfaction, employee and medical staff satisfaction, quality outcomes, materials management, product standardization, efficiency of operations (such as scheduling), and case management. Indeed, anything that is capable of objective development is potentially a metric if it measures improvement in the delivery or quality of care. The metrics could best be characterized as fitting within one of the following broad categories: quality improvement; efficiency enhancement; satisfaction of a constituent group; or outcome improvement. In ideal circumstances, the goals are established in a collaborative process with dialogue between physician and hospital leadership, perhaps with the aid of an independent third party. The common characteristics of these goals are that they: (1) are capable of objective measurement, both for a base line and for analysis of improvement; (2) do not directly relate to the financial performance of the program;

and (3) objectively relate to improved performance of the program. Moreover, recently cost savings has been recognized as a target for possible inclusion in CCMAs and, also, as a significant area of concern for legal and compliance personnel. [9]

Incentives then must be developed that are tied to the performance metrics. These incentives usually are in the form of a bonus payment that can be earned if all or a portion of the metric is achieved. The precise nature of the bonus and its measuring period offers some planning options for the practitioner. However, there are some compliance constraints. [10] The metrics should be capable of objective determination and actually relate in some meaningful manner to improved operations of the program. The overall compensation available for achieving the same, together with the base management fee, must fit within the concept of fair market value. The assistance of an independent third party is valuable and important, both to determine the actual goals and various incremental goals and to determine fair market value.

Finally, it may be desirable if the CCMA is broadly available to all physicians practicing in the program. In this manner, the compliance risk may not be exacerbated by an allegation that participation in the arrangement was available only to high utilizing referring physicians or to certain physicians or groups that had become favorites of hospital administration. [11] This broad participation may also help to assure that all members of the medical staff within the program are encouraged to help meet the predetermined goals.

With this background in mind, we will now briefly review the potential models for CCMA relationships and the history of similar arrangements. We will then turn to a more detailed analysis of various legal restraints impacting CCMAs.

Footnotes

1 42 U.S.C. §1320a-7a.

2 42 U.S.C. §1320a-7b.

3 42 U.S.C. §1395nn.

4 OIG Advisory Op. 12-22 (Dec. 31, 2012).

5 There were a number of prior OIG Advisory Opinions on gainsharing and similar programs that might be read to support the possibility of greater collaboration. *See*, *e.g.*, OIG Advisory Ops., 05-01, 06-22, 07-22, 08-15, 08-16, 08-21, and 09-06. The Patient Protection and Affordable Care Act of 2010, Pub. Law No. 111-148 (Mar. 23, 2010) (hereinafter The Affordable Care Act or the ACA), also contains features that relax impediments to collaboration in certain circumstances.

6 A medical director agreement, even without possible bonuses, offers several potential abusive situations: the work might not be at fair market value, it might not be performed or it might not be necessary. *See generally*, 42 C.F.R. §1001.952(d) (stating the Anti-Kickback Law safe harbor for personal service and management contracts).

7 *See*, *e.g.*, Joint Commission Standard LD 04.01.05, EP 7.

8 *See* 42 C.F.R. §1001.952(d) (personal service safe harbor), and 42 C.F.R. §1001.952(i) (employment safe harbor).

9 *See* OIG Advisory Op. 08-21 (Nov. 25, 2008); OIG Advisory Op. 12-22 (Dec. 31, 2012).

10 The means of determining and distributing the bonus must not vary based upon the volume or value of referrals. This is so in order to meet the personal service contract safe harbor, 42 C.F.R. §1001.952(d), among other matters. However, this requirement may have the effect of not rewarding the physicians most involved based on the volume or value of referrals. Of course, they are likely to be the biggest users of the service line.

11 *See*, *e.g.*, 42 C.F.R. §411.357(p) (indirect payments).

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There are several potential models for arrangements that are typically viewed as CCMAs. The model selected depends in large part upon the number of physicians practicing within the service line or program and the relationship of such physicians to the hospital. For example, a less detailed CCMA arrangement might suffice if the physicians are employees of the hospital or there is only one provider group practicing within the service line. As a general rule, the greater number of physicians practicing in the service line, the more complex the CCMA arrangement. With this in mind, the following three scenarios should encompass most CCMA arrangements: (1) employed physician incentive; (2) direct contract CCMA; and (3) management company arrangements. Each will be discussed in turn.

[A] Employment Incentive

A significant and growing number of physicians are now employed by hospitals. Initially, it might appear that such employment arrangements are beyond the purview of CCMAs that demand much special scrutiny. Certainly, such arrangements may be designed to fit within the employment safe harbor for the Anti-Kickback Law [12] and the Stark Law employment exception. [13] However, CCMAs have significant potential for implication of the CMP Act. Moreover, employment arrangements are not immune from attack by regulators based on potentially improper criteria for compensation, [14] especially bonus payments, and even other issues. Therefore, a brief discussion of employment arrangements in the context of CCMAs is included.

In the employment context, CCMA concepts could be introduced by including them as a part of the employed physician's management and oversight responsibilities for a specific service line. This could take the form of only a straight medical director component. However, if the hospital wishes to provide an incentive to the physician to achieve certain targets of quality, satisfaction or efficiency, an analysis under at least some of the developing law pertaining to CCMAs is appropriate. In such an arrangement, there needs to be adequate safeguards to assure that the CMP Act is not implicated and that there are no illegal referral inducements or payments under either the Anti-Kickback Law or the Stark Law. The model for such an arrangement would be a medical direction component to the physician's employment contract or arrangement that included both a base fee and incentive program. It would be prudent to review the incentive program under the rules applicable to CCMAs.

[B] Direct Contract

A CCMA can be established through a direct contract with a physician or physician group. In such a situation, the hospital would enter into a contract directly or indirectly with the members of its medical staff that practice in a particular service line to provide some level of medical direction. In addition, this contract may contain an incentive component that would be applicable if certain quality, safety, satisfaction, efficiency and/or cost-savings goals are met. This model would work best if there are a small number of physicians or physician groups practicing in the service line. This is so because it would be difficult to manage the responsibilities of multiple parties that were contracted to perform essentially the same service and because it may be desirable to extend the management arrangement to all physicians who practice in the service line and any incentive distributions may need to be made on a pro-rata basis. [15]

[C] Management Company

The hospital also could enter into the contract for medical direction for the service line that contained the performance incentives with a management company rather than directly with any particular physician or physician group. This model has the ability to accommodate a medical staff that has multiple unrelated physicians practicing within the service line. It involves having the hospital or the physicians involved establish a separate legal entity, likely a limited liability company that would contract with the hospital for provision of medical direction services. This entity would receive a base fee and may have the potential for incentive payments if certain targets related to quality, safety, satisfaction, efficiency and/or cost savings are attained. Both the base fee and the incentive are typically distributed to the participating physician based upon their membership interest or equity in the management company. All physicians practicing in the applicable service line are typically afforded the opportunity to participate as owners of the management company.

Footnotes

12 42 C.F.R. §1001.952(i).

13 42 C.F.R. §411.357(c).

14 U.S. *ex rel.* Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394 (4th Cir. 2012).

15 *See* §4.07(B)(1), *infra*; *see also* OIG Advisory Op. 08-21 (Nov. 25, 2008).

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[A] Gainsharing

The concept of developing a collaborative relationship between a hospital and its medical staff is not new. For the past 20 years, the concept of gainsharing has been considered as a potential basis for collaboration. The concept in gainsharing is that the hospital and its medical staff, or certain sections thereof, would work collaboratively to achieve certain predetermined financial or quality goals. Usually, these goals would be in the form of some financial incentive for which the hospital might qualify if certain goals are met. In the event that these goals are met, the hospital would then share some of the gain with the physicians whose collaboration helped achieve the goal. Obviously, such arrangements could implicate several health care law constraints including the CMP Act, Anti-Kickback Law, and Stark Law. This is because such arrangements involve a payment from or directed by the hospital to its physicians.

The concept of gainsharing initially was viewed with a certain amount of disfavor by the regulatory community. The initial guidance on gainsharing consisted of a July 1999 Department of Health and Human Services (HHS) OIG Gainsharing Bulletin [16] that gave a limited approval to the concept, but prohibited the gain to be shared from being based upon cost savings generated from any savings based upon items or services furnished to patients. This restriction limited the potential use of such arrangements to a limited set of quality-based programs. However, beginning in 2005, a number of OIG Advisory Opinions were issued that suggested greater viability for the concept may be possible. From 2005 through 2010 the OIG issued several favorable gainsharing and pay-for-performance opinions. [17] Three are worthy of review.

In OIG Advisory Opinion 08-16, [18] a hospital proposed to pay a physician-owned entity 50 percent of the pay-for-performance bonus provided by a health insurer for meeting certain specified standards of quality and

efficiency. The OIG concluded that, while the Anti-Kickback Act was implicated, it would not impose sanctions. This conclusion was based upon a variety of specific assumptions, limitations, and factors, including limitations on eligibility, payment caps, determination by the insurer as to whether goals were satisfied, term limitation, per-capita distributions, and an independent fair market value determination. [19]

In OIG Advisory Opinion 08-21, [20] a hospital received a favorable advisory opinion for an arrangement under which four cardiology groups and one radiology group shared in the hospital's cost savings through use of specific medical devices and supplies. The OIG concluded that the proposed arrangement could implicate the CMP Act and the Anti-Kickback Act. The program appeared to contain significant safeguards to protect against improper reductions in services. [21] The OIG also concluded that, because the proposal was limited to existing members of the medical staff, profits were distributed on a per-capita basis, the program had adequate specificity regarding the particular actions that generated the costs savings and there were other safeguards, it would decline to seek sanctions under the Anti-Kickback Act, subject to certain limitations and assumptions. [22]

Similarly, in OIG Advisory Opinion 09-06, [23] the OIG also concluded that it would not impose sanctions for implementation of a proposal by a hospital to pay its cardiology group 50 percent of the savings generated from management of cardiac catheterizations. Those safeguards included payment caps, limited duration of the arrangement, fair market value certification, a focus upon objectively determined criteria tied to waste reduction, product standardization, quality improvement, and a closed universe of potential participants. [24]

The various OIG Advisory Opinions share certain common characteristics. All were based on a specific set of facts and circumstances. Usually, the standards to be satisfied were set and monitored by an independent third party. Moreover, there were independent determinations that payments were at fair market value. In addition, such arrangements were for a limited duration and included a limited group of eligible participants, which group was closed to additional membership during the term of the program. Finally, concerns such as impact upon patient care, adverse selection, cherry picking, and disguised payments for referrals usually were addressed through safeguards that were in place. Of course, all of the Advisory Opinions are subject to various assumptions and limitations and narrowly limit reliance. The regulatory climate was such that when a proposed Stark Law exception was issued in the summer of 2008, [25] gainsharing appeared to be about to become a permanently recognized part of the regulatory landscape. The proposed exception was quite detailed and addressed many of the factors from the Advisory Opinions. However, the proposed exception was never adopted. This has led many in the legal and compliance community to question if it was only a limited concept.

[B] Affordable Care Act

Support and encouragement for the collaborative concept can be found in the Patient Protection and Affordable Care Act (PPACA). [26] PPACA provided the legal basis for the establishment of accountable care organizations (ACO), a legally recognized form of collaboration. In addition, the Affordable Care Act, for the first time, introduced the concept of outright waivers of the CMP Act, the Anti-Kickback Law, and the Stark Law in the context of ACOs. On October 20, 2011, the CMS and OIG issued a joint final rule waiving provisions of those laws for certain ACO shared savings programs. Specifically, this rule authorized five distinct waivers. [27] The specifics of each waiver are beyond the scope of this chapter. However, the purpose of such waivers is to help participants in ACOs find a way to collaborate without violating the applicable federal laws. The Internal Revenue Service (IRS) followed suit with the promulgation of Notice 2011-20 and Fact Sheet 2011-11 that provide similar potential relief under potentially applicable laws pertaining to tax exemption. [28] Conceptually, the ACO program, interim Final Rule, and IRS guidance demonstrate a basis for relaxation of certain of the legal requirements that made collaboration problematic even when such collaboration improved the quality and efficiency of patient care.

One problem with such waivers is that the ACO program applies to a limited set of potential arrangements and then only if the program participates in the waiver process. The waivers that are envisioned are only for significant, multi-service line collaborations, and require advance approval that is only available to a limited group

of applicants. This extensive form of collaboration may be the ultimate goal for patient care delivery systems, but may not be practicable in the more routine hospital/physician relationship where either more extensive integration is not possible or all the requirements for shared savings cannot be established. Is it possible to have a less involved collaboration with the same concepts in place? Could the ACO concept be extrapolated to the service line or program level? These questions may have been answered with "maybe" in a recent OIG Advisory Opinion.

[C] Advisory Opinion 12-22

On January 7, 2013, the OIG issued Advisory Opinion 12-22, [29] which may, for the first time, be construed to permit, in a very limited context, collaboration between a hospital and its medical staff that provides incentives for payments for achieving both quality and financial targets in the same program. As such, this Advisory Opinion could arguably be viewed as a watershed determination on the part of the OIG potentially authorizing a new level of collaboration between hospitals and their medical staffs reduced to the service line or program level. In short, this opinion may be construed as a potential legal support for broadened CCMAs. A review of the facts that served as the basis for this Advisory Opinion may prove illustrative.

The facts in OIG Advisory Opinion 12-22 are as follows. The opinion was requested by a large, rural acute care hospital located in an underserved area. The requesting hospital operated the only cardiac catheterization laboratory within a 50-mile radius of its facility. These laboratories were operated as provider based clinics in accordance with 42 C.F.R. §413.65. The hospital entered into a CCMA with a physician group (the Group) for three years, and numerous safeguards were in place to assure that the overall program was not abusive. [30]

The group involved in the CCMA was the only provider of cardiology services on the hospital's medical staff. The group only provided services at the hospital and the hospital had no other cardiologists. Under the CCMA, the group provided management and medical direction services to the hospital's labs in exchange for a co-management fee comprised of a fixed fee and a potential annual based performance incentive. [31] The fixed fee consisted of a fixed amount for overseeing the laboratory operations, providing strategic planning and medical direction services, developing hospital's cardiology program, service on medical staff committees, provision of training, credentialing and various other programs. [32]

The group could earn the performance fee by achieving certain components consisting of hospital employee satisfaction, patient satisfaction with hospital's labs, improved quality of care within the labs, and implementation of cost savings measures on laboratory procedures. [33] The cost savings measures constituted the majority of the performance targets (60 percent). The performance measures were based upon financial, purchasing, employee satisfaction, patient satisfaction, and quality data, as well as national cardiology quality measures. [34] Furthermore, the measures were based upon independent analysis or objective national data. Most of the measures included three potential achievement levels that would trigger a payment. If the lowest level was not achieved, no payment was allowed for the particular component. [35] The program also included an audit and refund procedure if an annual reconciliation demonstrated an overpayment. Any performance payments made were to the group, not individual members of the Group. The payments were distributed on a pro-rata basis based upon each shareholder's ownership interest. [36]

The performance components were arrived upon through collaboration with the physicians in the service line and generally were based upon objective clinical guidelines. Moreover, in order to assure quality of care and patient safety, there were no prohibitions against using other supplies or treatments if a physician determined the same were necessary or appropriate for a particular patient. [37] There were also safeguards in place to determine which cost-saving measures were appropriate. The program was to be reviewed annually by an independent third-party utilization review firm for appropriateness of the component part of the performance fee as well as the clinical appropriateness of the actual procedures performed in the laboratory. [38] In addition, payments were conditioned upon the group's physicians not taking any of the following actions: (1) stinting on

care; (2) increasing referrals to the hospital; (3) cherry picking; or (4) accelerating patient discharges. Finally, there were numerous levels of ongoing internal reviews and patients and their families were to be notified of the arrangement. [39]

The requesting hospital sought an opinion regarding potential implication of certain federal health care statutes, essentially to determine if the articulated safeguards were adequate to not constitute prohibited kickbacks or improper limitations or reductions in patient care. [40] The OIG analyzed the arrangement under several laws that were potentially applicable. The first statute analyzed was the CMP Act. The CMP Act establishes a civil penalty against any hospital or critical access hospital that knowingly makes a payment to a physician, directly or indirectly, as an inducement to reduce or limit services that are provided to a Medicare of Medicaid beneficiary. [41] Both the hospital and the physician are subject to a civil penalty of up to $2,000.00 per patient. The concern with the proposed arrangement was that the incentives, especially the cost-savings incentives, could cause physicians to limit or change available services and treatment options, thus implicating the CMP Act. [42]

The OIG concluded that many of the various component parts of the arrangement, specifically the fixed fee, employee satisfaction, patient satisfaction, and quality components did not implicate the CMP Act. It found additionally that the cost-savings component could implicate the CMP Act. However, the OIG found that there were several features that, when viewed together, provided sufficient safeguards so that the OIG would not seek sanctions for a potential violation (subject to various assumptions and limitations). [43] Those safeguards included: (1) the arrangement had sufficient monitoring programs to protect against inappropriate limitations or reductions in patient care; (2) the monitoring programs included reviews by the hospital's Board of Directors, internal audit program, and hospital staff committees; (3) the risk of a cost-saving measure being applied in a medically inappropriate manner was low (*i.e.*, because benchmarks were used, but physicians were free to use the most appropriate device or treatment for each individual patient); (4) the financial incentive tied to the cost-savings component was reasonably limited in duration and amount; and (5) receipt of any part of the performance fee was conditioned upon the group's physicians not stinting on care, increasing referrals, cherry picking, or accelerating patient discharges. In the aggregate the five listed restrictions were sufficient for the OIG to decide that sanctions were inappropriate (subject to various assumptions and limitations). [44]

The Advisory Opinion also addresses the potential applicability of the Anti-Kickback Act. [45] The Anti-Kickback Act makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services that are reimbursable under a federal health care program. [46] The Anti-Kickback Act has been construed by the courts to cover an arrangement under which one purpose of the remuneration was to induce the referral [47] A violation is a felony and may lead to imprisonment, monetary penalties, and exclusion from federal health care programs. [48]

The Anti-Kickback Act has potentially broad application and could be construed to prohibit most arrangements between a hospital and its referring physicians absent a statutory exception or regulatory safe harbor, especially in view of the line of cases that find a violation based upon the one purpose test. Therefore, in order to provide some level of assurance to providers, the government promulgated a series of safe harbors to delineate situations in which the Anti-Kickback Act would not be violated. [49] The arrangement in the Advisory Opinion potentially fell under the safe harbor for personal service and management contracts, 42 C.F.R. §1001.952(d). However, this safe harbor requires, among other matters that the compensation under the arrangement be set in advance and be at fair market value. There was no apparent problem with the fair market value requirement under the arrangement because fair market value was assumed and an independent review of the same was a component of the arrangement. However, the incentive portion of the arrangement was intended to vary based upon performance. Accordingly, the set-in-advance requirement would not be satisfied and the arrangement was expected to fall outside the safe harbor. Thus, there was a concern that the arrangement could be a means to disguise remuneration for referrals. [50]

Anti-Kickback Law safe harbors need not always be adhered to completely, however, because the requisite intent to violate the Anti-Kickback Law must also be present. The mere fact that an arrangement falls outside any existing safe harbor does not make it, *per se*, a violation of the Anti-Kickback Act. Under the Advisory Opinion, the OIG analyzed the probable risk of an actual violation under the arrangement and concluded that it would not impose sanctions (subject to various assumptions and limitations). [51] This was so, in part, because: (1) the compensation was at fair market value; (2) the compensation did not vary with the number of patients treated; (3) the hospital had the only cardiac catheterization laboratory within a 50-mile radius and the group practiced nowhere else, thus, potential for a shift in referral patterns or similar abuses was low; (4) the specificity of the performance measures helped insure that the arrangement's purpose was to improve quality rather than to reward referrals; and (5) the management agreement under the arrangement was for a limited duration. [52] In light of the foregoing factors, the OIG concluded that the arrangement posed a low risk for fraud and abuse. [53] The Advisory Opinion concluded with a determination that the OIG would not seek sanctions under the CMP Act or Anti-Kickback Act, subject to various assumptions and limitations. [54] However, before relying on this Advisory Opinion or taking comfort in its analysis, it is important to understand the limitations and caveats found in them. [55] Specifically, Advisory Opinion 12-22, as is typical for OIG advisory opinions, includes, among others, the following limitations: (1) it is only applicable to the requestor; (2) it cannot be used in evidence by anyone except requestor; (3) it is only applicable to specific statutes as specified; (4) it is not binding on any federal agency other than HHS; (5) it is limited in scope only to the particular arrangement; and (6) no False Claims Act or other improper billing opinion is given. The Advisory Opinion may arguably be read to break new ground because, for the first time, financial improvement incentives appear to be approved. However, the Advisory Opinion is also notable for what it did not address. It does not address potential violations of the Stark Law. [56] One of the requirements of both the Anti-Kickback Law safe harbor on personal service contracts and the Stark Law exception pertaining to the same is that the overall agreement also must be legal. [57] This Advisory Opinion does not address other potential legal obstacles that might be encountered in establishing a CCMA. It also does not address antitrust issues. It is with this in mind that we begin our review of certain potentially applicable legal requirements and certain potential legal obstacles to implementation of CCMAs.

Footnotes

16 Special Advisory Bulletin: Gainsharing Arrangements and CMPs Payments to Providers to Reduce or Limit Services to Beneficiaries (hereinafter 1999 Gainsharing Bulletin), 64 Fed. Reg. 37985 (June 14, 1999).

17 *See*, *e.g.*, OIG Advisory Ops., 05-01, 06-22, 07-22, 08-15, 08-16, 08-21 and 09-06.

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

19 OIG Advisory Op. 08-16, 11.

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

21 OIG Advisory Op. 08-21, 5.

22 OIG Advisory Op. 08-21, 14-15.

23 OIG Advisory Op. 09-06 (June 22, 2009).

24 OIG Advisory Op. 09-06, 11 (CMP Act), 12-13 (Anti-Kickback Act).

25 In July 2008, CMS proposed a Stark Law exception for certain incentive payments and certain shared savings arrangements. *See*, 73 Fed. Reg. 38502, 38604 (July 7, 2008).

26 Pub. L. No. 111-148 (Mar. 23, 2010).

27 76 Fed. Reg. 19528 (Apr. 7, 2011). The Joint Final Rule waived the CMP Act, the Anti-Kickback Law and the Stark Law for certain ACO programs and had five ACO-distinct waivers: (1) pre-participation; (2) participation; (3) shared savings distribution; (4) compliance with the Stark Law and gainsharing CMP Act; and (5) patient incentives; *see also*, 76 Fed. Reg. 67 (Nov. 2, 2011).

28 IRS Notice 2011-20 (Mar. 31, 2011).

29 OIG Advisory Op. 12-22 (Dec. 31, 2012).

30 OIG Advisory Op. 12-22, 2.

31 OIG Advisory Op. 12-22, 2-3.

32 OIG Advisory Op. 12-22, 3.

33 OIG Advisory Op. 12-22.

34 OIG Advisory Op. 12-22, 4.

35 OIG Advisory Op. 12-22.

36 OIG Advisory Op. 12-22, 3.

37 OIG Advisory Op. 12-22, 7.

38 OIG Advisory Op. 12-22.

39 OIG Advisory Op. 12-22, 7-8.

40 OIG Advisory Op. 12-22, 1.

41 OIG Advisory Op. 12-22, 9.

42 OIG Advisory Op. 12-22, 10.

43 OIG Advisory Op. 12-22.

44 OIG Advisory Op. 12-22, 10-12.

45 OIG Advisory Op. 12-22, 12-15.

46 42 U.S.C. §1320a7-b(b) ; *see also*, 42 C.F.R. §1001.952.

47 *See* United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d. 823 (10th Cir. 2000); United States v. Davis, 132 F.2d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d. (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

48 *See* 42 U.S.C. §1320a7-b(b).

49 *See* 42 C.F.R. §1001.952(a)-(y).

50 OIG Advisory Op. 12-22, 13.

51 OIG Advisory Op. 12-22, 15-17.

52 OIG Advisory Op. 12-22, 13-14.

53 OIG Advisory Op. 12-22.

54 OIG Advisory Op. 12-22, 14-15.

55 *See* OIG Advisory Op. 12-22, 15.

56 *See* OIG Advisory Op. 12-22, 9.

57 *See*, *e.g.*, 42 C.F.R. §1001.952(d)(c) (stating the Anti-Kickback Law safe harbor for personal services and management contracts which, in part (b), includes a requirement that the services "do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law").

Health Law and Compliance Update - Steiner, §4.04, ANTI-KICKBACK LAW

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Critics of co-management agreements (or, rather, any arrangement that encourages a physician to consider cost-effectiveness of health care services) contend that "a physician cannot easily serve his patients as trusted counselor and agent when he has economic ties to profit-seeking businesses that regard those patients as customers." [58] In response, some commentators have countered that patients are in fact *better* served by doctors who are financially involved in the provision of health care services, as the doctors themselves, constrained as they are by their conscience and mandatory ethical obligations, [59] are more qualified to assess their patients' needs than lay businesspeople. Normative judgments aside, it is perhaps not surprising, given recent changes in federal law designed to improve patient care, [60] that co-management agreements [61] have become increasingly popular. [62] With the increase in utilization of CCMAs comes the necessity to analyze the applicable federal laws that may affect (and could, in certain circumstances, frustrate) implementation of such organizational structures. [63]

As a general matter, gainsharing, the predecessor to many CCMAs, is a term used to describe an arrangements between a hospital and physicians or physician groups, pursuant to which the hospital agrees to share certain cost savings connected to patient care with physicians participating in the reduction. Despite gaining increased acceptance in recent years, gainsharing has been characterized as the "sorry step-child in the family of physician financial incentives—much neglected, overlooked, and misunderstood." [64] Of course, CCMAs can be structured without a gainsharing component.

In part, the rationale for such treatment stems from laws like the Anti-Kickback Act, [65] and the regulatory guidance issued thereunder, which has been adversely impacted by the Anti-Kickback Act. [66] Despite a recent loosening of this administrative interdict, as evidenced by recent opinions by the OIG, the statutory language and regulatory analysis require that any CCMA be examined to ensure compliance with the Anti-Kickback Law (as well as other applicable federal and state laws). While it is true that a CCMA differs from traditional gainsharing in one significant way—namely that a CCMA involves physicians in the planning for and management of the clinical service line—the OIG's historic suspicion toward gainsharing remains, making it difficult to assess whether a particular CCMA is permissible. [67]

[A] Anti-Kickback Law: An Overview

With certain narrow statutory "exceptions" and regulatory "safe harbors" excluded, the Anti-Kickback Act makes it a felony to "knowingly and willfully" solicit, offer, pay, or receive any "remuneration (including any kickback, bribe or rebate)" in return for or to induce referrals (a) "for the furnishing or arranging of any item or service" or (b) "for purchasing, leasing, ordering, or arranging for recommending purchasing, leasing, or ordering any good, facility, service or item" paid under any "Federal health care program." [68] In other words, the law prohibits *anyone* from giving, receiving, or offering to give or receive *anything* of value to induce referrals for businesses covered by Medicare, Medicaid, Tricare, or any other federally funded health care program.

The OIG is the agency tasked with the responsibility for interpreting the law and, in conjunction with the Department of Justice (DOJ), enforcing it. [69] A violation of the statute is punishable by a maximum fine of $25,000, imprisonment of up to five years, or both. A convicted party will also automatically be excluded from certain federal health care programs, including Medicare and Medicaid. In addition, violations under the statute may lead to the imposition of administrative civil money penalties. [70] Finally, while the law does not provide for a private right of action, individuals may bring *qui tam* actions alleging a violation under the statute under the False Claims Act.

Enacted in 1972, [71] the Anti-Kickback Act reflects Congress's attempt to prevent fraud and abuse in connection with the provision of goods and services to patients under federally funded health care programs, specifically its concern that such improper remuneration would "corrupt the health care system, including increasing the risks of overutilization of items and services, increased costs to the Federal health care programs, inappropriate

steering of patients, and unfair competition." [72] As one member of the House Ways and Means Committee has noted: "We must not tolerate hospitals paying physicians to reduce or limit services to the elderly." [73] Although Congress intended that the statute protect against the mistreatement of a vulnerable patient population—and so was not necessarily designed to enjoin arrangements that encourage quality and efficiency improvements—the text of the statute is undeniably expansive, making the law's application to a particular arrangement difficult to evaluate.

As compared with the Stark Law, the Anti-Kickback Law applies to all health care providers, not just physicians. Also, the statute ascribes liability to parties on both sides of a transaction involving an impermissible remuneration. It is perhaps not surprising that the OIG has acknowledged that the reach of the statutory proscription is "very broad," [74] a rather cryptic characterization that conveys little practical guidance to hospitals, physicians, and other providers.

Courts also have interpreted the Anti-Kickback Act expansively, applying its penalties to a "broad spectrum of compensation arrangements, ranging from obviously corrupt bribe and kickback schemes, to potentially beneficial patient management agreements between health care providers." [75] Moreover, with respect to the scienter element, the majority of courts and the OIG have adopted a "one purpose" test. [76] Under the "one purpose" test, if any "one purpose" of a compensation arrangement is to induce referrals, the statute is violated, even if the payments compensated for some legitimate services.

As to the question of whether a defendant must have specific intent to violate the statute, in *Hanlester Network v. Shalala*, the Ninth Circuit construed "knowingly and willfully" to mean that the prosecution must show that the defendants both knew of the anti-kickback prohibitions and acted with specific intent to violate the law. [77] A circuit split developed over the issue, [78] although the statute was amended to clarify that a party "need not have actual knowledge of this section or specific intent to commit a violation of this section." [79] This amendment appears to clear up the ambiguity surrounding the intent element. Thus, while the statute requires that the government do more than prove general intent to break the law, it need not prove that the defendant knew he was violating the Anti-Kickback Act. For these (and other) reasons, the law has been sharply criticized for focusing on the intent of the parties rather than "on the likely effects of a given compensation arrangement on cost and quality." [80]

Just as the Stark Law has exceptions, the Anti-Kickback Law provides for regulatory "safe harbors," [81] which are promulgated by the OIG. [82] Generally, these exceptions or safe harbors "identify the criteria of specific payment practices that do not violate the [law] and could protect, for example, paying physicians as employees… or for a physician's medical directorship position." [83] The OIG has stated that the purpose of the safe harbors is "to permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy." [84]

Currently, there are 25 safe harbors under the regulations. [85] These "safe harbors" identify certain payment and business practices that will not subject a party to criminal and civil prosecution under the Anti-Kickback Act due to their low risk for fraud or abuse. [86] OIG has explained that "[i]f a person participates in an arrangement that *fully complies* with a given provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision." [87] Unlike the Stark Law, the absence of an exception or safe harbor does not automatically result in a violation if the requisite intent is not present. In the event that an arrangement does not "fully comply" with an exception or safe harbor, OIG will assess it on a case-by-case basis: "the legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute." [88]

[1] Space Rental Safe Harbor, 42 C.F.R. §1001.952(b)

A lease arrangement may be prohibited under the law if the lease payments are simply a device used to mask illegal payments intended to induce referrals. Under the space rental safe harbor, "remuneration" does not include "any payment made by a lessee to a lessor for the use of premises," provided six prerequisites are met: (1) the lease is in writing and signed by the parties; (2) the lease describes the entire premises with particularity; (3) if access to the space is permitted only for "periodic intervals of time," the lease sets forth such intervals in advance so it is clear that the payments are not based on the number of referred patients; (4) the term of the lease is for at least a year (preventing more periodic adjustments to account for prior referrals); (5) the rental payment is set in advance and reflects "fair market value" without taking into account "the volume or value" of referrals; and (6) the space rented "does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental." [89] In short, to meet this safe harbor, among other requirements, the transaction must be at fair market value and pay compensation that in no way varies with referrals made between parties.

Fair market value is defined as follows:

> the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program. [90]

OIG has recognized that the determination of whether an arrangement is for fair market value is a question of fact that must be determined on a case-by-case basis. [91] Because of the OIG's refusal to opine on fair market value, this element presents a great deal of uncertainty.

The requirement that the rental payment be "set in advance" may also be difficult to meet—the OIG has concluded that percentage-based leases will fail this criterion. [92] This safe harbor similarly precludes "per use" rental agreements unless the number of uses is fixed by the lease. [93]

[2] Personal Services and Management Contracts, 42 C.F.R. §1001.952(d)

The regulations also provide a safe harbor for "personal services and management contracts." The safe harbor itself requires that a variety of standards are met, many of which mirror those included in the rental safe harbor (*i.e.*, that the agreement must be in writing and cover all the services for a period of at least a year, with the caveats that any part-time consideration is set forth in advance and the aggregate services are narrowly tailored). Most importantly, the joint venture or other arrangement involving payments for personal services or management contracts must demonstrate that the services are to be paid at "fair market value." Additionally, the agreement cannot "involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law." [94] This safe harbor, though often invoked, is narrow and more suited to a traditional and limited employee-employer independent contractor relationship.

[B] Anti-Kickback Law: Possible Applicability to Co-Management Agreements

A participant in a CCMA needs to be satisfied that the proposed transaction cannot be construed to involve *a purpose* to offer, pay, solicit, or receive any *remuneration to induce referrals* of items or services reimbursable by federal health care programs. The roadblocks to many CCMAs may include (1) the requirement for certain of the safe harbors that the remuneration be "set in advance," (2) the OIG's position that conduct can violate the law if even "one purpose" of the remuneration is to induce recommendation or referral, and (3) the OIG's refusal to opine on the definition of "fair market value." [95]

CCMAs often fail to meet either the space rental or personal services and management contracts safe harbors, given the shared savings or incentive payments made from hospitals to physicians under many models. Both safe harbors require that rent or compensation be set "in advance." Because the OIG takes the position that an agreement that utilizes percentage-based compensation fails to meet the personal services and management contracts safe harbor, many CCMAs may not qualify, "[b]ecause th[ese] safe harbor[s] require[] that compensation be predetermined and volume-neutral," instead of tied to cost savings achieved. [96]

Failure to meet an exception or safe harbor is not fatal under the statute. If an exception or safe harbor is not met, then the government may reach one of three conclusions: (1) the arrangement is not covered by the Anti-Kickback Act, "so there is no reason to comply with the safe harbor standards, and no risk of prosecution"; (2) a clear statutory violation exists, in which case "assuming the arrangement is obviously abusive, prosecution would be very likely"; or, most likely, (3) "the arrangement may violate the statute in a less serious manner," assuming any fair market value requirement is satisfied, although it is not in technical compliance with a safe harbor provision." [97] As to this third scenario, OIG has admitted, "there is no way to predict the degree of risk." [98] Instead,

> the degree of the risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution. Certainly, in many (but not necessarily all) instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor, but for reasons beyond their control are not in compliance with the terms of that safe harbor. In other instances, there may not even be an applicable safe harbor, but the arrangement may appear innocuous. But in other instances, we will want to take appropriate action.
>
> We do not believe the Medicare and Medicaid programs would be properly served if we assured protection in all instances of "substantial compliance," "technical violations," or "de minimis" payments. Unfortunately, these are vague concepts, subject to differing interpretations. In this regulation, we have attempted to provide bright lines, to the extent possible, for safe harbors in order to provide clarity and predictability as to what conduct is immune from government action. Our endorsement of the concepts mentioned above would only serve to blur these lines and produce litigation as to what "substantial," "technical" and "de minimis" really mean. The OIG therefore declines to adopt these concepts. [99]

Given these risks, it must be clear that the parties to the CCMA do not intend to induce referrals. Hospitals serving rural or under-served communities, or groups that provide services to only one hospital, for example, have had some success convincing the OIG that an agreement did not violate the "one purpose" test, because "it is unlikely that [the hospital] offered compensation to the [physician group] under the [CCMA] as an incentive for the [physician group] to refer business to the [hospital labs] instead of to a competing [lab]." [100] On the other hand, the OIG maintains that the "one purpose" test is met if *any purpose* of the compensation arrangement is to induce referrals, even if the payments compensated for legitimate, lawful services. This inquiry is highly fact specific and, as such, hospitals should avoid establishing any co-management objective that could be construed to reward physicians for increased utilization or the volume or value of their referrals.

The arrangement must also provide for compensation that is fair market value to avoid the implication that the fee is a disguised payment for referral services. As noted, the OIG steadfastly refuses to opine on whether compensation is fair market value for the services provided, but it may evaluate whether the method used to determine that a fee represents fair market value appears reliable and reserves the right to prosecute if it concludes that the fees are in fact not fair market value, [101] leaving providers with little guidance as to what constitutes fair market value. Given this dearth of advice, a CCMA's compensation structure must be closely

examined to ensure that fees to individual physicians reflect fair market value for the services provided. In addition, to the extent an investor receives profits under a CCMA, such payments should be proportional to the investor's original investment. In any event, it is generally not advisable to structure compensation based on a percentage of revenues of the hospital and compensation should not vary based on the volume or value of referrals generated by participating physicians for the hospital. When setting the compensation structure, it is prudent to engage an independent valuator to provide an opinion that the fees are reasonable and fair market value for the services provided and to review periodically the fee structure. [102] OIG Advisory Opinion 12-22 guidance suggests that a CCMA that includes (a) safeguards to assure that physician's referral patterns are not altered due to the CCMA, and (b) mechanisms to prevent physicians from "cherry-picking" patients may pass OIG scrutiny.

For most physicians, providers, and hospitals, the OIG's positions with respect to *de minimus* variations from the safe harbors, adherence to the "one purpose" test, and its declination to opine on fair market value is not reassuring. Despite recent positive OIG advisory opinions, which will be discussed, *infra*, parties to a CCMA will not be guaranteed that the arrangement is permissible under the Anti-Kickback Act (although an advisory opinion could reduce the risks). Nevertheless, consideration of the above areas of risk may help to alleviate the risk of prosecution under the statute.

Footnotes

58 Arnold S. Relman, "Practicing Medicine in the New Business Climate," 316 *New Eng. J. Med.* 1150 (1987); *see also* Marcia Angell, "The Doctor as Double Agent," 3 *Kennedy Inst. Ethics J.* 279, 283-85 (1993); M. Gregg Bloche, "Trust and Betrayal in the Medical Marketplace," 55 *Stan. L. Rev.* 919, 940-41 (2002). "Critics contend that financial incentives corrupt the healing ethos of medicine. They warn that financial incentives erode trust critical to the physician-patient relationship and can lead physicians to provide lower quality services, avoid sicker and more costly patients, and abandon ethical directives and fiduciary obligations to act always in their patients' best interests." Richard S. Saver, "Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives," 98 *Nw. U. L. Rev.* 145, 150-51 (Fall 2003).

59 It must be remembered that a physician, like a lawyer, is governed by a code of professional ethics, which arguably tempers his self-interest. *See, e.g.*, American Medical Ass'n, "Conflicts of Interest: Physician Ownership of Medical Facilities," 267 *J. Am. Med. Ass'n* 2355 (May 6, 1992).

60 *See, e.g.*, the provisions of the Patient Protection and Affordable Care Act designed to reduce hospital re-admissions. Affordable Care Act, Pub. L. No. 111-148 (Mar. 23, 2010); 42 U.S.C. §1395ww(q) (requiring a "hospital readmissions reduction program"); *see also* Jen Johnson, "Co-Management Agreements, Compensation & Compliance," ABA Health *e*Source (June 2011), *available at* https://www.americanbar.org/newsletter/publications/aba_health_esource_ home/aba_health_law_esource_1106_johnson.html (discussing governmental and commercial "pay for performance programs" generally).

61 A CCMA is an arrangement under which a hospital and group of physicians engage in a joint venture "through which the physicians are compensated for managing and improving care in a specific hospital service line (orthopedic surgery, cardiology, oncology, etc.)." Pamela H. Del Negro, "Service Line Co-Management Arrangements: Models & Practicalities," *ABA Health* e *Source* (Oct. 2012), *available at* http://www.americanbar.org/newsletter/publications/aba_health_ esource_home/aba_health_law_esource_1012_delnegro.html.

62 In fact, according to one recent survey, 24 percent of physicians participate in CCMA and 51 percent of physicians "are interested in pursuing this type of arrangement" in the near future. Jen Johnson, "Co-Management Agreements, Compensation & Compliance," *ABA Health eSource* (June 2011), *available at* https://www.americanbar.org/newsletter/publications/ aba_health_esource_home/aba_health_law_esource_1106_johnson.html.

63 While outside the scope of this chapter, the examination of any CCMA should not neglect review and analysis of any applicable state laws.

64 Arnold S. Relman, "Practicing Medicine in the New Business Climate," 316 *New Eng. J. Med.* 1150 (1987); *see also* Marcia Angell, "The Doctor as Double Agent," 3 *Kennedy Inst. Ethics J.* 279, 283-85 (1993); M. Gregg Bloche, "Trust and Betrayal in the Medical Marketplace," 55 *Stan. L. Rev.* 919, 940-41 (2002). "Critics contend that financial incentives corrupt the healing ethos of medicine. They warn that financial incentives erode trust critical to the physician-patient relationship and can lead physicians to provide lower quality services, avoid sicker and more costly patients, and abandon ethical directives and fiduciary obligations to act always in their patients' best interests." Richard S. Saver, "Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives," 98 *Nw. U. L. Rev.* 145, 151 (Fall 2003).

65 42 U.S.C. §1320a-7b(b) provides, in pertinent part, as follows:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $ 25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $ 25,000 or imprisoned for not more than five years, or both.

66 1999 Gainsharing Bulletin, 64 Fed. Reg. 37985. Technically, the 1999 Bulletin took the position that gainsharing violated the CMP Act provision; however, the OIG noted that gainsharing arrangements also raised concerns under the federal Anti-Kickback Act.

67 As discussed in §4.02, *supra*, typically, CCMAs involve one of three models—employment incentive, joint venture, or direct contracting. In the joint venture model, the hospital and physicians form a new entity (often, a limited liability company), which performs the co-management services (after entering into a contract with the hospital for the same). Under the direct contracting model, the hospital contracts directly with the physicians or practice group for performance of the co-management services. In any event, the CCMA often sets two types of payments—a base compensation and an incentive fee. As will be discussed, setting the parameters of the incentive fee can be difficult given the Anti-Kickback Law and other federal restrictions.

68 *Federal health care program* is defined as follows:

> (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code [5 USCS §§8901 *et seq.*]); or (2) any State health care program, as defined in section 1128(h) [42 U.S.C.S. §1320a-7(h)].

42 U.S.C. §1320a-7b(f).

69 Robert F. Leibenluft, et. al, "Hospital-Physician Collaborations: Antitrust and Health Care Fraud and Abuse Considerations," in *Health Law Handbook* §7.9 (Alice G. Gosfield ed., 2009), *available at* http://www.healthlawyers.org/Events/Programs/Materials/Documents/HHS10/leibenluft.pdf.

70 42 U.S.C. §1320a-7a(a)(7) (as amended by Pub. L. No. 105-33 4304(b), 111 Stat. 251 (Aug. 5, 1997)). In 1997, Congress expanded the nexus for civil money penalties in connection with violations of the Anti-Kickback Act by amending the statute to include any person who "commits an act described in paragraph (1) or (2) of 1128B(b)" to the list of persons subject to civil monetary penalties. Penalties may be imposed in the amount of $50,000 per violation plus "damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose."

71 The original anti-kickback legislation was included in the Social Security Amendments of 1972. Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972).

72 Medicare and State Health Care Programs: Fraud and Abuse, 67 Fed. Reg. 60202, 60202 (proposed Sept. 25, 2002) (to be codified at 42 C.F.R. pt. 1001); *see also* Timothy J. Aspinwall, "The Anti-Kickback Statute Standards of Intent: The Case for a Rule of Reason Analysis," 9 *Ann. Health L.* 155, 155 (2000); *see also* H.R. Rep. No. 92-231, *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093 (noting "certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the medicare and medicaid programs"). As originally enacted, violations were punishable as misdemeanors. It was not until 1977 that the law was amended to increase penalties, add a "knowingly and willfully" *mens rea* requirement, and expand coverage to include "any remuneration." Timothy J. Aspinwall, "The Anti-Kickback Statute Standards of Intent: The Case for a Rule of Reason Analysis," 9 *Ann. Health L.* 155, 161 (2000); *see* Pub. L. No. 95-142, 91 Stat. 1175 (1977).

73 144 Cong. Rec. H11,446 (Oct. 17, 1986).

74 Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37985, 37985 (July 14, 1999).

75 Timothy J. Aspinwall, "The Anti-Kickback Statute Standards of Intent: The Case for a Rule of Reason Analysis," 9 *Ann. Health L.* 155, 155-56 (2000).

76 United States v. Gerber, 760 F.2d 68 (3d Cir. 1985), *overruled on other grounds*, United States v. Gaudlin, 115 S. Ct. 2310 (1995); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 65 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001). The Fifth, Ninth, and Tenth Circuits have also adopted the "one purpose" test. United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States LaHue, 261 F.3d 993 (10th Cir. 2001). In contrast, the First Circuit stopped short of explicitly adopting the "one purpose" test, instead instructing the jury that the "primary purpose" must be improper in order to obtain a conviction under the Anti-Kickback Act. United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 32 (1st Cir. 1989). The U.S. Supreme Court has not addressed the scope of the Anti-Kickback Act.

77 51 F.3d 1390 (9th Cir. 1995).

78 The Eleventh Circuit disagreed with the Ninth Circuit and held that the government need only demonstrate that the defendant knew that his conduct was wrongful not that he knew it violated the Anti-Kickback Act. United States v. Starks, 157 F.3d 833 (11th Cir. 1998); *accord* United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996); *Bay State Ambulance*, 874 F.2d 20, 33. Although the Supreme Court has not resolved this circuit split, in other contexts, it has interpreted "willfully" to require only proof that the defendant was aware that his conduct was generally unlawful. Bryan v. U.S., 524 U.S. 184 (1998).

79 42 U.S.C. §1320a-7b(h) was added in 2003 as part of the Affordable Care Act. Affordable Care Act, Pub. L. No. 111-148 (Mar. 23, 2010).

80 Timothy J. Aspinwall, "The Anti-Kickback Statute Standards of Intent: The Case for a Rule of Reason Analysis," 9 *Ann. Health L.* 155, 155-56 (2000).

81 42 C.F.R. §1001.952.

82 It was not until 1987 that the law was amended to require the OIG to develop and promulgate safe harbor provisions, after many criticized the law for punishing "relatively innocuous commercial arrangements" that were nevertheless technical violations of the statute. Medicare and State Health Care Programs: Fraud and Abuse, 67 Fed. Reg. 60202, 60202 (proposed Sept. 25, 2002) (to be codified at 42 C.F.R. pt. 1001).

83 Robert F. Leibenluft, et. al, "Hospital-Physician Collaborations: Antitrust and Health Care Fraud and Abuse Considerations," in *Health Law Handbook* §7.9.

84 Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088 (proposed Jan. 23, 1989) (to be codified at 42 C.F.R. pt. 1001).

85 42 C.F.R. §1001.952. The current safe harbors are as follows: (1) investment interests, (2) space rental, (3) equipment rental, (4) personal services and management contracts, (5) sale of practice, (6) referral services, (7) warranties, (8) discounts, (9) employees, (10) group purchasing organizations, (11) waiver of beneficiary coinsurance and deductible amounts, (12) increased coverage, reduced cost-sharing amounts or reduced premium amounts offered by health plans, (13) price reductions offered to health plans, (14) practitioner recruitment, (15) obstetrical malpractice insurance subsidies, (16) investments in group practices, (17) cooperative hospital service organizations, (18) ambulatory surgical centers, (19) referral agreements for specialty services, (20) price reductions offered to eligible managed care organizations, (21) price reductions offered by contractors with substantial financial risk to managed care organizations, (22) ambulance replenishing, (23) health centers, (24) electronic prescribing items and services, and (25) electronic health records items and services.

86 Pamela H. Del Negro, "Service Line Co-Management Arrangements: Models & Practicalities," *ABA Health eSource* (Oct. 2012), *available at* http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1012_delnegro.html.

87 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 65 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

88 65 Fed. Reg. 35952.

89 The safe harbor, 42 C.F.R. §1001.952(b), is set forth as follows:

> Space rental. As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met—
>
> > (1) The lease agreement is set out in writing and signed by the parties.
> > (2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

> (3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
> (4) The term of the lease is for not less than one year.
> (5) *The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.* [Emphasis added.]
> (6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (b) of this section, the term fair market value means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.

90 42 C.F.R. §1001.952(b).

91 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 65 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001). Not surprisingly, this standard invites a so-called "battle of the experts" on the question of "fair market value." *See, e.g.*, United States *ex rel.* Goodstein & Grossman v. McLaren Reg'l Med. Ctr., 202 F. Supp. 2d 671 (E.D. Mich. 2002).

92 OIG Advisory Op. 07-11 (Nov. 16, 2011) ("Percentage compensation arrangements are inherently problematic under the anti-kickback statute, because they relate to the volume and value of business generated between the parties, rather than the fair market value of the services provided.").

93 Compare with the Stark Act, which does not require the total amount of rent to be set in advance.

94 42 C.F.R. §1001.952(d) states as follows:

> As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—
>
> > (1) The agency agreement is set out in writing and signed by the parties.
> > (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
> > (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
> > (4) The term of the agreement is for not less than one year.
> > (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the

volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

95 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 65 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

96 Betsy McCubrey, Cmt., "OIG Bulletin Highlights Schizophrenic Attitude in Cost-Saving Measures: Gainsharing Arrangements—Their History, Use, and Future," 79 *N.C. L. Rev.* 157, 163 (2000).

97 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 65 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001).

98 65 Fed. Reg. 35952.

99 65 Fed. Reg. 35952.

100 OIG Advisory Op. 12-12 (Dec. 31, 2012).

101 42 U.S.C. §1320a-7b(b).

102 Jennifer Breuer & John D'Andrea, *The Law Review: Structuring Co-Management Agreements* (Nov. 10, 2011), *available at* http://www.advisory.com/Daily-Briefing/2011/11/10/Law-Review-Considerations-in-structuring-co-management.

Health Law and Compliance Update - Steiner, §4.05, CIVIL MONEY PENALTY

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[A] CMP Act: An Overview

Under the CMP Act, [103] civil money penalties may be assessed against hospitals or doctors that "knowingly" make or receive payments to reduce or limit items or services provided to any federally funded health care program beneficiary. Each violation is punishable by a penalty of $2,000 against each participating individual. [104]

These broad statutory prohibitions indicate Congressional concern that hospitals and other health care providers not "have an economic incentive to pay physicians to discharge patients too soon—quicker and sicker—or otherwise truncate patient care." [105] Thus, "any hospital gainsharing plan that encourages physicians…to reduce or limit clinical services" may violate the CMP Act, regardless of whether the payment actually results in a reduction in care or in medically necessary services. [106] If, for example, a hospital pays its cardiac surgeons in exchange for the surgeon's selecting stints from a limited number of less expensive stints, such arrangement

could violate the law, this despite the fact that the stint selected may be as effective as more expensive ones. [107]

As previously discussed, the OIG has been historically suspicious of gainsharing arrangements. Consequently, CCMAs must be reviewed to insure that incentive arrangements do not raise concerns of generalized gainsharing (*i.e.*, payments tied to aggregate cost savings). In 1999, the OIG issued a "Special Advisory Bulletin" that declared that gainsharing arrangements "that directly or indirectly provide physicians financial incentives to reduce or limit items or services to patients that are under the physician's clinical care" violated the civil monetary penalty provisions. [108] Just a few years later, the OIG began issuing advisory opinions that pulled back from this flat prohibition somewhat.

In the first of these opinions, the OIG examined a hospital's proposal to pay a group of cardiac surgeons responsible for 85 percent of its cardiac admissions 50 percent of the first year's cost savings attributable to specific efficiency improvements in their operating practices (*i.e.*, substituting less costly items where appropriate, limiting use of an antihemorrhaging drug to high-risk patients only, and not opening surgical packs until needed). Consistent with the 1999 Gainsharing Bulletin, the OIG stated that gainsharing violates the CMP Act; however, the OIG exercised its discretion not to seek administrative sanctions because the arrangement contained sufficient safeguards to protect against patient and program abuse, such as the fact that compensation was based on a per capita, rather than a "per-click" basis, the incentives were limited in duration (one-year), amount (a cap), and scope (cost savings from anyone action limited by prior-year utilization levels), and participation was limited to cardiac surgeons already on staff. [109]

For the next few years, the OIG did not issue any additional advisory opinions declining to seek administrative sanctions on gainsharing. As one analyst observed in 2003, "hospital gainsharing…remains fraught with legal risk, and there is a dearth of gainsharing by hospitals." [110] In 2003, eight hospitals in New Jersey sought and received approval from CMS to begin a three-year "Hospital Performance-Based Incentives Demonstration" to encourage quality improvements among participating hospitals. [111] The project proposed to allow doctors "to earn bonuses of up to 25% more in Medicare fees if hospital operating efficiencies improved over the measurement period." [112] Hospitals excluded from the test sought an injunction in federal court to expand the program to include them, arguing, *inter alia*, that the program violated the CMP Act and the Anti-Kickback Act. The court agreed, but, in an ironic twist, placed a permanent injunction on the experiment. The court held that the project violated the CMP Act because the program's goal—namely, "the diminution of patient care and services for the sake of increased profits or reduced losses"—was the reduction of services expressly prohibited by the CMP Act, "albeit without sacrificing the quality of patient care." [113]

In 2005, the Medicare Payment Advisory Commission (MedPAC) issued a report on physician-owned specialty hospitals, in which it urged Congress to "grant the authority to allow gainsharing arrangements between physicians and hospitals and to regulate those arrangements to protect the quality of care and minimize financial incentives that could affect physician referrals." [114] The report explained that "properly structured, gainsharing arrangements have the potential to encourage physician and hospital cooperation to lower costs and improve care, but there should be safeguards to ensure that cost saving measures do not reduce quality or inappropriately influence physician referrals. These arrangements could serve as an alternative to physician owned specialty hospitals."

Although attempts by MedPAC and others to protect gainsharing by statute or regulation have been unsuccessful, [115] in 2005, OIG issued six advisory opinions approving various gainsharing arrangements on roughly the same grounds as the 2001 opinion. [116] While these opinions opened the door to gainsharing, the OIG required significant safeguards and the opinions were limited to the facts of each arrangement. Opinions in 2006 [117] and 2007 [118] echoed this analysis and focused on three areas of evaluation—accountability, quality controls, and safeguards against referral payments.

Opinions in 2008 [119] expanded the type of permissible arrangements to include "an arrangement involving an anesthesiology group, an arrangement between a hospital and orthopedic surgeons and neurosurgeons, as well as arrangements that are three years and two years instead of the one year that had been in place for the previous proposals." [120]

Most recently, in 2012, OIG issued a favorable opinion with respect to a cardiology group CCMA. The hospital entered into a three-year CCMA with a cardiology group. In exchange for its management and medical direction services (*i.e.*, overseeing the lab, developing the hospital's cardiology program, serving on medical staff committees, providing public relations services, etc.), the group was to receive a fee based on a fixed fee and a yearly performance fee, paid quarterly. The performance component was calculated to include a variety of benchmarks, including employee and patient satisfaction components, as well as cost-saving components that were then tiered to reflect three different achievement levels.

The OIG noted that "[i]ncentive compensation arrangements" like this one "are designed to align incentives by offering physicians compensation in exchange for implementing strategies to meet quality, service, and cost savings targets." Provided these arrangements are "properly structured," the OIG acknowledged, they can serve "legitimate business and medical purposes," including increasing "efficiency" and reducing "waste." Although the performance fee implicated the CMP Act, the OIG declined to exercise its authority to impose sanctions due to the hospital's certification that (1) the arrangement did not adversely affect patient care (as protected by internal audits, and Board of Director and staff committee monitoring); (2) the risk that physicians will use a cheaper stent in medically inappropriate circumstances was low (due to the three-tiered payment levels incorporating various benchmarks that assured the fee was based on aggregated performance by the group and not on meeting a specific standard in a particular case); (3) the performance fee was limited in duration and amount (*i.e.*, the agreement included a cap and was limited to three years); and (4) receipt of the performance fee was premised on the doctors not stinting on care provided to patients, not increasing referrals, not cherry-picking healthy patients or those with desirable insurance for treatment in the labs, or not accelerating patient discharges.

As to the Anti-Kickback Law, the OIG found that while the agreement did not meet the personal services and management contracts safe harbor because aggregate payments to the group were not set in advance, (a) the hospital certified that the compensation was fair market value for the services provided and did not vary with the number of patients or referrals, (b) the hospital operated the only cardiac catheterization laboratory within a 50-mile radius, minimizing the risk that the hospital offered the compensation as an inducement for referrals, (c) the benchmarks and achievement levels assured that the purpose of the arrangement was to improve quality not induce referrals, and (d) the agreement was limited in time and scope. [121]

[B] Civil Money Penalties: Possible Applicability to CCMAs

When structuring CCMAs to avoid penalties under the CMP Act, it is important to align specific quality or efficiency improvement goals with verifiable cost savings that do not change based on changes in volume or value of referrals. For example,

> Additional means to reduce risk of violation of the CMP Statute include: compensating physicians for specific actions that have been recognized as improving patient care; assuring that no incentive is paid where a specific standard is applied in medically inappropriate circumstances; the quality targets are reasonably related to the practices and patient population of the hospital; appropriate procedures are in place to notify patients of the program and to monitor performance under quality targets; and the performance measures that could result in compensation to the manager or management company are clearly and separately identified. [122]

As clarified in the recent 2012 OIG Opinion, a CCMA permitting physicians to benefit from cost savings, while technically implicating the CMP Act, may nonetheless be permissible provided that sufficient safeguards are in place to ensure that the arrangement protects patients. Notably, (1) mechanisms should be in place to ensure that the fee does not incentivize doctors to use cheaper or inferior items that may adversely affect patient care, (2) compensation should be limited in both duration and amount, and (3) and the agreement should be premised on doctors *not* (i) stinting on care provided to patients, (ii) increasing referrals, (iii) cherry-picking desirable patients, or (iv) accelerating patient discharges.

Footnotes

103 42 U.S.C. §1320a-7a.

104 42 U.S.C. §1320a-7a(b)(1) (2000) ("If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided…the hospital or a critical access hospital shall be subject…to a civil money penalty of not more than $2,000 for each such individual with respect to whom the payment is made."); 42 U.S.C. §1320a-7a(b)(2) ("Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject…to a civil money penalty of not more than $2,000 for each individual described in such paragraph with respect to whom the payment is made.").

105 *Hearing on Gainsharing Before the Subcomm. on Health of the H. Comm. on Ways & Means* (hereinafter *Hearing on Gainsharing*), 109th Cong. 8 (2005) (statement of Lewis Morris, Chief Counsel to the Inspector. Gen., U.S. Dep't of Health and Human Services).

106 *Hearing on Gainsharing*, 109th Cong. 8 (2005).

107 *Hearing on Gainsharing*, 109th Cong. 8 (2005).

108 1999 Gainsharing Bulletin, 64 Fed. Reg. 37985; *see also* Cmt., "Why Healthcare Fraud and Abuse Laws Should allow Appropriate Hospital Gainsharing" (hereinafter "Hospital Gainsharing"), 59 *Ala. L. Rev*. 539, 548 (2008) ("The dour outlook on gainsharing presented in the 1999 OIG Report appeared to ban hospital administrators from making gainsharing agreements with physicians.").

109 OIG Advisory Op. 01-1 (Jan. 11, 2001).

110 Arnold S. Relman, "Practicing Medicine in the New Business Climate," 316 *New Eng. J. Med.* 1150 (1987); *see also* Marcia Angell, "The Doctor as Double Agent," 3 *Kennedy Inst. Ethics J.* 279, 283-85 (1993); M. Gregg Bloche, "Trust and Betrayal in the Medical Marketplace," 55 *Stan. L. Rev.* 919, 940-41 (2002). "Critics contend that financial incentives corrupt the healing ethos of medicine. They warn that financial incentives erode trust critical to the physician-patient relationship and can lead physicians to provide lower quality services, avoid sicker and more costly patients, and abandon ethical directives and fiduciary obligations to act always in their patients' best interests." Richard S. Saver, "Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives," 98 *Nw. U. L. Rev.* 145, 150 (Fall 2003).

111 Robert Wood Johnson Univ. Hosp., Inc. v. Thompson, No. Civ. A. 04-142, 2004 WL 3210732, at *12 (D. N.J. Apr. 15, 2004).

112 Richard S. Saver, "One More Setback For Gainsharing," *Health Law Persp.* 4 (Aug. 27, 2004), *available at* http://www.law.uh.edu/healthlaw/perspectives/(RiSa)GainsharingNJ.pdf.

113 *Thompson*, 2004 WL 3210732, at *12.

114 *Medicare Payment Advisory Comm'n, Report to Congress: Medicare Payment Policy* (hereinafter Medicare Payment Advisory Comm'n Report) 47 (Mar. 2005), *available at* http://www.medpac.gov/publications/congressional _reports/Mar05_EntireReport.pdf.

115 Medicare Payment Advisory Comm'n Report 47, 153. As a result, a bill was introduced proposing to allow HHS "to establish criteria to allow gainsharing arrangements to better align hospital and physician incentives to undertake cost containment measures," but the bill met with opposition and died on the floor. Cmt., *Hospital*

Gainsharing, *Ala L. Rev*. 539, 555 (2008). Similarly, CMS's 2008 attempt to add a rule that would revise the "set in advance" requirement under the Stark Law to allow for percentage compensation arrangements failed.

116 *See* Advisory Opinion 05-01; Op. Dep't of Health & Human Servs., OIG Nos. 05- 03 & 05-04 (Feb. 17, 2005); Op. Dep't of Health & Human Servs., OIG Nos. 05-05, 05-06 & 05-07 (Feb. 25, 2005).

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

118 OIG Advisory Op. 07-21 (Dec. 28, 2007).

119 OIG Advisory Op. 08-09 (July 31, 2008); OIG Advisory Op. 08-15 (Oct. 6, 2008).

120 Robert F. Leibenluft, et. al, "Hospital-Physician Collaborations: Antitrust and Health Care Fraud and Abuse Considerations," in *Health Law Handbook* §7.17.

121 OIG Advisory Op. 12-12 (Dec. 31, 2012).

122 Jennifer Breuer & John D'Andrea, *The Law Review: Structuring Co-Management Agreements* 51 (Nov. 10, 2011), *available at* http://www.advisory.com/Daily-Briefing/2011/11/10/Law-Review-Considerations-in-structuring-co-management.

Health Law and Compliance Update - Steiner, §4.06, FALSE CLAIMS ACT

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Like the Anti-Kickback Act and the CMP Act, the False Claims Act is broadly drafted:

> Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit a violation…is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 as adjusted…, plus 3 times the amount of damages which the Government sustains because of the act of that person. [123]

"Originally enacted during the Civil War to combat the bilking of the government by corrupt defense contractors," [124] False Claims Act liability for Stark Law and Anti-Kickback Law violations often arises under the "false certification" theory, whereby the government alleges that the party submitting the claim for payment falsely certified that such claims were submitted in accordance with applicable law. [125] Litigation in this area has increased in recent years, and "a number of courts have accepted the theory that a violation of the Anti-Kickback Act can serve as the basis for a FCA claim, although through different approaches." [126]

Since 1986, the False Claims Act permits a private citizen to bring *qui tam* actions, and, if successful, such citizen (or relator) receives a percentage of the ultimate recovery as thanks for his "whistleblower" efforts. [127]

Footnotes

123 31 U.S.C. §3729(a)(1).

124 Shannon S. Quill, "The False Claims Act & The Anti-Kickback Act—A Potential Combination Against the Health Care Industry And Growing Even Stronger," *The Metropolitan Corporate Counsel* 42 (Oct. 2006), *available at* http://www.metrocorpcounsel.com/pdf/2006/October/42.pdf (hereinafter The False Claims Act).

125 *See* Rachel L. Grier et al., "False Claims Act Damages in Anti-Kickback and Self-Referral Cases," (hereinafter Damages), *ABA Health* e *Source* (June 2011), *available at* https://www .americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1106_ grier.html.

126 Shannon S. Quill, The False Claims Act, *The Metropolitan Corporate Counsel* 42 (Oct. 2006), *available at* http://www.metrocorpcounsel.com/pdf/2006/October/42.pdf ; Rachel L. Grier *et al*., Damages, *ABA Health* e *Source* (June 2011), *available at* https://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1106_grier.html.

127 31 U.S.C. §3730(d); *see* United States *ex rel* Mistick PBT v. Housing Auth. of City of Pittsburgh, 186 F.3d 376, 400 (3d Cir. 1999) (Becker, C.J. dissenting) (discussing primary aims of 1986 FCA Amendments).

Health Law and Compliance Update - Steiner, §4.07, STARK LAW: AN OVERVIEW

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The Stark Act was named after chief proponent Rep. Fortney (Pete) Stark (D. California). This law was a response to the perception that physician referrals to entities in which physicians were financially interested increased utilization. The original bill became known as "Stark I" and became effective, on a relatively limited basis, on January 1, 1992. Effective January 1, 1995, the bill was expanded to cover numerous "designated health services."

The Stark Law prohibits a physician from making a subject referral for the furnishing of a "designated health service" if the physician or a member of his or her immediate family has a direct or indirect "financial relationship" (which is quite broadly defined) with the person or entity to which a subject referral is made, unless the "financial relationship" fits within one of the Stark Law exceptions. Violation of the Stark Law can have significant adverse consequences to the referring physician as well as to an entity that bills Medicare for "designated health services" furnished pursuant to a tarnished referral.

42 C.F.R. §411.354(a) provides:

> (a) *Financial relationships.* (1) *Financial relationship* means—
>
> > (i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or
> >
> > (ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.
>
> (2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

According to 42 C.F.R. §411.351 :

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

There are exceptions that are applicable to both ownership interests and compensation arrangements. Then, there are other exceptions applicable to only ownership interests and still other exceptions only applicable to compensation arrangements.

Exceptions under 42 C.F.R. §411.355 that are applicable to both ownership interests and compensation arrangements relate to the following (although each is limited to narrow circumstances):

1. "Physicians' services";
2. "In-office ancillary services" (sometimes referred to as a group practice exemption);
3. "Services furnished by an organization (or its contractors or subcontractors)" (e.g., certain HMOs and prepayment plans);
4. "Academic medical centers" (faculty practice plan exception);
5. "Implants furnished by an ASC";
6. "EPO and other dialysis-related drugs";
7. "Preventive screening tests, immunizations, and vaccines";
8. "Eyeglasses and contact lenses following cataract surgery"; and
9. "Intra-family rural referrals."

Exceptions applicable only to ownership or investment interests under 42 C.F.R. §411.356 include the following (although each is limited to narrow circumstances):

1. Certain public companies and mutual funds; and
2. Certain rural providers and limited other specific providers.

Exceptions under 42 C.F.R. §411.357 that are applicable only to compensation arrangements relate to the following (although each is limited to narrow circumstances):

1. "Rental of office space";
2. "Rental of equipment";

3. "Bona fide employment relationships";
4. "Personal service arrangements";
5. "Physician recruitment";
6. "Isolated transactions";
7. "Certain arrangements with hospitals";
8. "Group practice arrangements with a hospital";
9. "Payments by a physician";
10. "Charitable donations by a physician";
11. "Nonmonetary compensation";
12. "Fair market value compensation";
13. "Medical staff incidental benefits";
14. "Risk-sharing arrangements";
15. "Compliance training";
16. "Indirect compensation arrangements";
17. "Referral services";
18. "Obstetrical malpractice insurance subsidies";
19. "Professional courtesy";
20. "Retention payments in underserved areas";
21. "Community-wide health information systems";
22. "Electronic prescribing items and services"; and
23. "Electronic health records items and services."

All of these exceptions have specific requirements and limitations that are not addressed above. The Anti-Kickback Law and Stark Law prohibitions may lead to government as well as *qui tam* enforcement.

[A] Stark Law: Possible Applicability to CCMAs

The Stark Law is not particularly accommodating to CCMAs involving hospitals and physicians. In fact, current Stark Law may prohibit many forms of CCMAs that do not cause any risks of harm of the types the Stark Law was adopted to address. Because the Stark Law is not dependent on harm or intent, this can be a real problem. For example, it has been noted:

> Under current law, Stark compliance would be particularly challenging with respect to compensation arrangements that involve the allocation among hospitals and physicians of shared savings, bonuses, or similar payments made to the hospital for the achievement of quality or cost containment goals. Although those challenges would be less acute when they involve the sharing of such payments between a hospital and its employed physicians, a compensation arrangement that includes or consists of the sharing of payments between a hospital and a physician group may not fit squarely within any of the current Stark exceptions, particularly (for example) if each physician participating in the arrangement shares in a portion of a bundled payment for each patient and DRG, regardless of whether the physician actually becomes involved in the care of that particular patient, or if all of the participating physicians share in a bonus or shared savings payment regardless of their personal involvement in achieving the performance goals on which the bonus or shared payment is based.
>
> *In sum, the current exceptions under the Stark law are insufficient to permit and encourage the kinds of new organizational structures and compensation arrangements that will be necessary to implement payment models like those that policy makes are proposing.* [128]

In June 2008, CMS proposed a Stark Law exception for certain incentive payments and certain shared savings programs. While the exception would have been relatively narrow and restrictive, it presumably indicated CMS

saw a benefit in this type of relationship. However, the fact that the proposed exception or another exception for these relationships has not been adopted may arguably add to the concerns regarding this type of relationship.

Also, while Stark Law waivers may be possible for the implementation of ACOs and sharing resulting savings under the Affordable Care Act, the protection such waivers offer may be limited and may not cover all relationships between a hospital and the physicians participating in a CCMA.

[B] Certain Concepts Important to an Analysis of the Applicability of the Stark Law

Before discussing the Stark Law exceptions that might be available for CCMAs, it is helpful to first consider the following concepts that will significantly impact the applicability of specific exceptions:

1. *Compensation Arrangement*. In analyzing most CCMAs, we will be looking for a Stark Law exception that will be applicable to "compensation arrangements" or, in some instances, possibly trying to structure a transaction that does not involve either a direct or indirect compensation arrangement. Before doing that, we need to understand direct and indirect "compensation arrangements." 42 C.F.R. §411.354(c) provides as follows:

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term "remuneration" at §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1) (i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(i) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(i) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(1) An *indirect compensation arrangement* exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family

member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv) (A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(A) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to "stand in the shoes" of his or her physician organization.

(1) (i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who "stands in the shoes" of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §411.355 and §411.357 of this part to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated "between the parties" are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

(i) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) as of September 5, 2007 (see 42 CFR parts 400-413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of §411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(i) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

An "indirect compensation agreement" contemplates that "[t]he referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section." Thus, it may be possible to structure a relationship with a management company and the physician that does not reflect referrals or other business or take into account the volume or value of referrals generated in a way that avoids the existence of an "indirect compensation arrangement" or any other form of "financial relationship" under 42 C.F.R. §411.354(a).

2. *Fair Market Value*. Just as "fair market value" is an important concept in connection with the Anti-Kickback Law requirements, it is also extremely important in the Stark Law analysis. In fact, a hospital or physician should not engage in a CCMA unless satisfied that it is at "fair market value." For purposes of Stark Law, *fair market value* is defined in 42 C.F.R. §411.351 as follows:

> *Fair market value* means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Participants in a CCMA should be strongly encouraged to not only be satisfied that the *fair market value* definition is satisfied but also to have an independent valuation prepared by a qualified appraiser.

3. *Set in Advance*. Several of the Stark Law exceptions that may be applicable to CCMAs have a "set in advance" requirement. 42 C.F.R. §411.354(d)(1) provides:

> (1) Compensation is considered "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (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. 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.

In the Anti-Kickback Law context, OIG Advisory Opinion No. 12-22, at page 12, states: "The Arrangement does not fit in the safe harbor because the aggregate payment to the Group is not set in advance." As a result, the personal services and management contract safe harbor under 42 C.F.R. §1001.952(d) was determined, in this Advisory Opinion, to be inapplicable. The standard for "set in advance" is not identical in the Anti-Kickback Law and Stark Law contexts. As noted above, assuming the other criteria are satisfied, the Stark Law permits compensation to be considered as being "set in advance" even if it is percentage based, based on units of time or service or based on similar formulas that are set in advance. [129] However, the Anti-Kickback Law safe harbor requires that the "aggregate compensation" be set in advance. [130] However, the compensation methodology considered in Advisory Opinion 12-22 would not leave many practitioners comfortable with the Stark Law risks to the extent the exception being relied on has the "set in advance" requirement. Of course, it may be possible to structure CCMAs that could satisfy the "set in advance" standards.

4. *Not Determined in a Manner that Takes into Account Volume or Value of Referrals or Other Business*. Satisfying a Stark Law exception may also require the participants to demonstrate compensation "is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties." 42 C.F.R. §411.354(d)(2) and (3) provides:

> (2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.
>
> (3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "other business generated between the parties," provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered "other business generated" by the referring physician).

[C] Analysis of Certain Stark Law Exceptions

Stark Law exceptions that may be helpful in connection with CCMAs could possibly include the following:

1. *Employment Exception*. The "bona fide employment relations" exception in 42 C.F.R. §411.357(c) provides:

> (c) *Bona fide employment relationships*. Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.
(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and
(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

2. *Indirect Compensation Arrangement Exception*. The "indirect compensation arrangements" exception in 42 C.F.R. §411.357(p) provides:

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at §411.354(c)(2), if all of the following conditions are satisfied:
(1) (i) The compensation received by the referring physician (or immediate family member) described in §411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—
(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated in the office space or to the services performed or business generated through the use of the equipment; or
(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in §411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.
(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

3. *Personal Services Exception*. The "personal service arrangements" exception in 42 C.F.R. §411.357(d) provides:

(d) *Personal service arrangements.* (1) *General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.
(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that

preserves the historical record of contracts. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).
(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).
(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.
(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at §411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.
(vii) A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.
(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.
(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at §422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §422.208 and §422.210 of this chapter.

However, in 2009, to limit the scope of the "indirect compensation" exception, CMS adopted the "stand in the shoes" concept. [131]

Fair Market Value Compensation Exception. The "fair market value compensation" exception in 42 C.F.R. §411.357(l) provides:

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or

services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement is set forth in an agreement that meets the following conditions:

> (1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.
> (2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.
> (3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on—
>
> > (i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or
> > (ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
>
> (4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.
> (5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.
> (6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.
>
> 4. *Risk-Sharing Exception*. The "risk-sharing arrangements" exception may not work for classic CCMAs, but there could be some instances where it might be considered. 42 C.F.R. §411.357(n) provides:
>
> > (n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO [managed care organization] or an IPA [independent practice association] and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings set forth in §1001.952(l) of this title.

However, this exception relates to compensation "for services provided to enrollees of a health plan" and may not be helpful for a CCMA of the type analyzed in Advisory Opinion 12-22, where the physician entity was being compensated for providing management and medical direction services for a hospital's cardiac catheterization laboratories rather than for services to the enrollees of a health plan.

Footnotes

128 Currier & Miller, "Medicare Payment Reform: Accelerating the Transformation of the U.S. Healthcare Delivery System and Need for New Strategic Provider Alliances," Vol. 22, Number 3, *Health Law*. 1 (Feb. 2010) (internal citation omitted) (emphasis added).

129 42 C.F.R. §411.354(d)(1).

130 42 C.F.R. §1001.952(d)(5).

131 *See also* §4.07[B] for the discussion above relating to compensation arrangements and 42 C.F.R. §411.354(c).

Health Law and Compliance Update - Steiner, §4.08, ANTITRUST ISSUES

John Steiner, Health Law and Compliance Update §4.08 (2018 Edition 2017)
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The potential applicability of antitrust laws needs to be considered because hospital and physician CCMAs are a form of collaboration. While there may be state or even foreign antitrust laws that might be implicated, we will limit our analysis in this chapter to Section 1 of the Sherman Act which declares as illegal "[e]very contract, combination…or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations…." [132]

In general, CCMAs that involve clinical or even financial integration resulting in improved care and added efficiencies will be more likely to be viewed in a positive light from an antitrust perspective. On the other hand, CCMAs that decrease competition and increase pricing will be viewed in a negative light, particularly if they do not result in improved care or added efficiencies.

In April 2000, the Federal Trade Commission (FTC) and the DOJ issued guidelines relating to their enforcement policies with respect to collaboration among competitors and potential competitors. [133] The Collaboration Guidelines include the following explanation:

> Two types of analysis are used by the Supreme Court to determine the lawfulness of an agreement among competitors: per se and rule of reason. Certain types of agreements are so likely to harm competition and to have no significant procompetitive benefit that they do not warrant the time and expense required for particularized inquiry into their effects. Once identified, such agreements are challenged as per se unlawful. All other agreements are evaluated under the rule of reason, which involves a factual inquiry into an agreement's overall competitive effect. As the Supreme Court has explained, rule of reason analysis entails a flexible inquiry and varies in focus and detail depending on the nature of the agreement and market circumstances.
>
> This overview briefly sets forth questions and factors that the Agencies assess in analyzing an agreement among competitors. The rest of the Guidelines should be consulted for the detailed definitions and discussion that underlie this analysis.
>
> ***Agreements Challenged as Per Se Illegal.*** Agreements of a type that always or almost always tends to raise price or to reduce output are per se illegal. The Agencies challenge such agreements, once identified, as per se illegal. Types of agreements that have been held per se illegal include agreements among competitors to fix prices or output, rig bids, or share or divide markets by allocating customers, suppliers, territories, or lines of commerce. The courts conclusively presume such agreements, once identified, to be illegal, without inquiring into their claimed business purposes,

anticompetitive harms, procompetitive benefits, or overall competitive effects. The Department of Justice prosecutes participants in hard-core cartel agreements criminally.

Agreements Analyzed under the Rule of Reason. Agreements not challenged as per se illegal are analyzed under the rule of reason to determine their overall competitive effect. *These include agreements of a type that otherwise might be considered per se illegal, provided they are reasonably related to, and reasonably necessary to achieve procompetitive benefits from, an efficiency-enhancing integration of economic activity*.

Rule of reason analysis focuses on the state of competition with, as compared to without, the relevant agreement. *The central question is whether the relevant agreement likely harms competition by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of the relevant agreement*.

Rule of reason analysis entails a flexible inquiry and varies in focus and detail depending on the nature of the agreement and market circumstances. The Agencies focus on only those factors, and undertake only that factual inquiry, necessary to make a sound determination of the overall competitive effect of the relevant agreement. Ordinarily, however, no one factor is dispositive in the analysis.

The Agencies' analysis begins with an examination of the nature of the relevant agreement. As part of this examination, the Agencies ask about the business purpose of the agreement and examine whether the agreement, if already in operation, has caused anticompetitive harm. In some cases, the nature of the agreement and the absence of market power together may demonstrate the absence of anticompetitive harm. In such cases, the Agencies do not challenge the agreement. Alternatively, where the likelihood of anticompetitive harm is evident from the nature of the agreement, or anticompetitive harm has resulted from an agreement already in operation, then, absent overriding benefits that could offset the anticompetitive harm, the Agencies challenge such agreements without a detailed market analysis.

If the initial examination of the nature of the agreement indicates possible competitive concerns, but the agreement is not one that would be challenged without a detailed market analysis, the Agencies analyze the agreement in greater depth. The Agencies typically define relevant markets and calculate market shares and concentration as an initial step in assessing whether the agreement may create or increase market power or facilitate its exercise. The Agencies examine the extent to which the participants and the collaboration have the ability and incentive to compete independently. The Agencies also evaluate other market circumstances, e.g. entry, that may foster or prevent anticompetitive harms.

If the examination of these factors indicates no potential for anticompetitive harm, the Agencies end the investigation without considering procompetitive benefits. If investigation indicates anticompetitive harm, the Agencies examine whether the relevant agreement is reasonably necessary to achieve procompetitive benefits that likely would offset anticompetitive harms.

The Collaboration Guidelines provide a useful beginning point for analysis of CCMAs. However, if the parties have a very large market share, additional considerations may be applicable, in addition to those summarized above. Also, as suggested above, there may be state or foreign antitrust laws that may need to be considered.

Among other matters, the Collaboration Guidelines also look to the competition that continues between the participant in activities apart from the joint activity, [134] duration of the competition, [135] less problematic alternatives, [136] etc. [137]

A recent advisory opinion issued by the staff of the FTC also may be instructive as to how the FTC staff looks at certain collaborations between a hospital and a group of physicians. [138] This advisory opinion involves

a request by the Norman Physician Hospital Organization (Norman PHO), an organization that anticipated contracting with providers on behalf of a number of participating physicians (initially 280) and the hospitals comprising the Norman Regional Health System. It had previously been using a "messenger model," [139] which may permit someone to carry a message to a participating provider as to the terms of a contract with a payor and carry back that participating provider's response. Norman PHO's request was to move to a more integrated model that would not only involve Norman PHO contracting with payors for the services of Norman PHO's physicians and hospital system but would also involve Norman PHO's physicians working "collaboratively to establish clinical practice guidelines, to create a high degree of transparency and visibility with respect to their practice patterns, and to provide mechanisms for monitoring and enforcing compliance with Norman PHO's clinical practice guidelines." [140]

Apparently, the service area of the Norman PHO overlaps with the Oklahoma City metropolitan area, including only about 10 percent of the hospitals and physicians in that area. However, in two particular counties the participating hospitals are responsible for about half of the patient discharges. In addition, the Norman PHO includes the only hospital system and the majority of the physicians in the Norman, Oklahoma area. [141]

Importantly, though, Norman PHO expects to contract with payors on a nonexclusive basis (its participants may contract with payors independently) and believes that its integrated activities will, in fact, benefit patients, payors, and the participating providers. [142] The participating physicians are required to provide financial support, maintain certain equipment and software, satisfy credentialing and staff appointment requirements, invest time and effort and satisfy other requirements of a "Participating Practitioner Agreement." [143]

The FTC staff also understood the participants in the Norman PHO would not seek to influence the contracting of other participants or "confront any payor with the group's aggregate bargaining power." [144] In fact, the opinion notes: "The network also will provide antitrust counseling and training to its participating providers and will specifically address the antitrust concerns associated with concerted refusals to deal." [145] The FTC staff also understood the Norman PHO would "take steps to ensure that competitively sensitive information (e.g., prices, pricing, or negotiating strategies or intentions) is not improperly shared between or among participants." [146] The opinion also reflects the FTC staff's view that Norman PHO and its providers "are responsible for developing and implementing appropriate and effective mechanisms (e.g., confidentiality agreements, internal firewalls, antitrust training of staff and board members) and preventing…[improper] "spillover effects" and failure to do so could result in serious antitrust violations."

The FTC staff concluded that, based on its understanding, the "Norman PHO's proposed activities appear unlikely to unreasonably restrain trade." [147] The opinion summarizes the applicable antitrust law as follows:

> The antitrust laws condemn as per se illegal "naked" agreements among competitors that fix prices or allocate markets. Where competing providers achieve clinical or financial integration in a manner that is likely to produce significant efficiencies that benefit consumers, and any pricing or other agreements among those providers that would otherwise be per se illegal are reasonably necessary to realize the efficiencies, those agreements will be analyzed under the rule of reason. A rule-of-reason analysis determines whether the formation and operation of the joint venture may have a substantial anticompetitive effect and, if so, whether that potential effect is outweighed by any procompetitive efficiencies resulting from the venture. [148]

The opinion then notes:

> With respect to Norman PHO's provision of physician services, staff determined that the network's proposed joint pricing and contracting activities qualify for rule-of- reason analysis because the

network reportedly will require its participating physicians to integrate their clinical services in a manner that appears to create the potential for significant efficiencies that benefit patients and payors *and* because the participating physicians' pricing agreements are reasonably necessary and subordinate to—that is, ancillary to—their integrative activities. Staff then determined that the venture's formation and operation do not appear likely to have a substantial anticompetitive effect in the provision of physician services, and any such potential effect is likely to be outweighed by plausible procompetitive efficiencies. Next, staff determined that Norman PHO's proposed new operations do not involve "vertical" arrangements that restrict providers in one market from dealing with non-network providers that compete in a different market. For example, Norman PHO represents that it will not limit the incentive or ability of its participating providers to participate in other network joint ventures or to contract directly with payors that do not wish to do business with Norman PHO (or vice versa).

Finally, staff determined that Norman PHO understands the antitrust risks associated with multiprovider networks, including "spillover effects," and has represented that it will take affirmative steps to ensure that both the network and its individual participating providers refrain from engaging in such anticompetitive conduct. [149]

The opinion indicates that concerns regarding the market power in Norman, Oklahoma and the fact that higher reimbursement may be required for physician services as a result of the increased physician involvement/ workload "are mitigated, however, by Norman PHO's representations that potential customers who do not perceive that Norman PHO offers an attractive product, or who for any other reason do not wish to contract with Norman PHO, will have the ability to bypass the network and contract directly with the individual providers." [150]

Footnotes

132 15 U.S.C. §1.

133 Antitrust Guidelines for Collaborations Among Competitors: Issued by the Federal Trade Commission and the U.S. Department of Justice (Apr. 2000), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf (hereinafter the Collaboration Guidelines) (internal citations omitted) (emphasis added).

134 Collaboration Guidelines, 18-19.

135 Collaboration Guidelines, 21.

136 Collaboration Guidelines, 24.

137 Additional guidance in the health care arena can be found in the August 1996, Statements of Antitrust Enforcement Policy in Health Care: Issued by the U.S. Department of Justice and the Federal Trade Commission, *available at* http://www.justice.gov/atr/public/guidelines/0000.pdf.

138 *See* FTC Advisory Op. (Feb. 13, 2013), *available at* http://www.ftc.gov/os/2013/02/130213normanphoadvltr.pdf.

139 FTC Advisory Op., 4.

140 FTC Advisory Op., 5.

141 FTC Advisory Op., 4.

142 FTC Advisory Op., 11.

143 FTC Advisory Op., 8-9.

144 FTC Advisory Op., 1.

145 FTC Advisory Op., 10-11.

146 FTC Advisory Op., 12.

147 FTC Advisory Op., 2.

148 FTC Advisory Op., 12-13 (internal citation omitted).

149 FTC Advisory Op., 14 (internal citations omitted).

150 FTC Advisory Op., 18-19.

Health Law and Compliance Update - Steiner, §4.09, TAX-EXEMPT PARTICIPANTS

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Each potential CCMA must be analyzed under the particular facts and circumstances of the contemplated transaction. The potential restrictions discussed in the preceding sections have potential applicability to CCMAs generally. However, there are other restrictions that must be considered in particular factual situations. If one or more of the participants in the CCMA is a tax-exempt entity, additional restrictions may apply. This section provides a brief review of such rules.

The hospital participant is the most likely tax-exempt participant in a CCMA. Hospitals may obtain exemption from taxation under Section 501(c)(3) of the Internal Revenue Code (Code). [151] A Code Section 501(c)(3) entity obtains exemption by filing an application for a determination of exempt status. At the time of application, the entity must demonstrate that it meets the criteria for qualification or revise its activity to meet such requirements. Moreover, the entity must continue to operate in a manner that satisfies the requirements of Code Section 501(c)(3) or either risk loss of tax-exempt status or intermediate sanctions consisting of financial penalties. [152]

In order to obtain tax-exempt status, a nongovernmental hospital must satisfy the requirements of Code Section 501(c)(3) and operate in compliance with the requirements set forth in applicable guidelines. [153] These guidelines generally require the hospital to have community-based governance, an open emergency department, and a demonstrable commitment to provision of a significant level of charity care. [154] The hospital must also satisfy general restrictions regarding prohibitions on private inurement, private benefit, and excess benefits. [155] In addition, restrictions can be based upon utilization of tax-exempt financing. [156] All of the foregoing could be implicated in the context of a CCMA.

Improper compensation arrangements are a potential compliance problem for Code Section 501(c)(3) tax-exempt entities. Compensation arrangements potentially implicate the restrictions on private inurement and private benefit. [157] In addition, depending upon the recipient of the compensation, it is possible that an excess benefit transaction could occur. [158] The private inurement prohibition is set forth in the statute. Private inurement occurs if the Code Section 501(c)(3) tax-exempt entity improperly shares its net revenue with a non tax-exempt party. There is an absolute prohibition on private inurement. Violation of this prohibition can cause the loss of tax-exempt status or monetary penalties. Alleged violations most frequently arise in the context of joint ventures or similar transactions under which the Code Section 501(c)(3) tax-exempt entity and another party receive distributions based upon the performance of the venture. Such an arrangement could be construed to constitute a sharing of the net revenue of the Code Section 501(c)(3) tax-exempt entity with a taxable party, thus, implicating potential prohibited inurement. In the context of a CCMA, such a violation is most likely to arise in the context of the incentive part of compensation that is savings based. Arrangements that tie the bonus to a percentage of savings and vary (increase) the bonus as savings increase could be suspect. In the ACO context, the IRS issued Notice 2011-20 and Fact Sheet 2011-11. [159] The guidance contained therein may support the position that shared savings programs of an ACO having a tax-exempt participant are consistent with such an

entity's tax-exempt purpose and do not constitute unrelated business income. Thus, cost savings arrangements may, in appropriate circumstances, arguably have tacit approval in the ACO context. However, it may present less risk if the bonus component for cost savings or other financial performance is a predetermined amount tied to specific targets rather than based upon a percentage.

The private benefit proscription is a doctrine related to private inurement, but potentially much broader in application. [160] It also may be implicated in compensation arrangements. Unlike private inurement, there is not an absolute prohibition on private benefit. [161] Indeed, some private benefit occurs whenever a Code Section 501(c)(3) tax-exempt entity pays a salary to an employee or compensation to a service contractor. The law recognizes that a limited amount of private benefit must occur as a part of operating the tax-exempt entity to compensate the persons who perform services for it. However, there is a limitation upon private benefit. This limit is measured against standards of reasonable compensation and necessity of the services generating the payment. [162] In order to assure that prohibited private benefit does not occur, the Code Section 501(c)(3) tax-exempt entity must be able to demonstrate that the compensation it pays under the CCMA is reasonable under the facts and circumstances of the arrangement. For the most part, this requirement should be satisfied through the fair market value analysis that is necessary to establish compliance with the health law restrictions such as Anti-Kickback Act and Stark Act. [163] However, the issues are not identical and the practitioner should not forget that there is a potential tax law consequence when a Code Section 501(c)(3) tax-exempt entity is involved in a CCMA transaction.

Finally, compensation issues can arise based upon the identity of the payee in a transaction involving a Code Section 501(c)(3) tax-exempt entity. This is so because the law pertaining to Code Section 501(c)(3) tax-exempt entities includes the concept of excess benefit transactions. [164] This concept is designed to assure that inappropriate private benefit transactions do not occur as a result of the relationship of certain persons to the tax-exempt entity. If this occurs, substantial penalties can be imposed upon the parties to the transaction and the transaction may need to be undone in order to avoid even more significant penalties. [165] An excess benefit transaction is a transaction between a Code Section 501(c)(3) tax-exempt entity and a person that meets the standard of being a disqualified person in relation to the entity. Disqualified persons are individuals or organizations that have too close a relationship with the Code Section 501(c)(3) tax-exempt entity for one to conclude automatically that a transaction is appropriate and not a result of the relationship. Examples of disqualified persons include substantial donors to the Code Section 501(c)(3) tax-exempt entity and key management of the entity. [166] In the CCMA context, an example of a possible excess benefit transaction would be the situation under which one of the physicians who would participate in the CCMA and its bonus distribution, is also a member of the board of directors of the tax-exempt entity. In order to avoid the potential of having an excess benefit transaction, and generally in order to assure compliance with tax laws for compensation arrangements, the Code Section 501(c)(3) tax-exempt entity in an CCMA transaction should follow the steps to create a rebuttal presumption of reasonable compensation set forth under the intermediate sanctions regulations. [167] These regulations detail a process for board of director approval, including a review of comparability data, a process for determination that the compensation is reasonable, and documentation of the board action.

Compliance issues also can arise when a tax-exempt entity is party to a CCMA, if the hospital, presumably the tax-exempt entity, has existing tax-exempt financing on the portion of the hospital facility that is being managed under the CCMA. The tax laws contain rules to assure that projects constructed with tax-exempt financing do not benefit, to an inappropriate amount, taxable persons or entities. These rules are designed to prevent the possibility that a project financed by tax-exempt financing ultimately is used to a significant extent for the purposes of non tax-exempt entities. The rules recognize that a project will have some level of involvement by non tax-exempt parties. For example, the hospital constructed or renovated with tax-exempt financing must allow members of its medical staff to practice in the hospital. However, arrangements that benefit the non tax-exempt community too much are not allowed. Thus, the laws have limitations on activities such as leasing space

to for-profit entities and management contracts. While both of these limitations could be implicated in the CCMA context, the limitation on management contracts may be the most likely prohibition to be encountered. [168]

The management contract limitation is designed to prohibit a tax-exempt entity from constructing a project with tax-exempt financing and then contracting out the significant management of the project to a for-profit entity. If this were to occur, the regulators have concluded that the benefit bestowed by the more favorable rate of tax-exempt financing may be improperly diverted to the for-profit sector. Having some management functions performed by for-profit entities is acceptable. Indeed, in some instances, the expertise of a for-profit entity is needed to meet the needs of patients. However, the restrictions are designed to prevent the possibility that the tax-exempt entity uses its status to obtain favorable financing and then turns over major operations to a for-profit entity. A CCMA potentially implicates these issues because, under most CCMAs, management of the program or service line are contracted to the various physicians practicing in the service line who are not tax exempt and who may not be employed by tax-exempt entities. The IRS promulgated Revenue Procedure 97-13 [169] to describe the limitations of management contracts. This Revenue Procedure recognizes the potential need for a management contract, but imposes limitations on duration and incentive payments, as well as certain other requirements. If a tax-exempt entity will be managed as part of the CCMA and that tax-exempt entity has existing tax-exempt financing, the requirements of Revenue Procedure 97-13 need to be satisfied.

Footnotes

151 26 U.S.C. §501(c)(3). The application process is described in IRS Publication 4220, *Applying for 501(c)(3) Status* (Jan. 31, 2013). The application is made by filing Treasury Form 1023 to request a favorable determination letter on tax-exempt status.

152 Penalties can include taxation of revenue, revocation of tax-exempt status, or intermediate financial sanctions.

153 The organizational test is described in Treas. Reg. §1.501(c)(3)-1(b). This is satisfied by having certain provisions in the organizational documents of the entity (e.g., Articles of Incorporation and By-laws). The operational test is set forth in Treas. Reg. §1.501(c)(3)-1(a)(1). It is satisfied by having the organization operate exclusively for its tax-exempt purpose. Exclusive is interpreted under the regulations to mean primarily, *see*, Treas. Reg. §1.501(c)(3)-1(c).

154 Rev. Rul. 98-15, 1998-121 I.R.B.; Rev. Rul. 69-545, 1969-2 C.B. 117; Rev. Rul. 56-185, 1956-1 C.B. 202.

155 Restrictions include prohibitions or limitations on private inurement, private benefit, political activity, lobbying, and disposition of assets upon dissolution. *See generally*, Treas. Reg. §1.501(c)(3).

156 *See* Rev. Proc. 97-13, 1997-1 C.B. 632 (Feb. 3, 1997).

157 The private inurement restriction is set out in Code Section 501(c)(3), and states *inter alia*, that "no part of (the organizations) net earnings inure to the benefit of a private individual or shareholder." *See also* Treas. Reg. §1.501(c)(3)-1(c)(2). The private benefit prohibition is a doctrine that has been judicially developed and essentially requires that private benefit may not occur more than an insubstantial extent, *see* American Campaign Acad. v. Comm'r, 92 T.C. 1053 (1989). *See also* Treas. Reg. §1.501(c)(3)-1(d)(1)(ii).

158 26 U.S.C. §4958.

159 FS 2011-11 (Oct. 20, 2011); *see also* Notice 2011-20, 2011-11 I.R.B. 652 (Apr. 18, 2011).

160 The concept can apply to insiders and other private persons, as well. In the *American Campaign Academy* case, 92 T.C. 1053, an educational institution was found to have violated the proscription because of the focus of its training programs (Republican candidates).

161 *See* Braun & Kaiser, C., *Exempt Organizations Continuing Professional Education (CPE) Technical Issues Program for Fiscal Year 2000*, "Physician Incentive Compensation," *available at* http://www.irs.gov/pub/irs-tege/eotopicc00.pdf.

162 *See* Rev. Rul. 2004-51, 2004-22 I.R.B. 974 (June 1, 2004); Rev. Rul. 75-286, 1975-2 C.B. 210; Rev. Rul. 68-14, 1968-1 C.B. 243.

163 42 C.F.R. §1001.952(b)(5) (Anti-Kickback Law); 42 C.F.R. §357(d) (Stark Law).

164 26 U.S.C. §4958.

165 The initial penalty is a 25 percent excise tax on the amount of the excess benefit transaction. This amount will grow to 200 percent if the transaction is not undone. *See* 26 U.S.C. §4958(a)(1), (b). A tax is also imposed upon the management officials of the entity that permitted the excess benefit transaction; 26 U.S.C. §4958(a)(2).

166 *See* Treas. Reg. §53.4958-3(a)(1), (b)(1) and (b)(2). "Disqualified Persons" include persons who can influence, have financial control, or are 35 percent owners of an entity that can influence or exercises financial control over the exempt organization.

167 Treas. Reg. §53-4958-6.

168 *See* Rev. Proc. 97-13, 1997-1 C.B. 632 (Feb. 3, 1997).

169 Rev. Proc. 97-13, 1997-1 C.B. 632.

Health Law and Compliance Update - Steiner, §4.10, PUBLIC ENTITIES AND OTHER ISSUES

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Compliance issues also can arise if one or more of the parties to a CCMA is a public entity. This is so because there are laws specific to public entities that must be satisfied under the CCMA in such circumstances. The practitioner must remember that the requirement that a transaction otherwise be legal is included both in the Anti-Kickback Law personal service safe harbor and the analogous Stark Law exception. [170] Therefore, when a public entity is involved, it is necessary to review other potential legal constraints and make certain that those can be avoided or satisfied. These issues are similar to those presented by tax-exempt entities, but sufficiently distinct to warrant separate mention here. While the number and nature of potential constraints will vary significantly from one jurisdiction to another and generally are beyond the scope of this chapter, a brief review of such issues may assist the practitioner in issue identification.

If the public entity has tax-exempt financing on the portion of its facility that will be managed under the CCMA, a similar analysis should be performed as in the case of an Code Section 501(c)(3) tax-exempt entity. This is so because similar restrictions apply to public entities that enter into management contracts with for-profit entities. [171] Similarly, public entities have restrictions upon contracting imposed under the applicable public purchasing contracts. These vary significantly from state to state. Some purchasing laws exempt professional service contracts while others subject such contracts to competitive bidding requirements. [172] The specific rules and exceptions of the applicable purchasing laws need to be consulted. Finally, each public entity will have an applicable set of ethical rules that have been imposed by statute or regulation. Such rules may prohibit or impose limitations upon contracting with key persons such as board members. [173] If one of the physician participants in the CCMA also is a board member or key employee of the public entity, it could impact the legality of the transaction.

Finally, if there are potential special status issues implicated by the proposed CCMA, additional issues may be presented. For example, if some of the overall responsibilities of the participating physicians under the CCMA involve operation or management of a provider based patient clinic, a federally qualified health center or a special government program, an additional set of rules may have to be considered and satisfied. Failure to comply could jeopardize the overall transaction. [174]

Footnotes

170 *See* 42 C.F.R. §1001.952(d)(1) (Anti-Kickback Law) and 42 C.F.R. §411.357(d)(iv).

171 Rev. Proc. 97-13, 1997-1 C.B. 632 (Feb. 3, 1997); *see also* 26 U.S.C. §141(b).

172 *Compare* Cal. Public Contract Ch. §10.335-10.381 (10.340) and Ky. Rev. Stat. §45A.050, *et. seq.* (KRS 45A.030 (24)), both of which require competitive bidding of professional service contracts, *with* N.J. Stat. Ann. §40A: 11-1, *et. seq.* (NJSA 40A: 11-5(1)(a)(8)) and Tenn. Ch. Ann. §12-4-106(a)(10), which provide exceptions to bidding requirements for professional service contracts.

173 A review of the various ethics laws is beyond the scope of this chapter. However, most governmental entities, whether state or local, are now subject to some form of ethics requirements. Most prohibit or limit contracts between the entity and officials, board members, key employees, and similarly situated persons in most situations. For a starting point for a review of ethics laws, *see* the National Conference of State Legislatures Web site, http://www.ncsl.org.

174 *See*, *e.g.*, 42 C.F.R. §413.65 (rules for provider based clinics); 42 C.F.R. §413.65(h) requires clinical staff that do not bill directly to be employed by the main provider (hospital).

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It is now appropriate after having reviewed potential legal issues and impediments in significant detail to take time and examine some general compliance considerations raised by a CCMA. This review includes the possible need for obtaining an OIG advisory opinion, review of existing contractual arrangements, value and cost of independent expert reviews, structure of a CCMA management company, duration of and resetting a CCMA and the possible need for better regulatory guidance. Each will be discussed in turn.

[A] Advisory Opinions

One of the initial questions that must be considered by legal and compliance personnel considering a CCMA is whether or not to request a specific OIG advisory opinion for a proposed CCMA. Obtaining an advisory opinion should always be considered, if practicable. However, even obtaining an OIG advisory opinion does not provide complete protection. This is so because the advisory opinion is always limited to the assumption that the factual certifications provided are accurate and that there has been a full disclosure of all relevant facts, as well as other restrictions. [175] Thus, even obtaining an advisory opinion does not afford complete protection because an advisory opinion could be attacked by the government based upon either claims of factual inaccuracy or material omissions. It also takes time to obtain an advisory opinion. While it would be preferable to obtain one in most cases, often the exigencies involved in attempting to improve management through the CCMA will make obtaining one impracticable or unreasonably delay the implementation of a needed program.

The decision to obtain or not to obtain an OIG advisory opinion is essentially a risk/benefit analysis. Factors to consider in determining whether to obtain one include the timeline needed for implementation of the CCMA program, criticality of the CCMA to the overall operations of the hospital at which it will be based, and how close the proposed CCMA can be made to resemble the fact pattern of a previously approved CCMA and how close the other circumstances are to those the OIG previously considered. Critical to this analysis is an understanding of exactly what has been approved already (even though direct reliance may not be possible). To date Advisory Opinion 12-22 is the only advisory opinion approving a cost savings based incentive. If the

proposed arrangement involves quality measures only, then there are a significant number of arrangements that have been approved. However, if there is a financial component, trying to make the proposal very similar to the fact pattern in Advisory Opinion 12-22 may be important. Of course, even if the facts are identical, only the recipient of an advisory opinion gets any direct protection and that is clear on the face of the opinion. But what actually did Advisory Opinion 12-22 approve?

Viewed in its most restrictive light, Advisory Opinion 12-22 advised the hospital provider that the OIG did not intend to seek sanctions against it under either the CMP Act or the Anti-Kickback Act under the particular arrangement described in the request (subject to various assumptions and limitations). [176] It offered no opinion regarding Stark Law compliance because that was outside the scope of the OIG's authority. [177] Moreover, under the facts presented, it was highly unlikely that there could be a significant shift in referral patterns since the hospital operated the only cardiology program within a 50-mile radius and the involved physicians practiced nowhere else. Thus, perhaps the only potential evils that might be encouraged by the CCMA involved changes in treatment and utilization. However, the overall CCMA contained numerous safeguards to make the occurrence of such problems unlikely. [178] Accordingly, the Advisory Opinion was issued based upon the facts as certified. This is a set of facts that may be difficult to replicate, so a higher level of caution is in order.

In determining whether or not to obtain an advisory opinion, one should consider, among other factors, the likelihood that there could be a shift in referral patterns caused by the proposed CCMA. If the service area contains more than one hospital offering a similar service line or program, it may be particularly important to obtain an OIG advisory opinion, at least until there is more detailed guidance available. Similarly, if the proposed CCMA will depart significantly from either the financial model or safeguards articulated in Advisory Opinion 12-22, an advisory opinion may be particularly important to consider.

[B] Review of Existing Relationships

One of the keys to a successful CCMA is being able to demonstrate that the services performed by the physicians participating in the CCMA are actually performed, necessary, and not duplicative of other services already being performed by physicians or hospital staff. If any of those three components cannot be demonstrated, the CCMA may be open to attack as being a sham arrangement to funnel more compensation to referral sources. Certainly, requiring documentation of the services is prudent and should be considered as a part of the overall CCMA. Moreover, the analysis that develops the goals for the CCMA and performance standards should also serve as the basis for establishing that the services are necessary. Demonstrating that the services are not duplicative may be more difficult, however.

It will be an unusual situation in which the CCMA is proposed for a service line that has no existing medical direction. This medical direction may take the form of an existing medical director contract or a part of the job description of an employed physician. Moreover, some aspects of the basic management of the service line, which most likely are performed by employed management staff of the hospital, may also become responsibilities of the physicians participating in the CCMA. In order to prevent or minimize claims of duplication of services, a detailed review should be conducted of all existing contracts for medical direction and similar services and the job descriptions of anyone performing management functions for the service line to determine if duplication may occur. The physician duties under the CCMA should be harmonized with these contracts and job descriptions. In some instances this may require modification to existing job descriptions and termination or modification of existing contracts. The job description modification has potential for raising employment issues. However, the contract termination or modification might also create potential compliance issues.

In order to be compliant, medical direction and similar contracts with independent physicians usually should meet the requirements of the personal service and management contract exception under Stark Law [179] and it may also be important to satisfy the analogous safe harbor under the Anti-Kickback Law. [180] This exception and the safe harbor both have requirements that the agreement be for at least a duration of one year.

[C] Evaluations, Independent and Otherwise

Another key to establishment and maintenance of a compliant CCMA is the use of the evaluative process throughout the formation and operation of the arrangement. Advisory Opinion 12-22 relied heavily upon the fact that the compensation to be paid, performance requirements and standards, and bonus structure were developed by or with the assistance of independent consultants. [181] The use of these consultants for ongoing reviews for purposes of verification and validation of services and target achievement also was considered as a significantly positive factor. Moreover continued internal monitoring of the operations of the CCMA by hospital management and its governing body also was viewed quite favorably by the OIG. In developing a CCMA, similar outside review and internal controls should be developed and implemented.

The hospital proposing the CCMA must recognize early in the development of the CCMA that the evaluations and the monitoring programs cannot be conducted without cost. It would not be prudent to establish a CCMA without outside review of compensation and performance measures. Failure to have such outside evaluations leaves the arrangement far too vulnerable to attack by regulators. However, such initial and continuing review will involve engagement of one or more consultants and initial cost as well as continuing cost during the term of the CCMA. In addition, hospital management and governance must devote time and effort to monitor the operations of the CCMA if it is to operate in a compliant manner. These costs in time and consulting expenses may very well be worth the cost in terms of improved service line performance. However, the hospital proposing a CCMA should conduct a thorough cost benefit analysis prior to implementation. In addition, the ongoing review will yield performance data that may not be complimentary to the hospital or service line. Hospital management should be prepared to deal with the possibility that it receives data that demonstrates that the CCMA is not working or not working very well.

[D] Duration and Resetting

Advisory Opinion 12-22 reviewed a proposed CCMA of three years. [182] It remains an open issue if a longer or shorter period of time also could be justified. A shorter period of time may not justify the transactional costs; while a shorter or longer period of time may call the validity of the performance goals in to question. The key to a successful CCMA is development of performance targets that are evaluated within a limited time frame. In order for these performance goals to have significance and for any bonus to be appropriate, the CCMA should be of limited duration so that precise achievement of goals can be measured as of a specific point in time and bonuses that are earned paid out to the recipient. As goals are met or missed, reevaluation and readjustment may be needed. Moreover, medical staff composition changes over time as physicians depart practice in that area and new physicians take their places. However, compliance issues may be raised if new physicians are included in the CCMA or if exiting physicians are cashed out early.

The foregoing leads to the possibility of CCMAs having a limited duration and periodic restructuring to include new physicians or removing departing physicians and reestablishing performance goals. However, to date, no second generation CCMA has received a favorable advisory opinion. This resetting necessary for the second generation of a CCMA raises a number of issues for consideration. First, what if the original performance goals were not achieved? Is it appropriate to include portions of those goals in a subsequent CCMA? Arguably it would be, however, the failure to meet prior goals may call the validity of the arrangement into question. A more complex issue is presented if the original goals are achieved. Must new goals be established? If so, is there room for improvement and is continued improvement worth the cost? For example, if the original CCMA improved performance of a service line to the 95th percentile, is it worth paying for potential continued improvement? Similarly, could a CCMA be predicated upon maintaining the status quo? If physicians have demonstrated that a performance target can be met, does continuing payments to sustain performance meet compliance requirements? The need for improvement may have been one of the factors that the OIG considered in issuing its advisory opinions. Once a target has been achieved, will the need justifying approval remain?

Finally the continuing cost for reevaluation and resetting must be considered. The second generation CCMA may require a second level of consulting review as well as the incurring of new transactional costs. The new CCMA must be evaluated in light of the needs at that time and compensation and performance goals reset preferably by or with the assistance of outside consultants. Will these costs which may be incurred periodically justify continuing the relationship in a second term? There also may be compliance issues attendant to such reevaluation and resetting.

[E] Management Company

In the CCMA model that involves utilizing multiple physicians with unrelated practices, the management company may be important for compliance. This management company, usually proposed as a limited liability company, is the entity that actually enters into the CCMA with the hospital. The management company receives the payments from the hospital and makes distributions of both the base fee and any bonus payments to the participating physicians. Proper operation of the management company helps assure compliance in several ways. First, the management company allows the hospital to contract with one party as opposed to having arrangements with multiple members of its medical staff. In this manner, the management company simplifies the CCMA transaction and its administration.

The management company also is the vehicle that assures that participation in the CCMA is open to all physicians practicing in the service line. In order to demonstrate that the CCMA is not a device for the hospital to funnel payments to its better referral sources, participation in the CCMA might be available to all physicians practicing in the service line. However, it may be impractical for the hospital to enter into service contracts with multiple physicians or physician groups. Affording each physician the opportunity to have a membership interest in the management company may be far more manageable operationally. Note that all physicians might not choose to actually participate, and that will not necessarily be a problem.

Interests that are offered should typically be on equal terms to all physicians and give all participating physicians an equal interest in the company. Making interests available on equal terms may help demonstrate that the CCMA was not an attempt by the hospital to reward key referral sources. Having equal interests helps assure that distributions from the management company are made on a pro-rata basis to the members of the management company. [183] This may help because one of the potential compliance concerns is that payments made to participating physicians vary based upon the number of referrals made by said physician. Doing so implicates both the Anti-Kickback Act and Stark Act. However, making distributions on a pro-rata basis to participating physicians may help avoid this concern. The internal documents of the management company, such as the operating agreement, also need to be considered in connection with distributions. Care also needs to be exercised if any function of the management company is going to be performed by a subcontract with one or more of the members, so that the resulting subcontract contains no provisions that are construed as varying with referrals or that otherwise unexpectedly raise compliance issues. It would be best to structure such an arrangement, if one is needed, to meet the Stark Law personal service contract exception.

The interests in the management company need to be exchanged in a compliant transaction as well. This is so because provision of something at less than fair market value to a referral source also has compliance implications. The cost for an interest should reflect fair market value for the interest at the time that it is issued. The cost of the interests in the management company should take into account the transaction costs for establishing and maintaining the management company, such as accounting and legal fees.

Finally, once the management company has been established, it is often advisable to close membership for the duration of the CCMA. This may help protect against claims that the permitted addition or withdrawal allowed the volume or value of referrals to impact the amount paid to participating physicians. If there is a membership change during the term of the CCMA, interests, as a percentage of ownership, would be either diluted or enhanced. The resulting adjustment in interest would vary compensation, perhaps in an impermissible manner. Closing the opportunity for membership precludes this. Of course, the death, disability, or relocation of members may need to be taken into account.

[F] Need for Better Regulatory Guidance

Before we end our review of compliance considerations, it is appropriate to consider briefly the need for better regulatory guidance in this area. CCMAs potentially provide an opportunity for hospitals and their medical staffs to collaborate in a legally permissible manner to improve the quality and efficiency of patient care delivery while reducing the cost of such care. However, there are numerous regulatory impediments that may limit the ability of providers to implement CCMAs and may also create potential risks from such implementation. While, it might be possible to obtain an advisory opinion prior to implementing such a transaction, time constraints and transactional costs may make obtaining such opinions impractical, and, in any event, may delay the implementation of programs that could provide significant benefits to patients. In the context of ACOs, the federal government has recognized the value of collaboration and acted to create a framework to do so in spite of otherwise existing health care law proscriptions. However, not every provider can establish a completely integrated system in the nature of an ACO. There also needs to be a framework to establish limited collaborative relationships. There have been prior proposals to do so that have not been implemented for a variety of reasons. As CCMAs become more commonplace, the federal regulators should promulgate guidance that would allow for efficient implementation of CCMAs while protecting the integrity of the health care delivery system. New exceptions or safe harbors under the Stark Law, the CMP Act, and the Anti-Kickback Law would have great value in that regard. One can only speculate upon the terms of such exceptions or safe harbors. However, durational limits, fair market value requirements, patient care safeguards, and objective compensation requirements are all likely requirements. Until and unless the regulators so act, we must continue to exist with a potentially unacceptable degree of uncertainty.

Footnotes

175 *Note*, Advisory Opinion limitations set forth at 42 C.F.R. Part 1008 ; *see also* limitations listed in OIG Advisory Op. 12-22, 15 (Dec. 31, 2012).

176 OIG Advisory Op. 12-22, 14-15 (Dec. 31, 2012).

177 OIG Advisory Op. 12-22, 9.

178 OIG Advisory Op. 12-22, 10-12.

179 42 C.F.R. §411.357(d).

180 42 C.F.R. §1001.952(b).

181 OIG Advisory Op. 12-22, 7 (Dec. 31, 2012).

182 OIG Advisory Op. 12-22, 2, 14.

183 *See* OIG Advisory Op. 12-22, 13.

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CCMAs may present an opportunity for hospitals and their medical staffs to collaborate legally in limited circumstances to achieve quality, safety, and efficiency goals. As such, the CCMA framework can fill a current void in the health care system. While the Affordable Care Act has encouraged collaboration between physicians and hospitals on an unprecedented level, the types of collaborations approved are quite substantial in nature and really are completely integrated systems. Also, gainsharing programs and related concepts have continued to achieve greater acceptance. This concept arguably obtained a significant endorsement when the OIG issued

Advisory Opinion 12-22. This Advisory Opinion, for the first time, "approved" (in a limited way) a CCMA program with an incentive plan that included a significant financial improvement component.

However, the current regulatory environment presents many potential risks and particularly the CMP Act, the Anti-Kickback Act, and the Stark Act all can be major impediments to CCMA implementation, The False Claims Act, antitrust laws, tax-exemption requirements, and a variety of transaction specific legal issues also present potential problems. We are hopeful that these problems can be managed, if the hospital and participating physicians are willing to spend the time and effort to design the CCMA to minimize the problem areas and comply with the applicable law. However, the current transactional costs may cause many hospitals to conclude that a CCMA presents unacceptable costs or risks. This is so because there currently is no real protection for the CCMA transaction without obtaining an OIG advisory opinion and, even then, numerous limitations will apply. The type of collaboration envisioned by CCMAs may both present real potential for program abuse and afford real opportunities to improve the quality, efficiency, and cost of health care delivery. Of course, these need to be balanced, but, without better guidance, CCMAs may be under-utilized because of the inherent uncertainty that may be present. The regulators should promulgate clear regulatory guidance in the area of limited collaboration, resulting in a reasoned balancing of the concerns and benefits so that hospitals and physicians will be encouraged to utilize, when appropriate, the CCMA concept with fewer compliance risks.