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—from a declaration of the American Bar Association

You Can't Have One Without the Other; Removing Regulatory Roadblocks on the Path to Healthcare Reform

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Introduction

Earlier this year, Congress passed sweeping healthcare reform legislation in the form of the Patient Protection and Affordable Care Act (PPACA),[1] which was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act),[2] which was enacted on March 30, 2010, and revises the PPACA (collectively, Healthcare Reform Legislation). Healthcare Reform Legislation contemplates broad changes to healthcare delivery and payment in this country. However, to implement fully and encourage the types of alliances and affiliations that will foster these reforms, current regulatory roadblocks will have to be removed. This article discusses some of the major roadblocks to reform presented by the Stark, Anti-Kickback, Civil Monetary Penalty (CMP), antitrust, and state laws, and proposes ways to clear the path for the next-generation healthcare delivery system.

Key Themes of the Healthcare Reform Legislation

Healthcare Reform Legislation contains several key themes. Primary among these is the concept that the American healthcare system is fundamentally flawed in the way providers are, for the most part, paid on a fee-for-service basis, which rewards those providers that order more or more expensive services without regard to whether the services are the most efficient or appropriate for the particular patient. To address this concern, Healthcare Reform Legislation contains a number of provider payment and delivery system reforms designed to encourage efficiency and quality. For example, the legislation establishes a new Independent Payment Advisory Board to recommend ways to reduce Medicare spending if the increases in Medicare per-capita growth rates exceed certain targets.[3] Beginning in 2014, if the projected per-capita Medicare spending growth rate exceeds a target growth rate, the board must submit to the president recommendations to achieve specific spending reductions. The president must then submit the recom-

mendations to Congress. The Secretary of the U.S. Department of Health and Human Services (HHS Secretary) must issue recommendations if the board fails to do so, and to implement the board's recommendations (or the HHS Secretary's recommendations) unless Congress enacts alternative proposals that achieve the same level of savings.

Although Healthcare Reform Legislation does not mandate any specific type of cost-savings recommendations for the Independent Payment Advisory Board and allows the board freedom to propose savings plans, other portions of Healthcare Reform Legislation give some insight into what types of proposals can be expected. For example, the legislation calls for several payment and delivery system innovations, including a pilot program related to post-acute care, value-based purchasing for providers, and the establishment of Accountable Care Organizations (ACOs). In addition, the Healthcare Reform Legislation creates a new Center for Medicare and Medicaid Innovation beginning in 2011 to test new payment and service delivery models to improve coordination, quality, and efficiency of healthcare services.[4]

Most of these payment innovations focus on bundled payments covering several different types of healthcare providers or on sharing cost savings or financial rewards for improving outcomes and quality of care. For example, ACOs that meet quality thresholds will share in the cost savings that they achieve for the Medicare program beginning in 2012.[5] To qualify as an ACO, organizations must agree in a three-year contract with the HHS Secretary to be accountable for the overall care of their Medicare beneficiaries, have adequate participation of primary care physicians, define processes to promote evidence-based medicine, report on quality and costs, and coordinate care.

The pilot program related to post-acute care involves bundled payments. Under this program, Medicare would pay one bundled payment for acute, inpatient hospital services, physician services, outpatient hospital services, and post-acute care services for an episode of care that begins three days prior to a hospitalization and spans thirty days following discharge. The Healthcare Reform Legislation requires the HHS Secretary to expand the pilot program if it achieves the stated goals of reducing spending while improving or not reducing quality. This pilot program will be established by January 1, 2013, and expanded, if appropriate, by January 1, 2016.[6]

Left unanswered in these payment and delivery reforms are questions such as how the acute care provider is expected to arrange for the physician services and post-acute services or how an ACO should incentivize physicians to share in its efforts to achieve cost savings in the delivery of care. Many providers believe that Healthcare Reform Legislation's goals are best achieved through a truly integrated provider delivery system in which physicians, acute care providers, and post-acute providers work together to achieve common goals in an integrated manner. This will, of course, require all providers, including physicians, to be financially rewarded in a way that ensures everyone is pulling together to achieve the same cost savings, quality, and efficiency goals.

Steps That Providers Are Taking Now to Prepare for Healthcare Reform Delivery System Changes

Because of this belief that the Healthcare Reform Legislation's delivery system reforms will be best achieved through a truly integrated provider model, many providers are taking steps now to prepare for such a payment model. For example, in a move reminiscent of the 1980s and early 1990s, many hospitals are buying physician practices and/or employing physicians. Many acute care providers are also buying or forming alliances with post-acute providers, such as rehabilitation hospitals or home healthcare providers. Still others are dusting off old provider network entities that may have been in disuse, such as preferred provider organizations or independent practice associations. At this point, it appears that few acute care providers have taken the next step of setting up profit (or cost savings) sharing models with the acquired practices or post-acute care providers. Instead, many providers are forming these alliances and employing physicians in order to have control of the full continuum of care and to be ready to move quickly as soon as there is more guidance on the implementation of the Healthcare Reform Legislation's payment structure. Many providers also may be concerned, and justifiably so, about how to achieve financial alignment of interests without running afoul of the healthcare regulatory restrictions.[7]

Regulatory Roadblocks to Achieving Reform Goals

Currently, there are roadblocks to a complete, integrated delivery system that makes sense and aligns financial incentives across all provider delivery points. These major regulatory roadblocks include the Stark Law, Anti-Kickback Statute, CMP Law, and federal antitrust laws, as well as certain state laws.

Stark Law

The Stark Law[8] is a strict liability statute that makes it illegal for a physician to refer a Medicare or Medicaid patient for items or services provided by a provider of designated health services (DHS)[9] with which the physician or a member of his immediate family has a "financial relationship," unless the financial relationship fits within an exception to Stark. A financial relationship can be through ownership or through a compensation relationship.

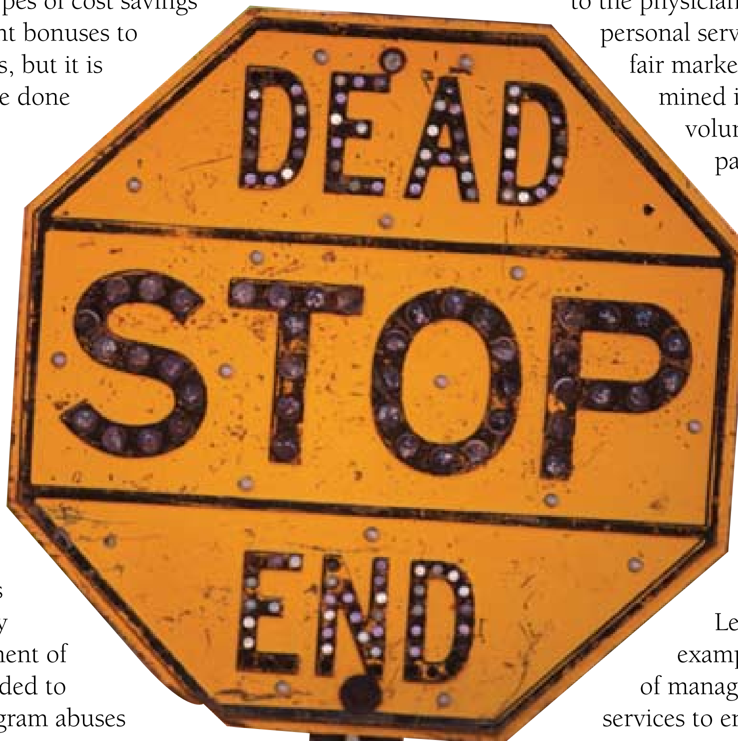
The Stark Law could impede healthcare reform arrangements because the implementation of a bundled or shared-savings arrangement will involve the creation of new financial relationships with physicians, and the current Stark exceptions[10] may not be broad enough to encompass the kind of bonus structures or payments necessary to change fundamental and long-standing practice behaviors. For example, a hospital that receives a bundled payment covering a diagnosis-related group (DRG) and related physician services will have to allocate a portion of the bundled payment to the physicians who provide the physician services. Similarly, a hospital that operates as an ACO and receives a bonus based on achievement of quality and cost-

savings goals will want to allocate a portion of this bonus among physicians who participate in the ACO. These payments to the physicians from the hospital would create Stark financial relationships between a provider of DHS (i.e., the hospital) and the physicians who make referrals to the hospital, so these relationships would have to fit within an exception.

Currently, there are only a few exceptions available, and each exception has elements that may be cumbersome or work against achieving true integration. For example, if the hospital directly employs the physicians, the Stark bona fide employee exception may be available. This exception contains three main elements: (1) the employment must be for identifiable services; (2) the amount of the employment remuneration must be consistent with fair market value and, with the exception of a productivity bonus based on services performed personally by the physician, must not be determined in any manner that takes into account, directly or indirectly, the volume or value of any referrals by the employed physician; and (3) the arrangement must be commercially reasonable even if the employed physician makes no referrals to his employer.[11]

Although the bona fide employee exception under Stark is broad, it still may not be broad enough to cover all of the quality and efficiency bonus structures the hospital needs to fundamentally change physician behavior. The requirement that the employment compensation be for "identifiable" services, for instance, can be problematic, as the statute and the regulations do not define the meaning of "identifiable services." The Stark statute, when enacted, did not contemplate payment for cost savings or payment for reducing unnecessary services or substituting less costly clinical modalities for patient care, yet physicians will be unlikely to alter their established practice patterns absent some sort of financial reward. Acute care providers need to be able to offer physicians these types of cost savings and quality improvement bonuses to achieve true cost savings, but it is unclear how that may be done under the current Stark provisions.

Moreover, the bona fide employee exception prohibits any payments to employed physicians that are determined (directly or indirectly) in a manner that takes into account the employed physician's referrals to his employer, other than a bonus based on services personally performed by the physician. This element of the exception was intended to prevent the kind of program abuses that can arise from compensation arrangements that encourage a physician to make referrals for unnecessary clinical services. However, the language of the exception does not address just compensation tied to a *greater* volume or value of referrals; rather, it simply prohibits basing compensation on the volume or value of referrals—whether that volume or value moves upwards or downwards. This makes cost-saving bonuses problematic in that such bonuses may be indirectly tied to the fact that the treating physician has ordered *fewer* hospital tests or less expensive hospital tests or services when different treatment modalities are available to appropriately treat the patient's condition.



Another Stark exception that is commonly used with non-employed physicians, the "personal services exception," also has elements that will create limitations in the clinical integration/healthcare reform setting. The personal services exception requires a written contract, for a term of at least one year, that covers identifiable, needed services, and that includes a fair market value compensation that is set in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.[12] The "compensation set in advance" and "not determined in a manner that takes into account volume or value of referrals" elements of this exception present problems for physician bonus systems based on cost-savings or achievement-of-quality benchmarks. Specifically, it may be difficult to have the kind of flexible bonus structure needed if a quality benchmark bonus payment formula has to be set in advance and cost-savings bonuses may be based in part on reducing the volume or value of referrals made by the physician.

Another possible Stark exception, the fair market value compensation exception, also requires a written agreement signed by the parties that specifies the compensation the DHS entity will pay to the physician.[13] Like the employee exception and the personal services exception, this exception requires a fair market value compensation that is not determined in a manner that takes into account the volume or value of referrals between the parties. As a result, this exception has the same limitations as do those exceptions with respect to the typical clinical integration cost-savings or quality-improvement bonus compensation model.

Other Stark exceptions that may apply are those for risk-sharing arrangements[14] and physician incentive plans.[15] However, those exceptions would need to be expanded to apply to all of the types of acute care provider bundled payments or ACO bonuses contemplated by Healthcare Reform Legislation. The risk-sharing exception, for example, is currently limited to specific types of managed care entities and for payments for services to enrollees of a health plan, and the physi-

cian incentive plans exception contains as one of its elements a prohibition on basing the physician bonus directly or indirectly as an inducement to reduce or limit medically necessary services.

Therefore, to open fully the possibilities for a truly integrated healthcare system that provides incentives for physicians to provide the best quality of care in the most cost-effective manner, healthcare systems need a new Stark exception to cover payments to physicians under an ACO or a bundled payment system. The Centers for Medicare & Medicaid Services (CMS) previously has proposed, but has not yet acted upon, a new "pay-for-performance/gain-sharing" Stark exception.[16] One solution may be for CMS to expand that proposed exception to cover physician payments under a bundled DRG or an ACO bonus plan.

Anti-Kickback Statute

The Anti-Kickback Statute makes it a felony for anyone to offer, pay, solicit, or accept any remuneration in cash or in kind, directly or indirectly, overtly or covertly, in exchange for the referral of or the arranging for the referral of patients to a person for the furnishing of items or services reimbursed under a federal healthcare program.[17]

A payment model in which an acute care hospital receives a "bundled" payment from Medicare for an episode of care and in turn is responsible for contracting with and compensating physicians and post-acute providers could create risk under the Anti-Kickback Statute. Similar to the Stark statute, there is an employee statutory exception,[18] as well as an employee safe harbor,[19] applicable to the Anti-Kickback Statute. There is also an Anti-Kickback Statute "personal services" safe harbor[20] that is similar to the Stark Law's "personal services" exception. However, this safe harbor is even more limited than the Stark exception; it not only requires that compensation not be based on the value or volume of referrals, it also requires that the physician's compensation be set in advance *in the aggregate*. It would be difficult, if not impossible to set the amount of a cost-sharing or quality bonus before the physician begins to provide the services.

In addition, the Anti-Kickback Statute, unlike Stark, applies not just to physicians but also to other providers and even non-providers. Therefore, the acute care provider's sharing of a bundled payment with a post-acute provider also raises risks under the Anti-Kickback Statute. In fact, sharing of bundled payments with both post-acute providers and physicians would create interesting new relationships in which, arguably, the hospital, and not the physicians, control referrals of business. If post-acute providers or physicians enter into contracts with a hospital to provide services to the hospital for less than fair market value, there is a risk that the government could view the discounted amount as a "kickback" or remuneration from the physician or the post-acute provider in exchange for the hospital's contracting with them.

To assure providers that they will not be violating the Anti-Kickback Statute inadvertently by entering into new healthcare reform payment structures, there should be a new Anti-Kickback safe harbor that clearly spells out the parameters for an acceptable contracting and payment structure between an acute care provider and those physicians and post-acute providers that work collaboratively with the acute care provider to achieve clinical efficiencies and quality improvement. An expanded pay-for-performance safe harbor similar to the proposed Stark exception mentioned above may be a good route to give providers the assurances they need to implement an integrated delivery system.

CMP Statute

Another fraud statute that currently would have a chilling effect on healthcare reform models is the CMP Statute.[21] This law makes it illegal for a hospital to knowingly make a payment to a physician (and for a physician to accept such a payment) as an inducement to reduce or limit services provided to Medicare or Medicaid patients.[22] A fully integrated healthcare delivery system that wants to encourage providers to perform as efficiently and effectively as possible must have a means of financially rewarding physicians for their efforts to provide quality and efficient care. The ideal way to align the providers' efforts would be to have a bonus arrangement based on cost-containment and quality thresholds. However, bonus arrangements based on cost-containment or other payment arrangements that may have, directly or indirectly, the effect of reducing or limiting services furnished to Medicare beneficiaries are potentially illegal under the CMP Statute.[23] Although there have been a handful of advisory opinions approving gainsharing proposals, those opinions do not give the green light to the types of cost-containment bonuses that are necessary for true healthcare reform because the structures they bless tend to be both costly and complex to implement, and limited in duration and scope.[24]

Consequently, the CMP Statute would need to be revised in one of two ways: either amend the current prohibition on making payments to physicians that would have the effect of reducing care to apply only to limiting or reducing medically necessary services, or create a specific exception or carve-out for physicians participating with hospitals and post-acute care providers in ACOs or bundled payment models.

Antitrust Laws

Providers will need to integrate to achieve the efficiencies necessary to make the new payment models work. It is basic economics that efficiencies and reductions in cost come from scale achieved through horizontal or vertical integration. Uniform processes, protocols, reporting, and monitoring at all stages in the patient-treatment lifecycle are needed not only to realize these efficiencies, but also to even participate in the Healthcare Reform Legislation's pilot programs. However, Federal Trade Commission (FTC) guidelines and rulings have the practical effect of dissuading fragmented providers from collectively negotiating fee schedules and effectively negotiating with private payors, for fear that they will run afoul of the Sherman Act and other antitrust regulations.[25] While FTC has stated that it "believe[s] antitrust laws allow—even encourage—doctors to collaborate in ways that lower costs and improve patient care,"[26] fear of antitrust scrutiny is not without foundation because of the lack of concrete guidance.

FTC has stated that so long as the government purchases the services and unilaterally sets payment levels and terms, there will not be an antitrust issue for ACOs;[27] however, this does not apply to ACOs if they move into the private sector or to other potential clinical integration and provider collaboration models. Even initial discussions between "competitors" regarding the variables necessary to determine whether an ACO or similar type of arrangement would be an attractive or viable option could be considered evidence of anti-competitive collusion to fix prices. How are providers expected to determine whether an ACO or similar collaboration arrangement would increase efficiencies and lead to cost savings if they face potential antitrust scrutiny for discussing prices, pricing policies, profit margins, and other key financial terms? How can providers work out a compensation model that would be acceptable to the parties involved without running unacceptable antitrust risk, even leaving other regulatory issues aside?

FTC has stated that it will not stand in the way of arrangements in today's healthcare context that have the potential to improve care and lower costs;[28] however, neither this cursory reassurance nor the FTC's current Statements of Antitrust Enforcement Policy in Health Care[29] are likely to be enough to ease providers' fears of antitrust scrutiny. FTC must either: (1) provide clear guidance on what healthcare providers can and cannot do to achieve the clinical integration that will be rewarded by Healthcare Reform Legislation; or (2) create a safe harbor for providers during the initial discussion phases regarding the development of potential clinical integration and cost-saving strategies. Currently, aside from obtaining an advisory opinion from FTC[30] or a business review by the U.S. Department of Justice,[31] there is no way for providers to know whether a proposed collaboration or initial discussions between providers will be free from antitrust scrutiny. Certainty with regard to antitrust implications is critical to incentivizing providers to have open communications and enabling them to evolve into the clinically integrated organizations capable of achieving the cost-savings, efficiencies, and improved patient care sought by Healthcare Reform Legislation. Providers can only hope that FTC will recognize and adequately address this problem in future guidance and regulations.[32]

State Laws

State laws prohibiting the corporate practice of medicine and fee-splitting may impede arrangements with and payments to physicians under an ACO or a bundled payment model. States with prohibitions on the corporate practice of medicine and fee splitting should re-examine those laws to consider whether they are still needed as a policy matter and, if not, repeal them. At a minimum, those states should amend such laws to permit employment of physicians and sharing of cost savings and quality payments contemplated by these new models.

Some state insurance laws may be interpreted to require an ACO or other organization receiving a bundled payment to be subject to such laws, and therefore required to meet minimum solvency requirements and obtain a license or other authorization. States should examine their insurance laws and permit ACOs and providers participating in an ACO or bundled payment arrangement to share the risk of a payment arrangement without having to comply with state insurance laws.

Finally, some states also have anti-kickback and self-referral laws that should be amended as discussed above in connection with the Anti-Kickback and Stark laws.

Conclusion

Healthcare Reform Legislation authorizes the HHS Secretary to waive the Stark, Anti-Kickback, and CMP laws for the purpose of implementing ACOs. As discussed above, HHS Secretary waivers or modifications to these and other laws will be required to remove the regulatory roadblocks to healthcare reform. Otherwise, those roadblocks are likely to frustrate the Healthcare Reform Legislation's purposes.

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1 Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).
2 Pub. L. No. 111-152 (2010).
3 *See* PPACA Section 3403, *as amended by* Reconciliation Act Section 10320.
4 *See* PPACA Section 3021.
5 *See* PPACA Section 3022, *as amended by* Reconciliation Act Section 10307.
6 *See* PPACA Section 3023, *as amended by* Reconciliation Act Section 10308.
7 The Advisory Board Company, Presentation, *Toward Accountable Care*, Special CEO Sessions (2010).
8 42 U.S.C. § 1395nn (2006).
9 *See* 42 U.S.C. § 1395nn(a)(1).
10 *See generally* 42 U.S.C. § 1395nn(b) *et seq.* and 42 C.F.R. § 411.357 *et seq.*
11 *See* 42 U.S.C. § 1395nn(e)(2) and 42 C.F.R. § 411.357(c).
12 *See* 42 U.S.C. § 1395nn(e)(3) and 42 C.F.R. § 411.357(d).
13 *See* 42 U.S.C. § 1395nn(b)(4) and 42 C.F.R. § 411.357(l).
14 *See* 42 U.S.C. § 1395nn(e)(3)(B)(II) and 42 C.F.R. § 411.357(n).
15 *See* 42 U.S.C. § 1395nn(e)(3)(B) and 42 C.F.R. § 411.357(d)(2).
16 *See* 73 Fed. Reg. 38548 (2008).
17 42 U.S.C. § 1320a-7b(b).
18 42 U.S.C. § 1320a-7b(b)(3)(B).
19 42 C.F.R § 1001.952(i).
20 42 C.F.R § 1001.952(d).
21 42 U.S.C. § 1320a-7a.
22 42 U.S.C. § 1320a-7a(b)(1).
23 *Id.*
24 *See, e.g.* OIG Advisory Opinion No. 01-1 (Jan. 11, 2001); OIG Advisory Opinion No. 05-01 (January 28, 2005); OIG Advisory Opinion No. 05-02 (Feb. 10, 2005); OIG Advisory Opinion No. 05-04 (Feb. 10, 2005); OIG Advisory Opinion No. 05-05 (Feb. 18, 2005); and OIG Advisory Opinion No. 05-06 (Feb. 18, 2005).
25 *See* Jon Leibowitz, FTC Chairman, Remarks As Prepared for Delivery Before the American Medical Association House of Delegates (June 14, 2010), at 2, *available at* www.ftc.gov/speeches/leibowitz/100614amaspeech.pdf (attempting to disabuse doctors of the stereotype that antitrust enforcement actions are portrayed as a barrier to improved care).
26 *Id.*
27 *Id.* at 7.
28 *Id.* at 6.
29 U.S. Department of Justice (DOJ) and FTC Statements of Antitrust Enforcement Policy in Health Care (1996), *available at* www.ftc.gov/bc/healthcare/industryguide/policy/index.htm.
30 *See* 16 C.F.R. §§ 1.1-1.4 (1993) (FTC's advisory opinion procedure).
31 *See* 58 Fed. Reg. 6132 (1993) (DOJ's expedited business review).
32 FTC, OIG, and the Centers for Medicare & Medicaid Services held a workshop on October 5, 2010, where Leibowitz announced that FTC will develop antitrust safe harbors for ACOs as well as an expedited review process for ACOs that do not qualify for those safe harbors. A transcript of the workshop is *available at* www.ftc.gov/opp/workshops/aco/index.shtml.