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Section Co-Chairs' Corner

We are pleased to present to you the Winter 2012 Edition of the Health Law Section's Health Law Reporter. The Health Law Reporter is an important source of information for many of us practicing in this dynamic field.

In this issue you will find a policymaker profile which provides an inside look at Mary Beckman, head of the Nonprofit & Charities Division of the Massachusetts Attorney General's Office. In addition, we think you will find the five articles featured in this edition both interesting and informative. Two articles focus on the relatively new concept of Accountable Care Organizations. As we go to press 5 of the 32 Medicare Pioneer Accountable Care Organizations are in Massachusetts. This partial move from volume- to value-based reimbursement creates a myriad of new and interesting issues for the health care bar. In light of the inevitable impact this will have on the healthcare market in our state, we are pleased to provide these thoughtful articles.

As always, we thank all of the individuals who devote countless hours of hard work to produce the Reporter. The Reporter is one of the many opportunities the Health Law Section provides for health care lawyers to work collaboratively with their colleagues. We encourage you to join our section and become part of one of our many committees. Finally, we would like to take a moment to thank the staff of the BBA for their tireless efforts. Their dedication makes our work possible.

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Inside this Issue

The Fiduciary Duty of a Charitable Corporation's Sole Corporate Member: New Law and New Questions

by Julia R. Hesse and David S. Szabo

Introduction

Brief Summary of Facts Underlying the Lifespan Case

Lifespan v. NEMC is a case about the break-up of a hospital from a hospital system – and, ultimately, about the fiduciary duties owed by that hospital system to its member hospitals.[1] Lifespan Corporation is a non-profit hospital system based in Rhode Island. In 1997, New England Medical Center ("NEMC", and now known as Tufts Medical Center) affiliated with Lifespan.[2] By all accounts, the affiliation did not work out and in 2002 Lifespan and NEMC agreed to disaffiliate.

Under the terms of the agreement ending the affiliation (the "Restructuring Agreement"), NEMC was required to pay Lifespan a series of break-up payments. NEMC made most, but not all, of these payments – refusing to pay the final two installments of $3.66 million out of the total $30 million required by their Restructuring Agreement. Lifespan initiated the lawsuit in 2006 on a breach of contract claim to compel NEMC to make the two missing payments. NEMC admitted that it did not make these payments but counterclaimed that Lifespan had engaged in misconduct during the affiliation, which entitled NEMC to indemnification.

The Massachusetts Attorney General, invoking NEMC's status as a public charity, intervened in the case on behalf of the public interest (pursuant to Fed. R. Civ. P. 24), and brought a counterclaim against Lifespan for breach of its fiduciary duty to NEMC, based on the same alleged misconduct.

The Court, holding that Massachusetts law governed all of the parties' claims in the case, found that Lifespan *did* owe a fiduciary duty to NEMC because of the extent of control it exercised over NEMC and also because of the "'faith, confidence and trust' NEMC placed in its judgment and advice."[3]

Scope of Article: Fiduciary Duty of Parent to Subsidiary

This article will focus on the Court's important holding that Lifespan owed a fiduciary duty to NEMC – and will analyze the scope and impact of that holding. This is only the second court (and the first under Massachusetts law) to hold that the member of a non-profit corporation (i.e., its corporate parent) owes a fiduciary duty to its separately incorporated affiliated hospitals.[4]

Lifespan Court's Ruling and Rationale

A. Definition of Fiduciary Duty

Each party had moved for summary judgment on the issue of whether Lifespan owed a fiduciary duty to NEMC.[5] The Court first determined that Massachusetts law governed the dispute, despite the fact that the parties had not included a choice of law provision in their Restructuring Agreement.[6] The Court then explained that Massachusetts law does not have a single definition of the fiduciary duty – instead, it is a mixed question of law and fact and exists when one party "reposes faith, confidence, and trust in another's judgment and advice."[7]

B. Factual Basis of the Decision

The Court made short order of holding that NEMC reposed "faith, confidence and trust" in Lifespan's judgment and advice. The Court made this determination based on the many ways in which Lifespan controlled NEMC during their affiliation, including Lifespan's majority control over NEMC's sole voting member. Through this entity, Lifespan oversaw key aspects of NEMC's finances and operations, strategic planning, policymaking, and payor contracting. Lifespan also had the authority to appoint and remove members of NEMC's board directors, as well as to hire, fire and set compensation for NEMC's CEO and CFO. The Court found that Lifespan essentially had become NEMC's corporate parent, and NEMC became a controlled subsidiary.[8]

C. Legal Basis of the Decision

Finding only one case on point, the Court relied extensively on scholarly work to hold that a corporate parent owes a fiduciary duty to its subsidiaries in the non-profit context. The Court explained that in the for-profit context, a corporate parent does not owe a fiduciary duty to its wholly-owned subsidiaries because their interests are aligned. At the same time, though, a for-profit corporate parent generally owes a fiduciary duty to its majority-owned subsidiaries in order to prevent the parent from "using

its majority control to advance its own interests at the expense of the subsidiary's minority shareholders."[9]

In the non-profit context, the Court found that a parent owes a fiduciary duty to its subsidiary not because of competing shareholder interests – but instead because each of the parent and subsidiary have its own independent charitable purpose, objectives, and most importantly beneficiaries. The Court explained "this is particularly true in the case of healthcare systems, where the interests of the system as a whole may diverge from those of a given hospital."[10] This analysis is discussed in more detail in Section III of this Article.

In reaching this conclusion, the Court relied extensively on a scholarly article that argued that "'it is appropriate to apply a fiduciary standard' to a healthcare system acting as the sole member of a non-profit hospital in order 'to constrain the [system's] powers and protect the interests of subsidiaries' beneficiaries,' just as courts (including those in Massachusetts) have done with respect to controlling shareholders in for-profit corporations."[11] The Court also looked to the Health Alliance case – the only other case on point, where the Ohio Court of Appeals also held that the parent entity in a non-profit hospital system owed a fiduciary duty to its member hospitals because the "hospitals reposed special confidence and trust in the [system], which resulted in a position of superiority on the part of the [system], the very essence of a fiduciary relationship."[12]

Contrasting the Court's Ruling to the Duties that Exist Within For-Profit Corporate Groups

The District Court was careful to point out that its decision was at variance with long standing law applicable to for-profit corporations. In general, the sole shareholder of a for-profit corporation has no fiduciary duty to the corporation. Indeed, the general rule is that directors of a corporation with only one shareholder owe a fiduciary duty to the shareholder, as well as to the corporation itself.

In the analogous situation of a for-profit corporate group with a single ultimate parent company, the parent company normally does not owe a fiduciary duty to each direct and indirect subsidiary, and is not required to selflessly promote the interests of each subsidiary over its own. Indeed, the duty of the parent (or more typically, the parent's board of directors) is to the parent's shareholders, and the parent may deal in the stock or assets of the subsidiaries in whatever manner advances the economic interests of itself and its own shareholders.

The few exceptions to this general rule arise when a subsidiary is insolvent, or in the "zone of insolvency." In these situations, directors of the subsidiary may have additional, or superseding duties to creditors. In a few situations, it has been argued that this duty to creditors extends to the sole shareholder of an insolvent corporation.

The District Court distinguished the general rule governing for-profit corporations, first, by noting that a majority but not sole shareholder, would have duties to the minority shareholders.[13] The Court then went on to state:

> In the non-profit context, the analysis changes somewhat. The concern there is not with competing shareholder interests, but with competing charitable objectives between parent and subsidiary. Even where the parent is the subsidiary's sole voting member, they may have different aims and different beneficiaries. This is particularly true in the case of healthcare systems, where the interests of the system as a whole may diverge from those of a given hospital. "In significant respects, the beneficiaries of the [hospital], namely its patients and community, stand in a position similar to the minority shareholders in a non-wholly-owned, for-profit subsidiary," in that they "are vulnerable to the power of the controlling entity."[14]

The Court adopted the characterization of Professor Reiser that patients and communities are like "minority shareholders" of a non-profit corporation, and the parent corporation, therefore, owes those stakeholders a fiduciary duty. The Court, however, also recognized the subsidiary itself as having interests differing from the parent, ruling that that parent must exercise its control over the subsidiary in a manner consistent with fiduciary duty.

The Court's holding should not be confused with the relatively straightforward assertion that the directors of the parent company are fiduciaries to it. By extension, if a corporation has a wholly-owned subsidiary, the parent company's directors' fiduciary duty would be to promote the interests of the corporate group over their own personal interests.

The ruling represents a sharp break with traditional law in the for-profit context.

How Does the Ruling Impact Multi-State Systems?

While the Lifespan case addresses an evolving area of the law, all non-profit institutions have reason to be interested in its holding. Both courts that have directly addressed the issue of fiduciary duties owed by a non-profit corporate parent to its subsidiaries (the Lifespan and HealthAlliance Courts) found that a fiduciary duty *does* exist. These issues will be of particular interest to systems that cross state lines.

In the first instance, hospital systems that span jurisdictional lines must determine which state's law governs their arrangement. In Lifespan, the parties had not made clear and consistent statements about governing law in their contractual documents – and the Restructuring Agreement that was in dispute during the litigation was silent about governing law.[15] The Court then looked to related contractual documents, and engaged in an interest-weighing analysis (including a review of factors such as predictability of result, and simplification of the judicial task) to determine that Massachusetts law governed the case.[16]

It is unclear whether the Court would have come to a different result if Rhode Island law had governed the case – but it is now absolutely clear that any affiliations that cross state boundaries must be mindful of the laws regarding fiduciary duty and non-profit governance in all relevant jurisdictions. Specifically, if an affiliation crosses a border into Massachusetts or Ohio (or in the First and Sixth Circuits, where courts may be more persuaded by the Lifespan and Health Alliance decisions), the parties should be aware that courts in these jurisdictions have already determined that a fiduciary duty exists and should contract accordingly.

A multi-state non-profit can find itself in a difficult situation if it proposes to sell assets in one jurisdiction and deploy those assets in another state, even if those assets are unrestricted. Banner Health was an Arizona-based non-profit hospital system that operated in eight states. In 2002, Banner Health proposed to sell its facilities in North and South Dakota to other nonprofit buyers. The Attorneys General in both states filed suit, alleging that the hospitals' assets should be subjected to constructive trusts in favor of the residents of each state, and that Banner should be barred from using the proceeds of the sales elsewhere. Both lawsuits were settled when Banner Health agreed to make payments to each Attorney General to be used to support local health programs.[17]

Benefits of Finding that a Parent Corporation is a Fiduciary

The Court's ruling could be used to the benefit of charities that are part of larger systems, or that are contemplating change of control transactions that could make them part of corporate groups.

It could well be in the interest of a charity that is surrendering control to a larger corporate group to make sure that the parent observes fiduciary duties to the subsidiary. This particularly is the case when the parent and subsidiary serve different constituents or have different missions, and the directors of the soon-to-be subsidiary are seeking assurances from the new parent company that the distinct mission of the subsidiary will be preserved and enhanced.

The existence of a fiduciary duty can also change the dynamic between a subsidiary board and a parent board. Subsidiaries are often subject to extensive "reserved powers" on the part of a parent. One of the burdens of serving on a subsidiary board, especially when the subsidiary is subject to extensive "reserved powers," is that the subsidiary's directors bear the burdens of governance without all of the authority normally associated with the role of directors.

The existence of a fiduciary duty on the part of the parent to the subsidiary could potentially provide a strong check on the discretion of the parent board, and could strengthen the authority of the subsidiary board in its dealings with the parent.

The ruling also potentially increases the Office of Attorney General Division of Public Charities' influence on non-Massachusetts entities. Even though Lifespan was not directly subject to the Division of Public Charities as an out-of-state charity, out-of-state non-profit corporate parents may now become subject to indirect regulation as a fiduciary to an in-state charity. Where both the parent and the subsidiary already are subject to the Division's jurisdiction, it is not clear that the ruling adds much to the Division's pre-existing authority.

Problems Arising from the Court's Ruling

A. Impact on Strategic Decision-Making

If a parent company owes a fiduciary duty to all of its non-profit subsidiaries, then the role and obligations of the parent board and the

parent itself will change. Arguably, every strategic decision must now consider the fiduciary duty owed to each subsidiary, versus the development of the system as a whole. This is a change.

Consider the following situation. Parent corporation controls two hospitals, Suburban Hospital and Midtown Medical Center. Suburban is profitable, and Midtown is not profitable, but owns very valuable urban real estate next to its main hospital facility. The Parent Board wants to obtain cash from Suburban, borrow additional funds secured by a mortgage on Midtown's real estate, and use the proceeds to develop a new health care facility in another part of the state.

Can this transaction be approved by the Parent corporation's board? Is it a breach of fiduciary duty owed to each of Suburban and Midtown? What if the Parent board wants to use cash generated by Suburban to fund operations at Midtown? Is this permitted, given that the Parent is a fiduciary to Suburban?

The situation of a hypothetical parent company is complicated if it has conflicting fiduciary duties. If Parent has duties to both of its subsidiaries, can it choose between them in the allocation of resources and pursuit of goals? Unfortunately, the Court's decision provides no guidance on how these kinds of conflicts should be addressed.

B. What Does the Ruling Mean for Existing Boards? Will Existing Boards Be Relegated to Advisory Board Status?

In Massachusetts, the Lifespan decision sets out a potentially untenable situation. On the one hand, boards of subsidiary organizations within a system owe a fiduciary duty to their individual organizations. Simultaneously, the board of the parent entity must also make its decisions in the best interests of the system as a whole. It is extremely unlikely that the interests of each entity within a corporate system will be perfectly aligned at all times, and it seems inevitable that the interests of the subordinate entities will conflict with those of another subordinate entity or to the organization as a whole. In light of the potential for conflict among boards within a system, it is extremely likely that non-profit systems will review the Lifespan decision and revise their corporate and contractual documents to make it absolutely clear that the board of the parent entity has authority to act on behalf of all of the entities in the system and to the extent that each subsidiary entity retains its own governing board (as further discussed below), it does so on an advisory basis.

Another potential implication of the Lifespan ruling is that parent entities will give more, and not less, power to its subsidiary entities to limit the risk that the parent entity will be accused of violating its fiduciary duty to its subsidiary entities. This approach could seriously undermine the parent's ability to operate the entities as a coordinated system, however.

Impact on corporate structuring and transactions

A. Can the Duty be Waived or Changed by Corporate Documents?

To the extent that the existence of fiduciary duty is sought to be minimized, one approach might be to attempt to solve the problem by carefully drafted provisions in the articles organization of a charity. If the purpose of each subsidiary was amended to include supporting the activities, purposes and goals of the parent, this might support the parent pursuing a unified governance strategy that allowed it to balance the needs of one subsidiary against another.

The Lifespan ruling casts doubt on the ability of entities to alter the scope of their fiduciary duties by contract. The Court noted that Lifespan had argued that the scope of any duties between the parties should be as set forth in their separation agreement, which also served as a settlement agreement. The Court rejected that argument, stating that fiduciary duty arose by operation of law, and could not be limited by agreement. The Court cited the following statement from the case of Wartski v. Bedford:

> . . . even if the partnership agreement can be interpreted as defendant claims, it cannot nullify the fiduciary duty owed by Bedford to the partnership. The fiduciary duty of partners is an integral part of the partnership agreement whether or not expressly set forth therein. It cannot be negated by the words of the partnership agreement. Labovitz v. Dolan, 189 Ill.App.3d 403, 136 Ill.Dec. 780, 786, 545 N.E.2d 304, 310 (1 Dist.1989). Or to put it another way: "Exculpatory provisions of corporate articles create no license to steal. They do no more than to validate otherwise invalid agreements *if such agreements are shown to be fair.*"[18]

If, as the District Court suggested, fiduciary duty arises by operation of law and cannot be negated by agreement, there is a legitimate question whether any revision in corporate articles or bylaws can empower a parent company to act

against the interest of any of its subsidiaries. By contrast, the liability of directors to the corporation and its members for breach of fiduciary duty can be waived by provisions in the articles of organization, at least in part.[19]

Perhaps instead of trying to negate fiduciary duties, systems could consider amending the corporate purpose of the subsidiary entities to align the purposes of the parent and the subsidiary entity (i.e., to amend the corporate purpose of the subsidiary entity so that it is identical to the corporate purpose of the parent entity). This may allow the parent entity to abide by its fiduciary duty to the subsidiary while simultaneously being able to make decisions on a system-wide basis – although the Lifespan opinion does not give any guidance about whether this approach would be effective.

It is interesting to note that the Court accepted Lifespan's arguments that a release contained in the Restructuring Agreement effectively waived NEMC's fiduciary duty claims, but that the release was not binding on the Attorney General.[20] This conclusion begs the question whether a release contained in transaction or corporate documents could ever be effective absent a ruling by the Attorney General.

B. Does Choice of Entity Matter?

Not all charitable entities are corporations. Some older charities are trusts, and in some cases charitable subsidiaries are organized as limited liability companies. However, since the Court did not rest its decision on any provision of either Rhode Island or Massachusetts corporate law, it seems unlikely that the Court's decision would have changed if either party had been organized under a different statute.

C. Does Choice of Jurisdiction Matter?

On one level, yes, jurisdiction does matter. There are only two jurisdictions where courts have found that a parent organization within a nonprofit system owes a fiduciary duty to its member organizations – Massachusetts and Ohio. Nonprofit systems that have part of their organizations in Massachusetts or Ohio must review their corporate and organizational documents in light of the Lifespan and Health Alliance cases, and determine whether their structure and operations are consistent with the fiduciary duties found in these cases.

On another level, nonprofit systems in all jurisdictions have reason to be interested in the Lifespan case. Although Lifespan is based on Massachusetts law, the Court did not have an extensive body of Massachusetts law on which it relied in making its decision. Instead, the Court looked to the widely-held standard for the existence of a fiduciary relationship (i.e., when one party reposes faith, confidence and trust in another's judgment and advice)[21] and then developed its legal analysis based on the reasoning in Professor Reiser's Rutgers Law Review article as well as the Health Alliance case. With a paucity of existing case law, courts in other jurisdictions may be equally persuaded by this reasoning and come to the same conclusion as the Court did in Lifespan.

D. Impact of Proposed Changes to Hospital Conditions of Participation?

On October 24, 2011, the Centers for Medicare and Medicaid Services (CMS) proposed a rule aimed toward administrative simplification that would eliminate a long-standing requirement that each hospital participating in the Medicare program (i.e., each hospital that has its own CMS Certification Number) have its own governing body.[22] The purpose of the governing body requirement is to ensure that each participating hospital has an effective governing body that is legally responsible for the conduct of the hospital – but CMS explained that based on its experience and anecdotal evidence, it is no longer necessary for each individual hospital within a multi-hospital system to have its own separate governing body.

Instead, CMS would now allow multi-hospital systems to have a single governing board overseeing the activities in all of its member hospitals, so long as that single board can effectively fulfill all of the obligations that had previously been imposed on the individual boards (such as having the authority to bind the member hospitals and being legally responsible for their actions). Multi-hospital systems that have a well-functioning parent entity will likely consider implementing a single governing board structure, which would certainly eliminate the confusion and potential conflict associated with multiple levels of governance and control and effectively address some of the fiduciary duty issues raised in the Lifespan case.

However, the single governing board might not address claims brought after a "spin-off" or disaffiliation transaction, when a new subsidiary board might challenge the decisions made by the parent board.

Could the Rule be Overturned by the Supreme Judicial Court?

When announcing its decision on the fiduciary duty claims, the Court noted:

> Where, as here, a federal court is confronted with a novel question of state law, it must make "[A]n informed prophecy of what the [state's highest court] would do in the same situation, seeking guidance in analogous state court decisions, persuasive adjudications by courts of sister states, learned treatises, and public policy considerations." Walton v. Nalco Chem. Co., 272 F.3d 13, 20 (1st Cir.2001). Based on these considerations, as just discussed, this court is confident that the Massachusetts Supreme Judicial Court would agree with the reasoning set forth by Professor Reiser and the Health Alliance decision, at least as applied to the facts of this case, and conclude that Lifespan owed a fiduciary duty to NEMC during their affiliation.[23]

Is the Court's "informed prophecy" correct? The Court's ruling is not based on any provision of Chapter 180 of the General Laws, or any other statute. Chapter 180 contains clear provisions setting forth the duties of directors to the corporation and to the members, but no provisions creating duties of the members to the corporation. Corporations are creatures of state law. Arguably, the Court has amended the statute, a prerogative that should be reserved to the Massachusetts legislature.

Perhaps, finding that a non-profit parent entity owes a fiduciary duty to its subsidiary entities is not as important as finding that the parent entity *breached* this fiduciary duty. In the Lifespan case, the Court found that Lifespan engaged in specific misconduct, including a violation of its own conflict of interest policies. The Court did not provide an example of a breach of a fiduciary duty in the absence of specific misconduct. So, for example, it is entirely unclear whether a court would find that a breach of fiduciary duty occurred based on a parent entity's good-faith decision about system-wide strategic matters, even if the parent entity's proposed strategy failed in practice.

In any event, counsel will be pressed to provide guidance to other multi-corporate non-profit groups, so they can understand their duties and rights under the new doctrine announced by the Lifespan Court.

(Endnotes)

1 This explanation of the facts follows Judge LaPlante's recitation of the facts in the May 26, 2011 Court ruling: Lifespan v. New Eng. Med. Ctr., Inc., 2011 WL 2134286 (D.R.I.) (May 26, 2011) at *1, *3-4.

2 For the sake of consistency with the Court rulings in this matter, we will refer to Tufts Medical Center as NEMC throughout this article.

3 2011 WL 2134286 (D.R.I.) (May 26, 2011) at *6, quoting the Court's prior ruling on fiduciary duty in Lifespan v. New Eng. Med. Ctr., Inc., 731 F. Supp. 2d 232 (D.RI. July 20, 2010) at 238-241.

4 The other ruling was the 2008 Ohio Court of Appeals decision in Health Alliance of Greater Cincinnati v. Christ Hosp., No. C-070426, 2008 WL 4394738 (Ohio App. Ct. Sept. 30, 2008) (discussed in more detail below). *See* Michael Peregine and James Schwartz, *New Intra-System Fiduciary Duty Decision*, American Health Lawyers Association Health Lawyers Weekly, Volume IX, Issue 23 (June 10, 2011).

5 Lifespan Corp. v. New Eng. Med. Ctr., Inc., 731 F. Supp 2d 232 (D.RI. July 20, 2010).

6 731 F. Supp 2d 232 at 239-240.

7 731 F. Supp 2d 232 at 239-240, quoting Doe v. Harbor Schs., Inc., 843 N.E.2d 1058, 1064 (Mass. 2006).

8 731 F. Supp 2d 232 at 240.

9 731 F. Supp 2d 232 at 240, quoting Donahue v. Rodd Electrotype Co. of New Eng., Inc., 328 N.E.2d 505, 593 (Mass. 1975).

10 731 F. Supp 2d 232 at 240.

11 731 F. Supp 2d 232 at 240, quoting Dana Brakman Reiser, *Decision-Makers Without Duties: Defining the Duties of Parent Corporations Acting as Sole Corporate Members in Nonprofit Health Care Systems*, 53 Rutgers L. Rev. 979, 1009 (2001).

12 731 F. Supp 2d 232 at 240, quoting Health Alliance of Greater Cincinnati v. Christ Hosp., No. C-070426, 2008 WL 4394738 (Ohio App. Ct. Sept. 30, 2008) at *6.

13 731 F. Supp. at 240, quoting Donahue v. Rodd Electrotype Co. of New Eng., Inc., 328 N.E.2d 505, 593 (Mass. 1975)

14 Id., citing Reiser, infra note 11.

15 731 F. Supp 232 at 238-239.

16 Id.

17 Evelyn Brody, *Whose Public? Parochialism and Paternalism in State Charity Law Enforcement*, 79 Indiana Law Journal at 968 (2004).

18 731 F. Supp. 2d at 241, citing Wartski v. Bedford, 926 F.2d 11, 20 (1st Cir. 1991), quoting Irwin v. West End Development Co., 342 F.Supp. 687, 701 (D.Colo.1972), *aff'd in part and rev'd in part on other grounds,* 481 F.2d 34 (10th Cir.1973), *cert. denied,* Vroom v. Irwin, 414 U.S. 1158, 94 S.Ct. 915, 39 L.Ed.2d 110 (1974) (emphasis added by the *Wartski* Court in its opinion).

19 Section 3 of Chapter 180 reads, in relevant part: "The articles of organization, in addition, may state a provision eliminating or limiting the personal liability of officers and directors to the corporation or its members for monetary damages for breach of fiduciary duty as an officer or director notwithstanding any provision of law imposing such liability; provided, however, that such provision shall not eliminate or limit the liability of an officer or director (i) for any breach of the officer's or director's duty of loyalty to the corporation or its members, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or (iii) for any transaction from which the officer or director derived an improper personal benefit."

20 Id. at 243.

21 This precise formulation was articulated in Massachusetts case law, but is a commonly-used standard derived from English common law and follows closely the definition used for fiduciary in the Black's Law Dictionary (where "fiduciary" is defined as "one who owes to another the duties of good faith, trust, confidence, and candor.") Blacks Law Dictionary, 9th Edition, at 702. *See also,* Tamar Frankel, *Fiduciary Law*, 71 Calif. L. Rev. 795 (1983); David J. Seipp, T*rust and Fiduciary Duty in the Early Common Law*, 91 B.U. L. REV. 1011, 1024-27 (2011).

22 The proposed change would revise the hospital Conditions of Participation at 42 CFR 482.12 to allow for a single governing body to oversee care provided in multi-hospital systems. 76 Fed. Reg. 65891 (October 24, 2011), at 65893.

23 731 F. Supp. at 241, emphasis added.

Antitrust Regulators Back Away From ACO Proposed Statement: Will the Guidance Be Sufficient to Protect Competition While Eliminating the Antitrust Deterrent to ACO Formation?

by Patricia A. Sullivan

Following a rulemaking process characterized by intense controversy, vigorous debate and acrimonious criticism of their proposed approach,[1] on October 20, 2011, the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ") issued their final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the "Policy Statement").[2] Responsive to the critical comments[3] and focused on the overarching goal of encouraging the formation of Accountable Care Organizations ("ACOs"), the final Policy Statement is significantly diluted from the proposed Policy Statement, which had been published on March 31, 2011.[4]

The final Policy Statement completely eliminates mandatory antitrust clearance as part of the ACO formation process and substitutes antitrust monitoring, coupled with a Safety Zone and guidance regarding how the agencies will evaluate specific conduct in determining whether to bring an antitrust challenge. This approach saves ACOs the substantial cost of performing an extensive (and expensive) Primary Service Area (PSA)/competitive effects analysis as part of the ACO formation process. The question is whether the guidance provided will be sufficient to eliminate the deterrent effect of the threat of antitrust enforcement on ACO formation, while still ensuring that competition is adequately protected.[5]

The dramatic course correction reflected in the final Policy Statement mirrors a similar shift in the final Medicare Shared Savings Programs regulations announced by the Centers for Medicare and Medicaid Services ("CMS") on the same day.[6] Commentators agree that the final rule goes a long way to reinvigorating interest in the ACO program.[7] The final rule differs from the proposal in many key respects, all of which improve substantially the business case for formation and operation of a successful ACO.

What is an ACO?

ACOs are a critical centerpiece of the health care reform legislation – the Affordable Care Act – passed with such fanfare (and controversy) in the spring of 2010.[8] As a qualified ACO, groups of health care providers meeting certain criteria work together to manage and coordinate care for Medicare beneficiaries. The Act encourages ACO formation by allowing a qualified ACO to share in a portion of any savings it creates, as long as it also meets quality standards established by CMS.[9] CMS has estimated that ACOs participating in this Shared Savings Program will service between one and five million Medicare beneficiaries during the program's first four years.[10] An ACO may include both physicians and hospitals, who share responsibility for improving the quality and reducing the cost of the care of the ACO's patients.

Antitrust Risks Posed by ACO Formation and Conduct

FTC and DOJ have acknowledged that a potential impediment to the formation of ACOs is providers' understandable fear of aggressive enforcement of the antitrust laws. These concerns are heightened when ACOs are negotiating with private payers since Medicare sets its own rates, which providers cannot negotiate.[11]

Whenever competitors come together, as they must to form an ACO, there is increased antitrust risk. It has long been clear that, without adequate integration, price agreements among competing health care providers are condemned as naked price fixing judged under the harsh *per se* rule.[12] Moreover, physician networks, which are a key component of an ACO, have been particularly vulnerable to antitrust enforcement.[13] Similarly, the high concentration levels in some hospital markets, and the existing competition between physicians and hospitals in many service areas, could cause potentially serious antitrust consequences as hospitals and physicians collaborate as ACO participants.[14]

Description of the Final Policy Statement

Both FTC and DOJ have seemed genuinely interested in trying to get the

balance of protection for ACO participants from antitrust risk and protection of competition properly calibrated.[15] The final Policy Statement is self-described as intended to ensure that health care providers have the antitrust clarity and guidance needed to form pro-competitive ACOs that participate in both the Medicare and commercial markets.[16] Instead of pre-formation review (analogous to the pre-merger review approach in the Hart-Scott-Rodino Act), it is patterned on the approach used in the 1996 *Statements of Antitrust Enforcement Policy in Health Care* ("1996 Health Care Statements")[17] – by establishment of a "Safety Zone," coupled with clear and simplistic guidance regarding conduct that increases antitrust risk. The only fragment of the proposed pre-formation review remaining is the now entirely voluntary expedited review available to newly forming ACOs that wish more certainty about their antitrust exposure.

The Policy Statement applies to any ACO and, except for the voluntary expedited review program, is not limited to those formed after March 23, 2010, the date on which the Affordable Care Act was enacted. Specifically, it applies to all collaborations among otherwise independent providers and provider groups that are eligible and intend or have been approved to participate in the Medicare Shared Savings Program.[18] The Statement acknowledges that most health care providers that form ACOs for Medicare beneficiaries will use the ACO structure seamlessly for their commercially-insured patients. Its guidance therefore applies equally to the conduct of the ACO in the private sector.

Ongoing Monitoring of Competitive Effects of ACOs

The Policy Statement makes clear that the antitrust agencies will be carefully monitoring the competitive effects of ACOs with information and data, as well as copies of the ACO applications, provided by CMS. They say they will vigilantly monitor any complaints about an ACO's formation or conduct. This may effectively mean that they will conduct an ongoing study of the competitive effects of ACOs.

Rule of Reason Analysis Applies to ACOs that Meet Certain Conditions

The elimination of the risk of *per se* analysis and the substitution of rule of reason treatment is the foundation of the Policy Statement.[19] By contrast with the *per se* rule, the rule of reason examines the anticompetitive effects of the collaboration to determine if they are substantial. If they are, the ACO may still defend its conduct by demonstrating that those effects are outweighed by its pro-competitive efficiencies. The difference between the rule of reason and the *per se* rule can be outcome determinative to the antitrust analysis.

Importantly, the Policy Statement extends rule of reason analysis to conduct in the commercial sector, as long as the ACO uses the same governance and leadership structure and the same clinical and administration processes as it uses for the Shared Savings Program. This extension of rule of reason protection will cover joint negotiations by ACO participating providers with commercial payers. Rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.

In adopting the rule of reason, the final Policy Statement focuses on the time-tested analysis in the agencies' 1996 Health Care Statements,[20] which discuss what level of financial and/or clinical integration is sufficient to justify rule of reason treatment for joint price setting or market allocation. They provide that, if the collaborating providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the pro-competitive benefits of the integration, the joint conduct is tested under the rule of reason.[21] In crafting the 2011 Policy Statement, the challenge for the antitrust regulators was how to view ACOs in this analytical framework. The solution seems to be based on a leap of faith.

Despite the absence of rigorous economic analysis justifying the conclusion, the Policy Statement asserts that the agencies have "determined" that the CMS criteria for eligibility in the Shared Savings Program are broadly consistent with the indicia of integration alluded to in the 1996 Heath Care Statements, so that organizations meeting the CMS eligibility requirements for the Shared Savings Program are reasonably likely to be organized via *bona fide* arrangements intended to improve quality and reduce costs through their participants' joint efforts. Therefore, the Policy Statement declares, because joint negotiations with private payers are reasonably necessary to an ACO's primary purpose of improving health care delivery, rule of reason treatment will be provided to ACOs that meet CMS's eligibility requirements for the Shared Savings Program and uses the same governance and leadership structure and clinical and administrative processes to serve patients in commercial markets.[22]

As a backstop to the assumption that a qualified ACO is sufficiently integrated as to analyze joint pricing and market allocation under the rule of reason, the antitrust agencies plan to study CMS's quality and cost data. They plan to monitor whether the CMS eligibility criteria in fact do require a sufficient level of clinical

and/or financial integration. At least one commentator has argued that the antitrust enforcement philosophy expressed in the Policy Statement, particularly the relaxed standards for hospital participation, is insufficiently robust.[23]

Safety Zone

Using parameters that echo those proposed to govern mandatory review in the initial Statement,[24] the final Policy Statement creates a "Safety Zone" for ACOs. The Safety Zone will apply where competing participants that provide the same service have a combined share in their PSA of 30% or less. An ACO in the Safety Zone not only has the benefit of the rule of reason, but also can be assured that the agencies will not bring a challenge under the antitrust laws, absent extraordinary circumstances. Extraordinary circumstances could include, for example, collusion or improper exchanges of price information or other competitively sensitive information with respect to services outside the ACO.[25]

Whether the ACO participants are exclusive or non-exclusive[26] affects whether the ACO falls into the Safety Zone. A hospital or ambulatory surgery center participating in an ACO *must* be non-exclusive to the ACO without regard to PSA share in order for the ACO to qualify for the Safety Zone. By contrast, physicians can be exclusive or non-exclusive without affecting the Safely Zone, except that ACOs with a "dominant participant" (defined as a provider with a greater than 50% PSA share of any service) must be non-exclusive with such participants.[27] The Policy Statement also expands the Safety Zone to permit ACOs in rural areas to qualify despite service areas that exceed the 30% PSA share. [28]

Measuring PSA Share

The PSA for each service is defined as the lowest number of postal zip codes from which the ACO participant draws at least 75% of its patients for the specific service.[29] The final Policy Statement includes an Appendix explaining how to calculate PSA share; [30] it includes examples to simplify what had been a highly criticized feature of the proposed Statement.[31] Unlike the proposed Statement, where every ACO had to incur the expense of performing a comprehensive PSA share analysis, the final Policy Statement no longer makes it essential, though it remains advisable. Under the final Policy Statement, PSA shares must be calculated to determine which service overlaps are in the Safety Zone and which are high enough to call for antitrust vigilence.

The Policy Statement asserts that PSA share is not a relevant antitrust geographic market, but is nonetheless a useful screen for evaluating potential competitive effects, and asserts that high PSA shares could be "indicia of market power."[32] It remains unclear, however, whether the agencies will truly treat PSA share as a surrogate for "market share," as the term is used in traditional antitrust analysis.

Conduct to Avoid

ACO service areas outside the Safety Zone raise potential antitrust concerns. To minimize these concerns, the Statement lists conduct to be avoided.

ACO participants must avoid colluding on price in the sale of competing services outside of the ACO. ACOs are urged to avoid sharing competitively sensitive pricing information for use in price setting for services provided outside the ACO. They are urged to implement firewalls or other safeguards against conduct that could facilitate such collusion.[33]

Where an ACO has high PSA shares (over 30%), the Policy Statement lists four categories of conduct to be avoided:

- Preventing or discouraging private payers from steering patients to certain providers, including non-ACO providers, through such devices as "anti-steering," "anti-tiering," "most–favored-nation," or similar provisions;

- Tying sales of ACO services to the private payer's purchase of other services from providers outside the ACO (such as an ACO hospital that requires a commercial payer to contract with all other hospitals in the same network);

- Exclusive contracts with ACO physicians, hospitals or ambulatory surgical centers or other providers; and

- Restricting the private payers from providing cost, quality, efficiency and performance information to their enrollees.[34]

Voluntary Expedited Review

The final Policy Statement offers expedited 90-day review by the FTC/DOJ to any newly forming ACO. The application should be submitted to the agencies before the ACO actually enters the Shared Services Program. An ACO looking for expedited review should submit a request with a cover sheet available on the FTC's/DOJ's websites. The agencies will promptly determine whether the review will be done by the FTC or DOJ; the documentation supporting the request is submitted only to the reviewing agency. As soon as the required information to perform the review is submitted, the 90-day clock

will begin to run.[35] The Policy Statement includes a detailed list of the documents that must be submitted with the application, as well as those additional documents that would be helpful.[36] The agencies have posted "Frequently Asked Questions About Voluntary Expedited Review."[37]

Limitations – The Policy Statement Does Not Bind Private Litigants or State Attorneys General

An FTC/DOJ Policy Statement does not alter the underlying antitrust laws. Therefore, the risk remains that a private litigant or a state attorney general may attack joint conduct by ACO participants as *per se* illegal. The fact that the conduct is governed by the rule of reason when examined by the FTC or the DOJ may be persuasive to a court, but is not dispositive.

Mergers Are Not Covered – Encouragement of ACOs Is Not Intended to Encourage Consolidation

The Policy Statement is intended to encourage integration and coordination, but not consolidation. Accordingly, it does not apply to mergers or to single fully-integrated entities such as a fully-integrated hospital system. Rather, mergers remain subject to the usual Clayton Section 7 analysis laid out in the Horizontal Merger Guidelines.

Internal FTC Controversy Over ACOs Persists

In early 2011, rumors flew about a turf war between the FTC and DOJ over control of the ACO review process. These rumors were confirmed by the dissent to the proposed Policy Statement by FTC Commissioner J. Thomas Rosch.[38] Commissioner Rosch expressed open disagreement with DOJ participation in the ACO review process. His rationale was based not only on the FTC's greater experience with ACOs, but also on the fact that the DOJ is embedded in the Executive branch and is more susceptible to lobbying and political pressure. He also candidly criticized DOJ's enforcement history – it has been too supportive of physicians and hospitals, he said.

With the final Policy Statement, Commissioner Rosch raised new concerns. On November 17, 2011, he addressed the ABA Section of Antitrust Law Fall Forum.[39] Derisively referring to the Accountable Care Act as "ObamaCare," he attacked the concept of ACOs, asserting that they will lead to minimal cost savings and could result in higher costs and lower quality care for consumers. He predicted that any reduction in costs by ACOs will be borne by commercial payers and that rationing of health care would be a likely consequence.

It bears noting that Commissioner Rosch had also been opposed to the 1996 Heath Care Statements to the extent that they created a safe harbor for competing providers who were merely clinically integrated – he called it "the biggest loophole in the antitrust laws I had seen," and the Advisory Opinions that decode them "about as clear as mud."[40] By grounding eligibility for rule of reason treatment in CMS approval of the ACO, an agency that lacks antitrust enforcement authority or expertise, Commissioner Rosch expressed fear that the Policy Statement perpetuates the inadequacy of the 1996 Health Care Statements. That said, he conceded that the regulations providing for both financial carrots and sticks to ACOs are a step in the right direction.[41]

Massachusetts – An ACO Incubator

To encourage ACO formation in a way that has the desired effects of promoting better care and outcomes at a lower cost, the CMS Innovation Center set up an initiative called the "Pioneer ACO Model," which selected thirty-two ACOs from a large applicant pool through a competitive process.[42] The Pioneer ACO Model will test the impact of several innovative payment arrangements. The selected ACOs were chosen for their significant experience offering quality care along with other criteria listed at www.innovations.cms.gov.

The chosen ACOs are spread over nineteen states. Remarkably, five are in Massachusetts (the most in any state except California, which has six). Of these, all serve patients in Eastern Massachusetts, and four of five are based in Boston or Cambridge.

Conclusion

It remains to be seen whether the final Policy Statement has hit the right balance between the protection of competition (deemed essential to sustained downward pricing pressure) and the goals of the Affordable Care Act (to encourage ACO formation). More importantly, the promise of ongoing monitoring of the competitive effects of ACO activities on pricing leaves open the real risk that ACOs, especially those anchored by a hospital system, could be the target of future antitrust inquiry.[43] Nevertheless, the relative certainty offered by the Statement to providers seeking to jump into the ACO waters is a welcome development.

(Endnotes)
1 P. Sullivan, *FTC and DOJ Propose a Regulatory Cure for Antitrust Concerns About Accountable Care Organizations*, 4 Bloomberg Law Reports-Health Law No. 6 (May 13, 2011), *available at* http://www.edwardswildman.com/files/News/39fe10a7-7b9d-4449-9281-b786425e7e44/Presentation/NewsAttachment/e0827adf-aba6-4f69-8a5e-b89c42f485c4/hllr%20-%206.6.11-ftc%20%20doj%20propose%20a%20regulatory%20cure.pdf.
2 The final Policy Statement may be found at: http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf (hereinafter "the Policy Statement").
3 For example, the American Hospital Association's assessment of the proposed Statement at the May 9 workshop was not positive: "Overall we think it fails to

accomplish its objective." *See* http://www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath+AHANEWS/AHANewsNowArticle/data/ann_050911_ACO&domain+AHANEWS.

4 The proposed Policy Statement may be found at: http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf. The Federal Trade Commission webpage with links to its work on ACOs may be found at: http://www.ftc.gov/opp/aco/

5 For a scholarly article discussing these issues with regard to ACOs and the Affordable Care Act, *see generally* A. Kasper, *Antitrust Review of Accountable Care Organizations: An Assessment of FTC and DOJ's Relaxed Approach to Regulating Physician-Hospital Networks*, 90 N.C.L. Rev. 203 (2011) (hereinafter "Kasper").

6 Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425), *available at* http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pfd (hereinafter "MSSP Rule").

7 *See generally* T.Bartrum, *CMS Attempts to Reignite Interest in ACOs: Commentary on the Final Medicare Shared Savings Program Regulations*, AHLA Connections (November 2011), *available at* http://www.healthlawyers.org/News/Connections/Documents/2011/November2011/Feature2_November2011.pdf; J.Ruggiero, T.Gustafson, T.Lotchin, H.Fox, *Hospitals & Health System: So You Want to Be an ACO? Prospects Improve, but Challenges Remain*, Bloomberg Law (December 27, 2011), *available at* http://wwwbloomberglaw.com/ms/document/X7SME00.

8 Pub. L. No. 111-148, 124 Stat. 119 (codified in scattered section of the Internal Revenue Code and 42 U.S.C.) (hereinafter "the Affordable Care Act").

9 MSSP Rule.

10 *Summary of Final Rule and Guidance for the Shared Savings Program: Accountable Care Organizations*, Gorman Health Group, 2 (December 2011), *available at* http://www.gormanhealthgroup.com/press/ghg-news-announcements/news/GHG%20Summary_CMS%20Final%20Rule%20for%20Medicare%20Shared%20Savings%20Program.pdf.

11 *See* Remarks of J. Thomas Rosch, *Accountable Care Organizations: What Exactly Are We Getting?*, at 3-4, *available at* http://www.ftc.gov/speeches/rosch/111117fallforumspeech.pdf.

12 *See* S. DeSanti, *ACO Antitrust Guidelines: Coordination Among Federal Agencies*, theantitrustsource.com, at 3 (December 2011), *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/dec11_desanti_12_21f.authcheckdam.pdf.

13 For example, on May 10, 2011, the Federal Trade Commission and the Texas Attorney General announced a settlement with a physician network accused of price fixing through collective negotiations with health plans. According to the Complaint, the physicians were not sufficiently integrated as to permit collective non-risk negotiations and their messenger model framework had devolved into prohibited collective negotiations. In re Southwest Health Alliances Inc., Federal Trade Commission File No. 091-0013

14 *See* Kasper, 90 N.C.L. Rev. at 236-240.

15 For the perspective that the antitrust enforcers are more worried that providers will use ACOs as an excuse to grab market power, *see* Code Red blog entry for April 25, 2011, by economist David Dranove of Northwestern University, Kellogg School of Management, *available at* http://dranove.wordpress.com/.

16 Policy Statement at 3.

17 U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy In Health Care, Statements 8 and 9 (1996), *available at* http://www.ftc.gov/reports/hlth3s.pdf.

18 Policy Statement at 3.

19 Rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration's potential pro-competitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws. Policy Statement at 4.

20 1996 Health Care Statements 8 and 9.

21 Policy Statement at 4.

22 *Id*. at 5-6.

23 See Kasper, 90 N.C.L. Rev. at 251.

24 One of the most controversial aspects of the proposed Statement was mandatory FTC/DOJ antitrust approval for certain ACOs. To implement this requirement, the Policy Statement divided ACOs into three categories based on their potential for competitive significance. The determination of the category, which in turn controlled how the ACO would come to qualify as an ACO, was based on the combined share of ACO participants that provide competing services in their "Primary Service Area ("PSA"). Thus, a granular analysis of ACO shares and competitive effects was effectively required as part of every ACO application.

25 Policy Statement at 6 & n24.

26 The Policy Statement emphasizes that non-exclusivity must be factual; for example, exclusivity may be demonstrated by conduct alone. *Id.* at 7-8.

27 *Id*. at 8. In addition, an ACO with a "dominant participant" cannot require a private payer to contract exclusively with the ACO.

28 The rural exception applies when the higher PSA share is caused by the inclusion of only one physician or physician group practice per specialty for each county that contains at least one "isolated rural" or "other small rural" zip code, provided that the participation is on a non-exclusive basis. *Id*. at 8-9.

29 This PSA definition is based on the Stark II regulations. Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,094 (Mar. 26, 2004). *See also* Policy Statement at 15 & n.54.

30 *Id*. at 15-18. The FTC also has set up an email box to which ACOs may send questions regarding PSA share calculations at aco_psa_questions@ftc.gov.

31 The likely cost of the PSA share analysis had been seen as a significant – perhaps fatal – impediment to ACO formation. Under the proposed Policy Statement, every ACO would have had to engage a consultant or economist to perform the analysis, estimated as likely to exceed tens of thousands of dollars for a simple ACO. This significant upfront investment to obtain the antitrust clearance essential for the ACO to form was a significant deterrent to ACO formation, thereby undermining the goals of the Affordable Care Act.

32 *Id*. at 6-7, 10.

33 *Id*. at 10.

34 *Id*. at 10-11.

35 *Id*. at 11-12.

36 *Id*. at 12-14.

37 The agencies have provided FAQs about voluntary expedited review, which may be accessed at http://www.ftc.gov/os/2011/10/111020acofaq.pdf.

38 The Federal Trade Commission's press release (including reference to Commissioner Rosch's dissent) may be found at: http://www.ftc.gov/opa/2011/03/aco.shtm.

39 Remarks of J. Thomas Rosch, *Accountable Care Organizations: What Exactly Are We Getting?*, *available at* http://www.ftc.gov/speeches/rosch/111117fallforumspeech.pdf.

40 *Id*. at 7-8 & n. 21.

41 *Id*. at 3-4, 8-9.

42 *Selected Participants in the Pioneer ACO Model,* Center for Medicare & Medicaid Services (December 19, 2011), *available at* http://www.innovations.cms.gov/documents/pdf/PioneerACO-Descriptions_12_19_11_FINAL_dfedits.pdf.

43 S.Mahinka, J.Everett, A.Shay, D.Brenneman, *FTC/DOJ Final Policy on Accountable Care Organizations: Important Antitrust Issues Remain Uncertain for Healthcare Collaborations*, The National Law Review (December 28, 2011), *available at* http://www.natlawreview.com/article/ftcdoj-final-policy-accountable-care-organizations-important-antitrust-issues-remain-uncerta

ACOs and the Medicare Shared Savings Program: Training Wheels for the Future's Risk Based Environment

by Regina S. Rockefeller

Introduction

Accountable care organizations (ACOs) are a creation of the Patient Protection and Affordable Care Act (Pub. L. 111-148) enacted March 23, 2010 and amended a week later by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152). These two laws together are known as the Affordable Care Act (ACA). Section 3022 of ACA describes ACOs. On April 7, 2011, the U.S. Department of Health and Human Services (HHS) issued hundreds of pages of proposed ACO rules. In response, HHS received 1,320 public comments, many critical.

The Centers for Medicare and Medicaid Services (CMS) became understandably concerned in the summer of 2011 that few health care providers would voluntarily apply to become ACOs. To reignite industry interest in ACOs, CMS issued 696 pages of final interim ACO regulations on October 20, 2011, increasing the financial incentives, reducing the financial risks and easing some compliance burdens for ACOs. HHS will learn in early 2012 (when providers file notices of intent and formal applications with CMS for ACO status) whether these regulatory liberalizations are sufficient to generate widespread voluntary participation by health care providers in non-Pioneer ACOs.[1]

The mounting U.S. deficit, the unsustainable continued growth of health care expenditures in the United States, the disadvantage that these health care costs place on U.S. employers competing in the international marketplace and the growing Medicare-insured population make Track 1 ACOs an attractive experiment worth a closer examination by ACO-eligible health care providers. Track 1 ACOs present a relatively risk-free opportunity for health care providers with robust health information technology systems to learn to navigate successfully from the current predominantly fee-for-service health care environment to the quality-based accountable health care marketplace of the future.

This article discusses the current health care economic environment, how voluntary ACOs are likely to work during the coming three years, and what ACO-eligible providers and their legal advisors should know in deciding whether to participate voluntarily in the Medicare Shared Savings Program.

Historic Growth in U.S. Health Care Costs Is Not Sustainable.

Health care economists and policy analysts agree that the current upward trajectory of our nation's health care spending is not sustainable. In the U.S., we spent $2.6 trillion in 2010, or nearly $8,000 per American, on health care. For the past 30 years, health care costs have grown 2% faster than the overall economy.[2] At this rate, without significant change, by 2035 one of every three dollars would be devoted to health care. This expenditure on health care alone is not sustainable and would competitively hobble the U.S. in the international marketplace.

Aging demographics and the rising U.S. national deficit make inaction in controlling health care costs an option our country and our economy cannot afford. Each day in 2011, seven thousand more individuals turned 65 and became eligible for Medicare, a program to which they contributed with each pay check during their working lives. The day before their 65th birthday, many of these same individuals enjoyed employer-based commercial health insurance. On their 65th birthday, they suddenly became eligible to be insured through Medicare, a program that historically has paid providers less for health care services than commercial insurers. Given this demographic wave of aging baby boomers and our rising national deficit, the United States cannot afford to allow health care expenditures to consume more than 17% of our gross domestic product.

The U.S. Must Control Health Care Expenditures to Remain Internationally Competitive.[3]

Americans spend about 25% more on health care than is spent by some of the most admired health care systems in the world. With a gross domestic product of $2.6 trillion compared to ours of $14.6 trillion, France is the fifth largest economy in the world. We in the United States spend on health care alone what all of the 65 million people of France spend on everything – education, defense, the environment, scientific research, vacations, food, housing, cars, fashion and health care.

The United States spends 35% more per person than the next highest spending countries of Norway and Switzerland. Instead of spending nearly $8,000 per person as the U.S. does, Norway spends $5,352 while Switzerland spends $5,144 in 2009 dollars, the most recent figures available. Even after correcting for the increased cost of brand name drugs in the U.S. and higher compensation for American doctors and nurses, the U.S. still spends 15% more per person on health care than Norway spends per person on health care.

China's gross domestic product stands at $5.9 trillion compared to the $14.6 trillion U.S. gross domestic product. The U.S. population is one-quarter of China's. Yet, Americans spend on health care slightly less than half of what China spends on everything. It is not an exaggeration to say that America's future competiveness in the global economy depends on our collective will to fix our health care payment system.

Higher health care expenditures do not equate with better health. Within the U.S., no clear link exists between higher spending on health care and longer life, less disability or better quality of life. When compared to France and Germany, both countries that spend considerably less on health care, the U.S. compares unfavorably when measured by life expectancy, survival for persons with specific diseases such as asthma, heart disease and some cancers, rates of medical errors and patient satisfaction. As a money saving innovation, can ACOs achieve their triple aim of better care for individuals, better health for populations and reduced growth in Medicare Part A and B expenditures?

How Will ACOs Work?

Through the Medicare Shared Savings Program (MSSP), seven types of health care providers can voluntarily form ACOs and, if the ACO can keep the health expenditures of its assigned population of Medicare beneficiaries below a target benchmark, the ACO will be eligible to earn financial bonuses. As discussed below, these health care entities are referred to as ACO participants. CMS will update this target benchmark annually by the average national growth in per-Medicare beneficiary expenditures. CMS will assign patients to an ACO based on the patients' historical primary care utilization.[4] Structured around primary care providers, ACOs will accept utilization risk for a retrospectively assigned cohort of Medicare patients. While ACO providers (e.g., physicians) will not know with certainty in advance which patients will ultimately be assigned to the ACO, CMS will provide prospective predictive data to ACOs about patients who have historically used the ACO's participating primary care providers. Unless a patient "opts out" of having CMS share his or her claims data with an ACO, as is a patient's right to do, CMS will provide ACOs with regular access to patient data across the entire health care continuum. A primary care physician in an ACO will know not just what services he or she and others in the same group medical practice personally provide to a particular patient but also what other health care services (e.g., specialists, hospitals, pharmacy, physical therapy, imaging, post-acute care, home health, hospice) that same patient has consumed in the preceding calendar quarter.

CMS will calculate the savings to be shared with an ACO based upon the use of health care services by the patients assigned to the ACO. The ACO must notify the patients that they are being treated by an ACO and that the ACO has an incentive to provide improved care coordination and quality. ACO participants must post signs in their facilities informing Medicare beneficiaries that they are being treated by an ACO. At the same time, ACO providers cannot restrict in any way where or how often a patient chooses to obtain care. In an ACO, unlike in managed care, no gate keeper prevents the patient from choosing an expensive and clinically inappropriate care option outside of the ACO. Just as importantly, an ACO cannot "cherry pick" by avoiding Medicare beneficiaries who are "at risk" for incurring high health care costs. [5]

ACOs come in two types. Track 1 offers upside financial potential

to the ACO and no down side risk during the first three years. Track 2 offers down side financial risk in exchange for greater financial rewards. In both tracks, rewards are earned if and only if the ACO satisfies 33 highly specific quality metrics. Thus, to succeed financially, an ACO must deliver high quality, coordinated care.

Forming or Joining an ACO is Voluntary.

ACO formation is entirely voluntary. Health care organizations that are advanced on the clinical integration continuum are considering founding themselves or joining ACOs being formed by or with other providers. Other less clinically integrated health care organizations and providers without access to health information technology will likely remain on the ACO sidelines.

The American Hospital Association estimates that small ACOs will need $5.3M in start-up capital and another $6.3M per year for operating costs. For large ACOs, these AHA estimates jump to $12M and $14M. Where are the sources of accessible capital? "These costs present a degree of risk that many smaller health care entities may be unable to [make.]"[6] Are these capital and operating costs overstated or realistic?

ACOs are Based on Fee-For-Service Reimbursement, Not Capitation.

HHS notes in the summary to the ACO final interim regulations, "Under these provisions, providers of services and suppliers can continue to receive traditional fee-for-service (FFS) payments under Parts A and B and be eligible for additional payments if they meet specified quality and savings requirements."[7] The value based purchasing theory of ACOs is that physicians, hospitals and other health care providers will work together in a coordinated manner to care for a specific population of assigned Medicare patients. Through care coordination, in theory, an ACO may be able to reduce medical errors, avoid duplication of services, avoid unnecessary and comparatively ineffective services, reduce hospital readmissions, re-direct care to less expensive clinical settings than hospitals and hospital emergency departments, encourage and support patients to adopt healthier lifestyles (e.g. weight control, exercise, smoking cessation, better nutrition) and thereby save money for Medicare. To succeed as an ACO, health care participants in an ACO must change from providing health care to the sick to proactively maintaining the health of a population of patients. Medicare will pay a portion of any achieved savings to the ACO. The ACO will then distribute savings to its participants (e.g. physicians), and perhaps to others outside of the ACO as a reward for their reducing health expenditures and providing quality care to the ACO's assigned Medicare-insured patients.

Federal Multi-Agency Collaboration Supports ACO Formation.

To clear the way of feared regulatory obstacles, several federal agencies collaborated and generated ACO-specific guidance. On October 20, 2011, CMS and HHS' Office of the Inspector General jointly published an interim final rule with comment period describing regulatory waivers pertaining to the anti-kickback statutes, the Stark law, beneficiary inducements and gainsharing. In April of 2011, the Internal Revenue Service issued Notice 2011-20 which set forth the IRS' thinking on the participation of exempt organizations in ACOs. The IRS confirmed its adherence to Notice 2011-20 in Fact Sheet 2011-11 issued on October 20, 2011, the same day as the ACO regulations were issued.[8] Finally, also on October 20, 2011, the Federal Trade Commission and the Department of Justice issued a joint Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the MSSP "intended to insure that health care providers have the antitrust clarity and guidance needed to form pro-competitive ACOs that participate in both Medicare and commercial markets."

What is an ACO?

An ACO is a "legal entity that is recognized and authorized under applicable State, Federal or Tribal law, is identified by a Taxpayer Identification Number (TIN) and is formed by one or more ACO participants that is (are) defined at 425.102(a) and may also include any other ACO participants described at 425.102(b)."[9]

Who Can Be an ACO Participant?

An ACO participant is an individual or group of ACO provider(s)/supplier(s), that is organized as a separate legal entity within its own Medicare Enrolled TIN, that alone or together with one or more other ACO participants comprises an ACO, and that is included on the list of ACO participants submitted by the ACO to HHS as part of the ACO's application to become an ACO.

Who Can Be an ACO Provider or Supplier?

An ACO provider or supplier is an individual or entity who is a provider or a supplier as defined in Section 400.202, is enrolled in Medicare, bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO Participant in accordance with Medicare regulations and who is included on the list of ACO providers/suppliers on the ACO application to HHS required under Section 425.204(c)(5).

Who is Eigible to Form an ACO?

Not every player in the health care arena is eligible to form an ACO. For example, health care insurers cannot form an ACO. On their own, hospitals that do not employ ACO professionals cannot form an ACO. Seven specified groups/entities are eligible to form an ACO. These are:

(1) ACO professionals in group practice arrangements. An ACO professional means an ACO provider/supplier who is either:

A physician legally authorized to practice medicine and surgery by the State in which s/he performs such function or action; OR

A practitioner who is one of:

- A physician assistant as defined in 410.74(a)(2)
- A nurse practitioner as defined in 410.75(b)
- A clinical nurse specialist as defined in 410.76(b).

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint ventures between hospitals and ACO professionals.

(4) Hospital employing ACO professionals.

(5) Critical access hospitals that bill under Method II (Section 413.70(b)(3);

(6) Rural Health Centers.

(7) Federally Qualified Health Centers.

Others are eligible to participate in an ACO formed by any of these seven groups/entities.

Must an ACO Be a Separate Legal Entity?

An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants. However, for example, a single group medical practice could itself be an ACO without forming a new legal entity. For liability protection and other reasons, a single medical group practice may wish to consider formation of an ACO legally separate from its existing group practice. An ACO must be a legal entity formed under State, Federal or Tribal law and authorized to conduct business in each state in which it operates for the following purposes:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses (Track 2 only) or other monies determined to be owed to CMS.

(3) Establishing, reporting and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in the ACO regulations.

How large must an ACO be?

An ACO must include primary care physicians or allied health professionals sufficient in number to care for the assigned fee-for-service (FFS) Medicare beneficiaries (minimum 5,000 Medicare FFS beneficiaries per ACO). Only physicians who have a primary specialty designation of internal medicine, general practice, family practice, geriatric medicine or, for services furnished in a federal qualified health center or rural health center, a physician included in an attestation by the ACO will qualify as a primary care physician. If an ACO's total number of assigned Medicare beneficiaries dips below 5,000, CMS will issue a warning and place the ACO on a corrective action plan. If at the end of the next performance year, the ACO is still below 5,000 Medicare beneficiaries, then the ACO's agreement with CMS will be terminated and the ACO will not be eligible to share in savings for that next performance year.

An ACO must be willing to be accountable for quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. An ACO must enter into an agreement with CMS to participate in the Shared Savings Program for not fewer than three years, subject to the right of the ACO to terminate that agreement on 60 days' notice. This ability of the ACO voluntarily to terminate its participation in the Medicare Shared Savings Program on short notice is an important escape hatch and should make entering

the MSSP program less risky and more attractive to health care providers.

CMS Imposes ACO Governance and Leadership Requirements.

An ACO must have an identifiable governing body with authority to execute the functions of an ACO including having processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.[10] The ACO's governing body is responsible for oversight and strategic directions of the ACO and is charged with holding the ACO's management accountable for the ACO's activities. That governing process must be transparent. Members of the governing body have a fiduciary duty to the ACO and must act consistently with that duty rather than in their own self-interest or that of their employers. Where an ACO consists of multiple, otherwise independent, ACO participants, then the governing body must be separate and unique to the ACO. If the ACO is an existing entity, e.g., a group medical practice, then the ACO governing body can be the same as the governing body of the existing legal entity.[11]

ACO participants or their representatives must have meaningful participation in the composition and control of the ACO's governing body.[12] With certain permitted exceptions, the ACO's governing body must include a non-conflicted Medicare beneficiary who is served by the ACO and the ACO participants must control 75% of the ACO's governing body. Members of the governing body may also serve in similar capacities for an ACO participant. For example, the President of a group medical practice could also serve on the Board of the ACO.

An ACO must adopt and enforce a conflict of interest policy applicable to its governing body. Each member of the governing body must disclose relevant financial interests pursuant to the ACO's procedures and policies for determining and handling conflicts of interest. Failure to comply with the ACO's conflict of interest policy must result in the ACO's taking remedial action against the offender.

The ACO must have clinical and administrative systems that promote the triple aim of better care for individuals, better health for populations, and lower growth in expenditures. A manager must manage the ACO operations, subject to appointment and removal by the ACO's governing body. Clinical management and oversight must be managed by a senior level medical director who is a physician, is one of the ACO providers/suppliers, and is physically present on a regular basis at an ACO participant's location. Note that the ACO itself need not have a dedicated location. Each ACO participant/provider and supplier must demonstrate a "meaningful commitment" to the ACO's mission. CMS has not yet explained in the ACO regulations how that meaningful commitment is to be demonstrated.

The ACO's focus must be "patient-centeredness." The ACO must promote patient engagement by conducting patient experience surveys and, in most cases, having a Medicare/ACO beneficiary serve on the ACO's governing board. The ACO must evaluate the health needs of the ACO's population by partnering with community stakeholders. ACOs must communicate clinical knowledge and evidence-based medicine to Medicare beneficiaries in a way understandable by the beneficiaries. The ACO must take into account the unique needs, preferences, values and priorities of its assigned beneficiaries and involve them in shared clinical decision-making.[13]

Each ACO is charged with developing an infrastructure for ACO participants/providers and suppliers to internally report on quality and cost metrics. This infrastructure is to be designed to enable the ACO to monitor, provide feedback and evaluate the ACO's participants/providers' and suppliers' performance to improve patient care over time. This ongoing self-monitoring will require a substantial investment in health information technology by the ACO.

Coordination of care is critical to the generation of shared savings. Care is to be coordinated throughout an episode of care, such as a hip replacement, and during transitions, from hospital to primary care physician, to specialists, both inside and outside the ACO. Remember an ACO cannot restrict a patient's choice to the ACO's own providers. As part of its application to CMS, a prospective ACO must submit a description of its individualized care program, with sample individual care plan and explain how it will be used to promote improved outcomes, at a minimum, for high risk and multiple chronic condition patients and describe additional target populations that are expected to benefit from individualized care plans. ACOs may choose to tackle the so-called "dual eligibles," that is, patients who are eligible for Medicare due

to advanced age or disability and who are also low income so as to be insured through Medicaid. Dual eligible patients consume health care at a much higher rate than higher income patients.

Prospective ACOs must formally apply to CMS.

An ACO must submit a completed application to CMS by the deadline established by CMS. An ACO must certify that it, its participants, and its providers/suppliers have agreed to become accountable for quality, cost and overall care of Medicare beneficiaries to be assigned to the ACO. The ACO applicant must also disclose any prior participation of these same players in another shared savings program.

With its application, the ACO must submit to CMS supporting materials to demonstrate that the ACO satisfies all ACO eligibility requirements. These documents must describe the ACO participants' and providers/suppliers' rights and obligations in and representation by the ACO, including how the opportunity to receive shared savings or other financial arrangements will encourage them to adhere to a quality assurance and improvement program and evidence-based clinical guidelines. The application must describe how the ACO will implement the required processes and patient centeredness including remedial processes and penalties for non-compliance.

The ACO must submit its participation agreements, employment contracts, operating policies, organizational charts, management structure, list of committees and names of committee members, compliance plan, list of all ACO participants with the Medicare enrolled TINs and designate which of these participants are primary care physicians. The applicant must show that the governing body of the ACO is an identifiable body comprised of representatives of the ACO's participants and that those participants have at least 75% control of the governing body.

Though there is some flexibility on this point, the ACO should ideally be able to show that its governing body includes a Medicare beneficiary served by the ACO who does not have a conflict of interest with the ACO and who has no immediate family member with a conflict of interest with the ACO. For example, that Medicare beneficiary should not be the ACO President's mother.

The application submitted to CMS must include a copy of the ACO's compliance plan. CMS can request additional documents relating to the ACO's formation and operation, such as Articles of Organization, corporate bylaws, and financial statements. The application must include resumes and other documentation required for ACO leaders. An ACO can request exceptions to the governing body requirements and leadership and management requirements. Additional ACO eligibility requirements also apply, including requirements pertaining to ACO marketing materials and activities.

Importantly, the ACO's application to CMS must describe:

(1) How the ACO plans to use shared savings payments, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.

(2) How the proposed plan will achieve the specific goals of the Shared Savings Program.

(3) How the proposed plan will achieve the triple aims of better care for individuals, better health for populations, and lower growth in expenditures.[14]

ACOs Come in Two Alternative Tracks.

An ACO applicant must select one of two tracks. Under Track 1, the ACO will be eligible for savings but not responsible for losses for at least three years so there is no downside financial liability risk for the ACO. Under Track 2, the ACO is eligible for greater savings but will also be responsible to CMS for losses so Track 2 ACOs face downside liability risk. Track 1 may be a reassuring way for an ACO to improve its care coordination and quality performance skills. Track 1 is a bit like a bicycle with training wheels. The rider won't fall over but the training wheels will slow the ride. Under Track 2, the training wheels are off, the rider can go faster but risks falling over and painfully skinning knees and elbows.

For an ACO to qualify for a shared savings payment under Track 1, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable benchmark by at least the minimum savings rate (MSR) established for the ACO. The MSR is a sliding scale ranging from 3.9% to 2% depending on the number of Medicare beneficiaries assigned to the ACO. Under Track 1, the shared savings payment is 50% of all savings under the updated benchmark but capped at 10% of the updated benchmark itself.

Some ACOs May be Eligible for an Interim Advance Payment.

If an ACO chooses a start date of April 1 or July 1, 2012, then the ACO may, as part of its ACO application, request an interim payment calculation based on the anticipated financial performance for its first 12 months of program participation and quality performance for calendar year 2012. This advance payment may enable physicians to assume the challenge of ACO formation without the involvement of hospitals with their traditionally greater access to capital. "The Advance Payment Initiative allows ACOs without large inpatient facilities to receive upfront pre-payments of expected shared-savings returns to help defray investment costs and smooth cash flow concerns. Physicians-only ACOs represent a potential threat to hospitals, raising the specter that physicians will work to destroy inpatient demand while the hospital shares no part of the reward. This risk brings some urgency to the decision by hospitals whether to invest in building a performance-focused physician network."[15]

CMS Will Calculate the Shared Savings.

How will CMS determine whether there are savings to share with the Track 1 ACO? CMS will determine whether the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services are *below* the applicable updated benchmark determined under Section 425.602.

To calculate the shared savings and losses for a Track 2 ACO, CMS will determine for each performance year whether the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B are above or below the updated bench mark by the minimum savings or loss rate determined under Section 425.601. If below (good news) then the ACO will share up to 60% of all savings but not more than 15% of its updated benchmark. If above (bad news), then there won't be any savings for the ACO to share. Instead, there will be losses for the ACO to share with Medicare. The Track 2 ACO must make payment to CMS in full within 90 days of receipt of notification from CMS. Loss recoupment is, fortunately, limited to 5% of the updated benchmark in the first year, 7.5% in the second year and 10% in the third and subsequent performance years.

A Track 2 ACO must have the financial ability to repay losses for which it may become liable, as well as any other monies determined to be owed upon the first performance year reconciliation equal to 1% of the ACO's total per capita Parts A and B FFS expenditures for the assigned Medicare beneficiaries. An ACO can meet the financial reserve requirement by obtaining reinsurance, maintaining escrow funds, obtaining surety bonds or lines of credit, or another appropriate mechanism. A new ACO with no financial track record may have difficulty qualifying for these credit enhancing mechanisms in today's constrained lending market. In addition, in some states, a Track 2 ACO may be subject to state insurance laws because it is assuming financial risk.

All ACOs Must Enter into a Participation Agreement with CMS.

Each ACO must enter into a participation agreement with CMS for not fewer than three years. That agreement can start April 1, 2012, July 1, 2012, January 1, 2013 or each January 1st thereafter. For each year, ACOs must submit performance on measures in the form and manner required by CMS.

Transparency is a prevailing value of ACOs. An ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers and other individuals and entities involved in ACO governance. In its contracts between and among the ACO, its participants, providers/suppliers and others performing functions or services related to ACO activities, the ACO must require compliance with the requirements of the Medicare Shared Savings Program.

An ACO Can Change During the Term of its CMS Participation Agreement.

ACO participants and providers/suppliers may change during the three year term of an ACO's participation agreement with CMS. ACOs must notify CMS within 30 days of the addition or removal of an ACO participant (e.g., physician) or provider/supplier (e.g., rehabilitation hospital). Based on these changes, CMS may adjust the ACO's benchmark, risk scores and preliminary prospective assignment of Medicare beneficiaries. For example, if a primary care physician participating in an ACO retires, CMS may re-assign his or her preliminarily assigned Medicare beneficiaries to another ACO that includes the primary care physicians who have recently accepted the retired primary care physician's Medicare patients.

The ACO has the obligation of notifying CMS if an ACO no longer meets eligibility or program requirements, also known as a "Significant Change." If a "Significant Change" occurs, several options exist. CMS can allow the ACO to continue to operate under its new structure, terminate the ACO agreement with CMS and require the ACO to submit a new ACO application to CMS, terminate an ACO if it no longer meets eligibility criteria, or the ACO and CMS can terminate the ACO's participation agreement by mutual consent. Thus, the ACO itself should proactively monitor its continuing eligibility as an ACO.

CMS has discretion to take less draconian actions prior to terminating the ACO's participation in the Medicare Shared Savings Plan. CMS can issue a warning notice regarding non-compliance with one or more program requirements, request a corrective action plan (CAP) from the ACO and thereafter monitor compliance with the CAP, or place an ACO on a special monitoring plan.

In the event of the ACO's failure to comply with the Medicare Shared Savings Program requirements, CMS can terminate the ACO on 60 days' notice. Grounds for termination by CMS include:

(1) non-compliance with ACO eligibility or other requirements;

(2) imposition of sanctions or other actions taken against an ACO by an accrediting organizations, State, Federal or local government agency leading to an inability to comply with the Medicare Shared Savings Program requirements; or

(3) violation of the Stark self-referral law, Civil Money Penalties, Anti-Kickback Statutes, anti-trust or any other Medicare laws, rules or regulations relevant to ACO operations.

If an ACO terminates its participation on 60 days' notice, the ACO will not share in any savings for the performance year during which the ACO notifies CMS of its decision to terminate its participation agreement. Thus, an ACO's decision to terminate participation in the Medicare Shared Saving Program should be carefully timed so as not to forfeit savings earned in a final performance year. A voluntarily or involuntarily terminated ACO can again participate in the MSSP only after the date that the original three year agreement would have expired, had it not been prematurely terminated. Unless the agreement was terminated less than half way through its original term, a previously Track 1 model ACO may only reenter as a Track 2 ACO. A Track 2 model ACO can only re-enter as a Track 2 ACO.

ACOs Must Satisfy 33 Quality Measures in 4 Domains.

For an ACO to be eligible to receive any shared savings, an ACO must demonstrate that it has satisfied quality performance requirements as well as met all other applicable ACO requirements. Pay for quality measure performance will be phased in over three years, with payment solely for reporting in year 1, a mixture of pay for reporting and pay for performance in year 2, and in year 3 only pay for performance.

Quality measures fall into four equally weighted domains whose scores CMS will average to determine the ACO's overall performance score and shared savings rate. These four domains are:

(1) Patient/Caregiver Experience based on CMS-certified vendor surveys in 2014 and later;

(2) Care Coordination/Patient Safety;

(3) Preventive Health; and

(4) At-Risk Populations.

The first two domains are designed to assess whether the ACO is providing better care for individuals, which is the first aim of the triple aim of the Medicare Shared Savings Program. Six measures of Patient/Caregiver Experience domain will be assessed based upon externally conducted patient surveys, asking such questions as:

(1) Do you receive timely care, appointments and information?

(2) How well do your doctors communicate with you?

(3) How well do you rate your doctor?

(4) Do you have satisfactory access to specialists?

(5) Do you receive satisfactory health promotion and education from your ACO?

(6) Are you able to share in clinical decision making about your care?

Health and functional status will also be measured and reported in this domain.

Unless patients award satisfactory ratings, an ACO will not share in any savings. Thus, having too

many grumpy patients may defeat an ACO's entitlement to any shared savings. Recent research has indicated that, out of 295 hospital markets, those with the least satisfied patients were:

› Manhattan, the Bronx and East Long Island, N.Y. (Red Sox fans are not surprised.)
› Newark and Paterson, N.J.
› Takoma Park, Md.
› Chicago, IL
› Fort Myers and Ocala, FL.[16]

Jordan Rau of The KHN Blog for Kaiser Health News speculated about why New Yorkers rate their health care so harshly. He blamed the low ratings on New York's old, cramped hospital buildings, double-occupancy patient rooms, the mix of poor patients in bad health with wealthy entitled patients, the frenetic environment of teaching hospitals with multiple residents and specialists poking at patients and, perhaps most importantly, the New York cultural norm that encourages individuals loudly to voice dissatisfaction. Because low patient satisfaction can prevent an ACO from receiving any Medicare Shared Savings Payments at all, New York ACOs will face the added challenge of addressing this cultural norm to achieve satisfactory patient scores.

The second domain of Care Coordination/Patient Safety assesses five measures:

(1) Risk standardized, all condition readmissions to hospitals;

(2) Ambulatory sensitive condition, admission of Chronic Obstructive Pulmonary Disease (COPD) and Congestive Heart Failure (CHF);

(3) Percentage of primary care physicians who qualify for an electronic health record incentive payment;

(4) Medication reconciliation after discharge from an inpatient facility; and

(5) Screening for fall risk.

The second of the triple aim of the Medicare Shared Savings Program is better health for populations. To assess whether the ACO is achieving better health for populations, the third domain of Preventive Health will measure:

(1) Influenza immunization;
(2) Pneumococcal vaccination;
(3) Adult weight screening and follow-up;
(4) Tobacco use assessment and cessation;
(5) Depression screening;
(6) Colorectal screening;
(7) Mammography screening;
(8) The proportion of adults 18+ years who had blood pressure measured within the preceding 2 years.

The fourth quality domain addresses At Risk Populations. Six quality measures within this fourth domain relate to diabetes management. [17]

ACOs must report all measures within each of the four domains. Each quality measure will receive a score. Individual scores are converted into a quality score for each of 4 domains. Scores across the 4 domains determine the amount of shared savings an ACO will receive (i.e., 50% in the Track 1 model or 60% in the Track 2 model). [18] An ACO must score above the minimum attainment determined by CMS on 70% of the measures in each of the four domains. If not, then CMS can take certain termination and/or sanction actions against the ACO. The minimum attainment level is set at 30% or the 30th percentile of the performance benchmark. CMS can audit and validate data provided by the ACOs. No credit will be given for a particular quality measure if a CMS audit shows a discrepancy in excess of 10%.

ACOs will, as a practical matter, be compelled to use health information technology (HIT) to glean information efficiently from electronic health records for each of the 33 quality measures. With a minimum of 5,000 Medicare beneficiaries in each ACO and 33 separate quality measures, HIT is critical to reporting efficiently on these quality metrics. While the final interim proposed ACO regulations do not explicitly require any level of electronic health record implementation, without HIT, quality reporting would, as a practical matter, be impossible.

Track 1 ACOs Offer Providers a Low Risk, Reward Opportunity.

The final question, of course, is: should your health care clients who are eligible to form or join an ACO do so? The Advisory Board, a prestigious Washington, DC health care think tank, recently counseled its membership:

> In summary, ACO success hinges on development of a transformed care delivery infrastructure. Organizations without the necessary physician relationships, IT platforms, or medical management capabilities will likely find it challenging to even qualify for SSP [Shared Savings Program], let alone achieve a savings payout. Those organizations should

delay SSP participation until they have developed the requisite capabilities of an ACO.

On the other hand, many organizations have already invested extensively in care management infrastructure. Often this investment has been made in advance of external reimbursement – preparing to compete in a risk based environment, but still acting squarely in the fee-for-service world.[19] These organizations achieve cost and quality improvements, but risk undermining their own financial success in the process. For this group, SSP participation represents an opportunity to move the dial, allowing them access to a major reimbursement stream designed to reward them for their early embrace of care transformation principles.[20]

As a country with a growing national deficit and a rapidly aging population of baby boomers, we cannot afford to continue to pay for health care as we have been doing since Medicare was established in 1965. These next three years offer participants within Track 1 ACOs the opportunity to learn how to manage health care in a relatively protected environment. At some point soon, all providers may be compelled to keep total health expenditures for the Medicare population below a target benchmark or suffer the financial consequences of exceeding those benchmarks. Practicing how to manage expenditures during the coming three years may well be to the long term economic advantage of those who join or establish ACOs now. If the goal is to learn to ride confidently in the risk based environment of the future, then ACOs may today provide helpful training wheels.

(Endnotes)
1 CMS has recently named 32 so-called Pioneer ACOs, five of which are based in Massachusetts. The discussion of Pioneer ACOs is beyond the scope of this article.
2 Id.
3 This section on international competitiveness relies heavily upon the opposition editorial of Ezekiel J. Emanuel, M.D., New York Times, October 30, 2011.
4 Assignment of Medicare beneficiaries to an ACO is a two-step process. First, if a Medicare beneficiary has used a primary care physician during the relevant performance year, then CMS will use a plurality of allowed charges for services rendered by all primary care physicians and will assign that Medicare beneficiary to the ACO that includes the primary care physicians who rendered that plurality of primary care services. Florida snowbirds that winter in Florida but live nine months of the year in Massachusetts, for example, might be assigned to an ACO in Florida if they use less primary care in the summer. Secondly, if a Medicare beneficiary has not used any primary care physician at all during a performance year, then CMS will use the plurality of charges for services rendered by any other ACO professional in determining the ACO to which to assign this patient. CMS will assign beneficiaries in a preliminary manner at the beginning of the year based on the most recent 12 months of available data. CMS will then perform a retrospective reconciliation of those preliminary assignments based on the most recent 12 months of data.
5 The ACO regulations do not define "at-risk beneficiaries." However, based on the preamble to the proposed ACO rule and some clarification in the final ACO rule, "at-risk beneficiaries" is likely to include those who have a high risk score on the CMS-HCC risk adjustment model, have two or more hospitalizations or emergency department visits each year, are dually eligible for Medicare and Medicaid, have a high utilization pattern for health care services, have one or more chronic conditions such as diabetes, congestive heart failure, coronary obstructive disease or other chronic conditions, are entitled to Medicare not because of their age but because of their disability, and those with mental health or substance use disorders.
6 Health Capital Consultants, St. Louis, Mo.
7 HHS Summary, ACO Final Rules, issued 10/20/2011.
8 Discussion of these ACO related pronouncements by other agencies is beyond the scope of this article. For further information, see "FAQs on the final ACO regulations" posted December 28, 2011 at NixonPeabody.com.
9 Section 425.20.
10 Section 425.106.
11 Id.
12 Id.
13 Section 425.112.
14 Section 425.204(d).
15 Health Care Advisory Board, The Medicare Shared Savings Program Rulebook, *Analysis of the Final Rule and Strategic Implications for Providers,* p. 53 (2011).
16 *Kaiser Health News* analysis of Medicare data, 11/8/2011.
17 The first is the Diabetes Composite that will measure hemoglobin A1c Control, low density Lipoprotein, blood pressure, tobacco non-use and aspirin use. The second measure pertains to Diabetes Mellitus and hemoglobin A1c Poor Control. Other measures with the At Risk Populations domain include blood pressure control for hypertension, for ischemic vascular disease the complete lipid profile and LDL control and use of aspirin or another antithrombotic and for heart failure, Beta blocker therapy for left ventricular systolic dysfunction.
18 Additional percentages may be available if an ACO includes a Regional Health Center or Federally Qualified Health Center.
19 The Advisory Board calls this phenomenon having "a foot in two boats." One boat is fee-for-service reimbursement that rewards increasing volume. The other boat, the Shared Savings Plan, requires the reduction of volume. As any sailor knows, there is no less secure stance than having a foot in two boats.
20 The Medicare Shared Savings Program Rulebook, *Analysis of the Final Rule and Strategic Implications for Providers*, The Advisory Board Company, 2011, p. 58.

Sunshine Is On the Way: Federal Reporting Law Proposed Rule

by William A. Mandell

The "Sunshine Law" provisions of the Affordable Care Act ("ACA")[1] establish the first ever national public reporting system of pharmaceutical and medical device company payments to physicians and teaching hospitals. This federal law preempts to a significant extent the Massachusetts gift ban/public reporting law.[2] The exact level of pre-emption, however, cannot be known until final regulations are promulgated under the Sunshine Law.

The United States Centers for Medicare and Medicaid Services ("CMS") proposed rule to implement the Sunshine Law[3] does shed some more light on the scope of this national reporting system and its preemptive effect. Nevertheless, CMS is still undergoing an extensive process of soliciting public comments on how best to implement the federal reporting system within the parameters established by Congress. This is clearly a massive undertaking, and as summarized below, the Proposed Rule leaves much to be determined at a later point by CMS.

Overview of the Sunshine Law

The Sunshine Law establishes U.S. policy on the regulation of the independence of clinical, academic and research activities in medicine and conflicts of interest arising from industry financial relationships. This policy does not limit physician and hospital relationships with pharmaceutical, device and biotech companies beyond the limits already imposed by existing federal fraud and abuse laws, such as the anti-kickback statute.[4] It is intended to use the transparency of public disclosure, via a national searchable database, to expose those financial relationships – regardless of their compliance with legal and ethical standards - to the light of day.

The Sunshine Law requires payments or transfers of $10 or more[5] made by pharmaceutical, medical device and biotechnology manufacturers operating in the U.S. or its territories to physicians[6] or teaching hospitals to be tracked and reported to the United States Department of Health and Human Services ("HHS"). In addition, the Sunshine Law requires tracking and reporting to HHS payments and other transfers to physicians (or their designees) who have an ownership or interest in Group Purchasing Organizations ("GPOs").

ACA mandates that the reported information, identifying the recipient, amount, and nature of each payment, become part of an on-line searchable and downloadable public database to "go live" on September 30, 2013.

Based on the Proposed Rule, here is a summary of what is certain (and what is still to be determined) about the scope of mandatory reporting and its preemptive impact on existing state laws, such as the Massachusetts Gift Ban and reporting law.

Who Has to Track and Report Data?

The Proposed Rule defines "applicable manufacturer" very broadly to include any company which operates in the United States, or a U.S. territory, possession, or commonwealth, and is engaged in the production, preparation, propagation, compounding, or conversion of a drug, device, biological, or medical supply that is reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program.

This broad definition would subject companies that are located and/or produce products outside of the U.S. to the reporting requirements if they sell just one product that is reimbursable under the federal programs in the U.S.

CMS is also covering any company under "common ownership" that assists a manufacturer in the distribution or marketing of a drug or device, but has not expanded the mandate to independent distributors or marketing companies.[7]

What Transactions Must be Reported Under the Sunshine Act?

Under the Sunshine Law and the Proposed Rule, covered manufacturers will be required to track and report to HHS the following information for each reportable

payment or transfer on an annual basis:

(1) The recipient's name.

(2) The business address of the recipient and, if the recipient is a physician, his or her specialty and National Provider Identifier ("NPI").

(3) If the company is aware that the payment will be indirectly provided to a physician, the name of the entity physician.

(4) The amount of the payment or other transfer.

(5) The date on which the payment or other transfer was provided.

(6) A description of the form of the payment or other transfer.

(a) cash or a cash equivalent;
(b) in-kind items or services; or,
(c) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Although the Sunshine Law authorized HHS to establish other forms of payment to be reported, CMS did not add any forms of payment in the Proposed Rule beyond those outlined in the statute because it believes what is provided in the statute is sufficient to describe payments and other transfers of value. However, CMS asked for comments on whether other categories are necessary or would be helpful. CMS's apparent intent to stick to the statute's scope of required information about each reportable payment is a welcome development.

The nature of the payment or other transfer of value must also be disclosed as:

(a) consulting fees;
(b) compensation for services other than consulting;
(c) honoraria;
(d) gifts;
(e) entertainment;
(f) food;
(g) travel (including the specified destinations);
(h) education;
(i) research;
(j) charitable contribution, defined by CMS to be those made to a Section 501(c)(3) organization;
(k) royalties or licenses;
(l) current or prospective ownership or investment interest;
(m) direct compensation for serving as faculty or as a speaker for a medical education program;
(n) grant; or
(o) any other categories to be later designated by HHS.

CMS proposed that each payment or transfer be reported separately, but asked for public comment on whether aggregated reporting could be used. It will be helpful if CMS can provide in the final rule further explanation and details on what it intends to be captured by requiring disclosure of "prospective" ownership or investment interests.

As to food, CMS wants manufacturers to take the total amount of the food provided to medical groups at their offices and divide it by the number of physicians in the group and require a report on each physician, even if some of the group physicians did not come to the meeting and/or partake of the meal. Thus a food spread worth $30 provided by a drug company representative to a practice with three doctors would result in a Sunshine Law report of a $10 food item being given to each of the three physicians under CMS's proposed reporting rules even if only one of them actually attended the meeting and ate.

Such an approach could result in a very extensive and costly internal tracking mandate for reporting companies, and more extensive disclosures and listings for physicians, especially those in larger groups that have more frequent visits by company representatives where food is supplied. This approach would also make it impossible for physicians who elect not to partake in company programs and food offerings to avoid public listing as a recipient of company-provided meals. This does not seem to be a fair and equitable way to achieve accurate public reporting.

Payments and transfers not provided to a physician directly are still reportable if the company was aware that the payment will be indirectly provided to the physician, CMS suggests that the "awareness" standard should be based on the Federal False Claims Act standard. This would apparently trigger a reporting requirement if the company, or its employees or agents, knew or should have known a payment would be provided indirectly to the physician. This indirect reporting standard may open up to public disclosure payments made by companies to health care facilities, medical schools, group practices, and CME companies that may in some way be used to help underwrite the activities of particular physicians in

their clinical and research and teaching activities.

The Sunshine Law will also require disclosure of the name of the drug, device, biological, or medical supply if the reportable payment or other transfer of value is related to marketing, education, research specific to a covered drug, device, biological, or medical supply.

CMS proposed that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported as required under the Sunshine Law regardless of whether the particular payment or other transfer of value "is associated" with a covered drug, device, biological, or medical supply. CMS did not provide any meaningful guidance or explanation as to what point a payment or transfer is sufficiently "associated" with a product to trigger a required report.

Also, in the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient (e.g., a payment made to a charitable disease organization at the request of a physician), the applicable manufacturer would be required to disclose that payment or other transfer of value under the name of the covered recipient.

To What Extent Will State Laws Regulating Industry Financial Transactions and Reporting Be Pre-Empted?

The federal Sunshine Law preempts any state statute or regulation that requires any entity that meets the federal definition of "manufacturer" to disclose or report, in any format, the type of information reportable to HHS regarding payments or other transfers of value to physicians or teaching hospitals worth over $10.

Under the Sunshine Law, any state law that requires manufacturers to disclose or report the same type of information that is reportable to HHS is preempted. It does not preempt any state laws that require the disclosure or reporting of information that is not reportable under the Sunshine Law database or that cover a broader category of reporting parties or recipients than defined under the ACA and the CMS Rule.

Based on the ACA and the Proposed Rule, the Massachusetts law will be preempted only to the extent that the Massachusetts law requires tracking and reporting of "sales and marketing activity"[8] interactions with Massachusetts physicians or teaching hospitals that are reportable to HHS under the Sunshine Law.

The Sunshine Law does not preempt any state laws that require the reporting of information that is exempt or not subject to reporting under the federal law. Thus, the Massachusetts reporting system can continue to require the reporting of:

- Sales and marketing activity from independent distributors that take title (as opposed to consignment) to products;

- Sales and marketing activities with non-physician licensees who are authorized to prescribe, as well as with non-teaching hospitals, nursing homes and pharmacists;

- Sales and marketing activities that are exempt from the Sunshine Law[9] – but the interplay between activities that are exempt from Sunshine but still reportable to DPH are not exact and require careful analysis.

Furthermore, there is no preemption of state laws that require reporting to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

The Sunshine Law and CMS Proposed Rule do not alter the duty of manufacturers and distributors, subject to the Massachusetts law, to adopt and comply with a compliance program and a Marketing Code of Conduct that conforms to the DPH regulations, 105 CMR 970.000,[10] and annually submit compliance plan information and certifications to DPH.

Massachusetts, and other states, will continue to be able to pass state laws prohibiting and regulating interactions between industry and health care providers that do not involve governmental or public disclosure without any level of federal preemption.

The Massachusetts limits on company gift-giving to physicians – which is not a total gift ban as it permits certain educational items worth less than $100 – or the Massachusetts requirements for permissible consulting and other service relationships will not preempted. The Massachusetts law is more than a "gift

ban." It requires drug and device manufacturers and distributors to enact and follow a stringent compliance plan and code of conduct covering financial interactions with physicians and other prescribing health professionals.

The reporting system under the Massachusetts law will be dramatically preempted by the Sunshine Law. The DPH public database, which has been operational since 2010, does require reporting of financial transactions that substantially overlap with those also required to be reported under the Sunshine Law. The preempted transactions appear to be those that come within the definition of "sales and marketing activities" under the DPH regulations that are made to Massachusetts licensed physicians, dentists, podiatrists, optometrists or chiropractors. Payments or items of value worth $50 or more made to other Massachusetts licensees who can prescribe would not be preempted.

On December 28, 2011 DPH did issue a guidance letter to Pharmaceutical and Medical Device Manufacturers in reaction to the CMS Proposed Rule. In the letter DPH acknowledges the Sunshine Law's inevitable pre-emptive effect on Chapter 111N and its own regulations that require "the collection and reporting of the same data elements . . ." as the Sunshine Law. Noting the CMS delay under the Proposed Rule of the effective date for the collection and reporting of data under the Sunshine Law, DPH stated in relevant part that:

> Until CMS publishes a final rule and certain Massachusetts requirements are preempted, pharmaceutical and medical device manufacturing companies must continue to collect and submit disclosures on all covered recipients as currently defined under the law, including physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, all hospitals, nursing homes, and all other purchasers, prescribers, or dispensers of drugs, biologics, or medical devices.[11]

DPH further noted in this letter that all other requirements under 105 CMR 970.000 remain in effect, and that the annual registration requirement and associated fee submitted to DPH and the annual self-audit will not be pre-empted by the Sunshine Act. Furthermore, DPH confirmed that the mandatory marketing Code of Conduct established under Chapter 111N and 105 CMR 970.000 "remains in effect and will not be altered by federal preemption."[12]

Thus, DPH has confirmed that it intends to continue to impose the annual fee of $2,000 on companies that are subject to the reporting obligations under Massachusetts law, whether they actually file any reports to DPH or not.

How Does the Sunshine Law Treat Research Differently Than the Massachusetts Law?

The possible preemption and differing approaches toward research relationships is of great importance to Massachusetts health lawyers due to the prevalence of teaching hospitals, research centers and product development in Massachusetts. Under the current Massachusetts reporting system, DPH exempts otherwise reportable financial relationships if they involve clinical trials[13] or genuine research.[14] The Sunshine Law does not exempt research related relationships from tracking and disclosure.

Thus, manufacturers will be required to track and report to HHS any payment or transfer of value worth $10 or more related to research or pre-market approval activities. However, such reported interactions do not immediately become public. Information submitted to HHS with respect to a payment or other transfer of value made pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology; or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply; or in connection with a clinical investigation regarding a new drug, device, biological, or medical supply; is reportable to HHS annually, but will not be made immediately available on the public database.

Under the Sunshine Law such research-related payments and transfers of value become public on the earlier of the FDA approval date, or four calendar years after the date such payment or other transfer of value was made. During the non-public phase of such reported data, the information in the hands of HHS is not subject to the Freedom of Information Act.

CMS's proposal limits reportable research-related payments to bona fide research activities,

including clinical investigations that are subject to a written agreement between the applicable manufacturer and the organization conducting the research, as well as a research protocol.

The Proposed Rule also addresses indirect research payments, including those made by a manufacturer (or a contract research organization on its behalf) to a clinic, hospital or other research institution, which in turn pays one or more physicians to act as principal investigator(s). Such indirect research payments are reportable under the principal investigator's name and NPI, and CMS has proposed that both indirect and direct payments be reported in the aggregate, but to avoid any misleading public information is suggesting it will not include indirect research payments under the physician's public database listing.

It must be questioned whether the Sunshine Law's research reporting requirements (that go beyond Massachusetts obligations under Chapter 111N) could undermine the collaboration of industry and academia, as many teaching hospitals and faculty may steer away from arrangements that may become public. Clearly, the possible undesired side effects of the Sunshine Law's mandate on public disclosure of research funding should be tracked to see if this new law has any deleterious effect on bio-technical research and medical innovation.

CMS is seeking further comment and hopefully it will clarify how and to what extent reported research payments will be publicly disclosed.

What Else Has CMS Told Us Under the Proposed Sunshine Rule?

The deadlines to start tracking transactions and filing reports to CMS for 2012 payments and transfers are likely to be changed. CMS is seeking comment on whether the March 31, 2013 reporting deadline established in the statute is still feasible given that the final rule may not be issued until the later part of 2012.

The delay by CMS in issuing Sunshine Law regulations has also impacted the date when companies must start tracking their interactions with health care providers for ultimate reporting. While the Sunshine Law requires certain manufacturers and group purchasing organizations ("GPOs") to start collecting reportable information as of January 1, 2012, the commencement date has now been delayed due to the late arrival of the CMS Proposed Rule. In the Proposed Rule, CMS granted manufacturers, distributors and GPOs a reprieve from starting their mandated data collection efforts until 90 days after the publication of the final CMS Rule, expected sometime later in 2012.

The Sunshine Law grants reporting companies and recipients an opportunity to review and submit corrections to the information submitted for at least 45 days prior to such information being made available to the public. CMS has proposed that this 45 day period for reporting entities and physicians to review submitted reports for errors prior to its public release can cover both current and previous year data. For data disputed by a physician, CMS suggests that the physician directly contact the reporting company to first try to reconcile the dispute. If the dispute cannot be resolved within the 45 day period, CMS further suggests in the Proposed Rule that both versions of the disputed information be made available on the public website. While the final rule should have a more definitive process for handling disputed information, CMS has made clear that it does not intend to try to arbitrate any such disputes between reporting manufacturers, GPOs and physicians.

CMS has not fully explained how it will provide for prior review effectively and accurately in this short time period in view of the enormous number of hospitals and physicians who may dispute information in the public database. CMS will need to adopt a notational or rebuttal process much like is used with the National Practitioner Data Bank, in which both company and recipient get to post their version of the facts.

Who Could Find Themselves Named in the Database as Recipients?

The CMS Proposed Rule follows the Sunshine Law definition of "physician" and includes any medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist or chiropractor who is legally authorized to render services within the scope of his or her license.

"Teaching hospital" (which had not been defined in the Sunshine Law) is defined in the Proposed Rule as any hospital that receives direct Graduate Medical Education ("GME") payments or indirect Graduate Medical Education ("IME") payments. This

definition, if finally adopted, will exempt payments and transfers to any hospital that may have an accredited residency program but does not receive any GME or IME Medicare payments. CMS is seeking public comment on its definition of "teaching hospital" so changes to the scope of the definition could be in store for the final rule.

Summary

As has been the experience with other CMS rules on the regulation of physician financial relationships, such as the Stark law, the agency's deliberate approach will result in many lingering questions on the timing and scope of this mandate.

In the most extreme scenario though, tracking and reporting will commence sometime in 2012, meaning that companies and recipients subject to the Sunshine Law need to immediately start the process of establishing and/or modifying and enhancing their tracking systems.

As the possible repeal of ACA will be heard by the Supreme Court sometime later this term, it is still not clear whether the Sunshine Law could be struck down if the Court rules that the ACA is unconstitutional.[15] Until the Supreme Court case reviewing the constitutionality of the ACA is decided and CMS issues final and more detailed rules giving manufacturers, distributors, physicians, and hospitals more details on the Sunshine Law requirements, the full scope and cost of this massive national mandate is still significantly unknown.

CMS should ensure that the final Sunshine Law Rule completely addresses the open questions identified above, and confirms the exact scope of preemption, so that states like Massachusetts that have chosen to regulate this area can be clear on which parts of their state's laws will no longer be in effect.

(Endnotes)
1 42 U.S.C. §1128G (Section 1128G of the Social Security Act), added by Section 6002 of the Affordable Care Act (signed into law on March 23, 2010) entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests."
2 Massachusetts General Law, Chapter 111N and implementing agency rules, DPH regulations 105 CMR 970.000.
3 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (Dec. 19, 2011).
4 42 U.S.C. §1320a–7b (Section 1128B(b) of the Social Security Act).
5 Transfers of value worth less than $10 are not reportable unless the aggregate amount transferred to, requested by, or designated on behalf of the recipient by the manufacturer during a calendar year exceeds $100. These thresholds will be increased annually by the CPI.
6 The law references the definition of physicians found in 42 U.S.C. §1395x(r), which includes dental surgeons, podiatrists, optometrists, chiropractors as well as physicians.
7 "Common ownership" would be defined by CMS as the same individual, individuals, entity, or entities, directly or indirectly, owning any portion of two or more entities. The common ownership definition would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations. It is also soliciting comments on whether to limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. CMS is also suggesting that companies under common ownership that each meet the definition of manufacturer must report separately but any other companies under common ownership that are subject to the reporting obligation could choose to report separately or together.
8 "Sales and marketing activity" is defined under 105 CMR 970.004 as sales and marketing activities including "advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force ... [as well as] any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose."
9 The Sunshine Law exempts from reporting the following:
- Payments or other transfers of value less than $10 (unless the aggregate amount paid or transferred by a reporting company to the recipient exceeds $100 per calendar year).
- Product samples that are not intended to be sold and are intended for patient use (although there will a separate non-public database).
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an

administrative proceeding.
10 The Massachusetts mandated Marketing Code of Conduct in many respects is more stringent than the standards set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009 and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009. The Massachusetts mandated Marketing Code of Conduct also requires CME programs to adhere to the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support (even if ACCME accreditation is not secured).
11 See, http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pcoc/ma-pharm-code-of-conduct-circular-letter-12-28-2011.pdf.
12 Id.
13 105 CMR 970.009 states that reportable "sales and marketing activity does not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or 'new use' or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. "Clinical trial," is defined by 105 CMR 970.004 as "a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency."
14 "Genuine Research Project" is defined under 105 CMR 970.004 as "a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry."
15 The Supreme Court has agreed to hear appeals from a case in which the United States Court of Appeals for the 11th Circuit struck down the individual mandate to purchase health insurance in the ACA. See, *State of Florida, et al. v. U.S. Dep't of Health & Human Services., et al.,* Nos. 11-11021 & 11-11067 (11th Cir., Aug. 12, 2011), available at http://www.uscourts.gov/uscourts/courts/ca11/201111021.pdf. In taking the appeal, the Supreme Court has agreed to decide not only whether the mandate is constitutional but also, if it is not, how much of the balance of the ACA must be struck down as well.

Perspectives: An Act Promoting Equity and Efficiency in Rates

by Karen Granoff and Eric Linzer

Karen Granhoff, Massachusetts Hospital Association

The hospital community recognizes the importance of comprehensive healthcare payment and delivery system reform. The Massachusetts Hospital Association (MHA) board supports the systemic evolution of the healthcare system away from the traditional fee-for-service payment system toward more integrated models of care such as global payments. Hospitals are already doing their part in this effort and are committed to further advances. As we move down this road, guided by both state and national reform laws, it is also critical that every stakeholder - consumers, providers, employers, and both public and private payers – play an active role in the reform effort if it is to be successful.

MHA's position has been and continues to be that the successful transition of our healthcare system should be voluntary and anchored in rewarding the provision of coordinated, efficient, high quality care delivered in the right setting and at the right time, rather than the current fee-for-service model that rewards volume. While it is unclear whether the "Act Promoting Equity and Efficiency in Rates" (PEER Act) will be part of the reform discussion in Massachusetts, MHA is very concerned with several provisions of the bill.

Although well intentioned, the bill misses a couple of fundamental components of the evolving healthcare reform. First, the cost of health care is not determined solely by price. To bring the formula to its simplest terms, cost is comprised of both price and utilization. By dealing only with price, the bill ignores the effect of rising utilization on costs. Second, government payers dictate their payment to all hospitals - there is no negotiation. And because of the extraordinary consolidation of the Massachusetts health insurance industry, private insurers have disproportionate power in negotiations with hospitals. The PEER Act would simply enhance the insurance industry's power by allowing it to leverage government's power.

The PEER Act would significantly increase government regulation of contracts between providers and private health insurers. The stated intent of the bill is to "require health plans to reduce the rates they pay to certain high-cost providers and to increase rates to some of the lowest-paid providers," presumably leveling the playing field for providers and lowering premiums for consumers and employers. However, the very consequences it seeks to prevent – price variation among providers – is little understood. Even among the members of the Special Commission on Provider Price Reform, there was no consensus on what constitutes justified or unjustified variations. Before the Commonwealth moves to a state-controlled model of regulation for this circumstance, MHA believes that there should be additional verification of the extent of variation in the system, an understanding of how it differs, if at all, from the rest of the country, and a careful study and review of the reasons behind variation. If price variation is important enough for government to control, then it is incumbent on government and policymakers to fully understand it before imposing new requirements.

Before the state acts to intervene in extraordinary ways into the health care market, it must be recognized that there is ample evidence that the market is already responding voluntarily to cost reduction efforts in a number of ways, including creating new limited and tiered network products, developing and adopting alternative payment methodologies, increasing focus on improving patient safety and decreasing hospital readmissions, promoting the patient centered medical home model, and increasing transparency around cost and quality. The result has been a moderation in healthcare cost trends, as demonstrated by the following facts:

- *Medical Expenses for the 4 major insurers and health plans decreased by 3% in the past 12 months [Source: Q3 2011 NAIC Quarterly Statements]*

- *The average private health insurance premium in MA (vs. US) has dropped from #1 in*

2009, to #9 in 2010. [Source: The Commonwealth Fund]

- *Rapid adoption of At-Risk contracts - Since initial AQC agreement in January, 2009, approximately 15 additional AQC contracts have been added. In total, nearly 500,000 HMO Blue members (44% of HMO Blue membership) are now covered by AQC contracts.*

- *The Group Insurance Commission incentivized more than 10,000 state employees to switch to limited network plans.*

- *Blue Cross Blue Shield executives say they have seen a steady 30 percent adoption rate each month for the tiered product Hospital Choice Plan among small businesses and individuals that are renewing their plans (Patriot Ledger June 4, 2011).*

Legislation such as the PEER Act could significantly constrain further progress along the lines described above, stifle innovation, and create insecurity among providers. MHA agrees that government has helped to promote some positive changes and should have a continuing role, but it is also critical to continue to support these voluntary efforts and measure their success as we decide exactly what government's role should be. According to MHA's CEO Lynn Nicholas, "Requiring increased transparency on cost, price, benefit design and quality are examples of constructive government leadership. Partnering with providers, employers, insurers and consumers to establish goals that all stakeholders should be accountable for makes sense." But government must also hold itself accountable. The PEER Act is inconsistent in its approach to cost containment. Among the several items in the bill that raise concerns are:

- Government interference in private contracts between payers and providers based on arbitrary distinctions in reimbursement among the top, middle, and lowest 20%.

- A prohibition on cost shifting, making it a Chapter 93A violation.

- A requirement that every provider accept payment according to this proposal as a condition of licensure.

- Creation of a default rate for covered out of network services.

More specifically, MHA believes that:

- Price variations are not unique to Massachusetts; they are present in every state in the nation – even in the few states with rate regulation. Government enactment of legislation to support market movement to more integrated delivery systems, supported by an aligned payment system is one thing, but government micro-management of price variations that exist in every state is something entirely different. There should be balance between the role of government and the role of the market. Government setting rates and redistributing revenues breaks that balance.

- The PEER Act requires providers to accept this form of payment as a condition of licensure which could lead to providers deciding not to practice in Massachusetts. Reimbursement methodology should never be a criterion for licensure of a physician or hospital.

- The bill prohibits cost shifting and would make it a 93A violation, while failing to acknowledge one of the primary issues inherent in the cost problem - that of government underpayment. Government is 60% or more of the average hospital's revenue, and both the federal and state government significantly underpay for the cost of care. Thus, government knowingly creates a major revenue deficit for hospitals, then under this bill would prohibit attempts to recoup even a portion of that payment. That isn't fair or practical. Making cost shifting a 93A violation subject to penalties through the Office of the Attorney General will only serve to further exacerbate payment inequities.

- This bill could significantly harm many hospitals, forcing them to discontinue the most under-paid services, such as behavioral health, close needed beds, and reduce workforce.

- The distinction between the top 20%, the middle group, and the lowest 20% is arbitrary - those who seemingly benefit may be as little as a fraction of a percentage point below those who get nothing or who have to reduce their payments. It could end up hurting critical access hospitals as well.

Additionally, no one has been able to explain how the redistribution would actually work. For example, would low price hospitals increase their price? Would that result in less patient volume coming to a hospital?

- The bill does not take into consideration acknowledged and justifiable reasons for variation such as medical education, research, and other beneficial societal needs.

Most importantly, the artificial rate regulation suggested by this legislation distracts from the real mission of trying to reform the health care system and reduce the overall rate of growth in health care costs. Government can and has helped to jumpstart the transition, but the market is best suited to keep it going under the government's watchful public eye.

Eric Linzer, Massachusetts Association of Health Plans

We face a critical moment in health care. Rising health care costs are crippling our economy. The continued cost increases are squeezing employers, particularly small businesses, taking away resources they could use to hire more workers, fund capital expenditures and make other investments to grow our economy. Unfortunately, the continued increases have not resulted in better care.

Over the last three years, nearly half a dozen comprehensive reports from various state agencies – including the Attorney General and the Division of Health Care Finance and Policy ("the Division") – have outlined the key drivers of rising health care costs in the state.

Report-after-report has identified provider price increases, not increases in utilization, as the major cause for most of the increases in health care costs during the past few years in Massachusetts, with higher priced providers gaining market share at the expense of lower priced providers.

Independent analyses by both the Attorney General and the Division have concluded that prices vary significantly and are not correlated to issues such as the acuity, complexity or quality of care. Instead, the market clout of certain providers is the main factor driving increases in the cost of health care.

As the Division's 2011 analysis noted, "Prices paid for the same hospital inpatient services and for physician and professional services vary significantly for every service examined. There was at least a three-fold difference for every service and for most, a variation of six- or seven-fold."

The PEER Act, filed by House Majority Leader Ronald Mariano, is an important measure in dealing with the disparities in rates by addressing the market dysfunction and providing meaningful relief to consumers and employers. The legislation would require health plans and providers to share in the responsibility to contain health care costs.

The PEER Act would reduce rates paid to certain high-cost providers and increase the rates paid to lower-cost providers, while requiring that any savings be reflected in premiums for employers and consumers. The legislation would serve as an important step as the state moves toward reforming the payment system, laying the appropriate foundation to ensure that the current payment distortions aren't memorialized in new payment arrangements.

As part of its 2011 analysis, the Division examined the potential savings of reducing payment variation and found that if private payer prices among hospital inpatient services and physician and professional services were narrowed to reflect a range spanning the existing 20th percentile to 80th percentile of payments, the potential total savings would be approximately $267 million. However, the Division's analysis only included a limited number of outpatient services, which if expanded would result in greater savings.

Getting health care costs under control requires dealing with what we pay for medical care. Last year's health care law (Chapter 288 of the Acts of 2010), imposed the nation's strictest standards on health insurance premiums, including limiting insurers' profits and requiring that 90 cents of the premium dollar is spent on care. Chapter 288 also required that health plans offer limited or tiered network products that are at least 12 percent less expensive than a similar full-network plan.

However, premiums continue to rise because the cost of care continues to go up. For the health care system to function properly and more efficiently, closing the gap between lower-paid providers and higher-cost providers needs to be the next area we address.

As the Attorney General's 2011 report noted, while tiered and limited network products and commercial market transparency can improve market function, temporary statutory restrictions are necessary to reduce health care price distortions. The need for short-term

state intervention to close the gap in the rates paid to different providers was echoed by several hospital CEOs during the Division's June 2011 health care cost hearings.

Since House Leader Mariano filed the PEER Act, several other proposals to deal with the distortions have been introduced. Among them:

- The Special Commission on Provider Price Reform, which included representatives from state government, academia, physician organizations, hospitals, and health plans, outlined a series of recommendations aimed at enhancing competition, fairness, and cost-effectiveness in the health care market though the reduction of reimbursement disparities. Among the recommendations was a proposal to establish a short-term process to ensure that higher prices more closely correlate to quality and thereby reduce costs. The proposal would require that providers and insurers work together to reduce unjustified price variation. However, if a provider makes a request for a rate of payment that exceeds the market-based plan median, and the health plan rejects the requested rate increase because it determines that the higher price is not justified, the provider would have the ability to submit its request to an independent panel, which would determine whether the requested price is justified based on demonstrated quality. If the panel determines the rate increase is justified, then the insurer would have to accept the requested increase. If the panel determines the rate increase is not justified, then the provider would have to accept the lower of either the market-based plan median rate or the rate it received from the insurer in their preceding contract.

- In November, at MAHP's annual conference, the Attorney General offered a proposal to correct the variations in provider prices for health services. The proposal would set clear benchmarks for cost containment and allow the market time to correct itself over the next three years. If those goals are not met by 2015, then temporary price restrictions would be enforced. As an example, the Attorney General suggested that prices would have to fall within 20 percent above or 20 percent below a health plan's average price from the previous year. This intervention would be temporary, with a sunset provision after three years to re-evaluate the system and determine whether it would be necessary to continue beyond 2018.

The PEER Act and these other proposals are essential to achieving the long term cost control goals associated with reforming the payment system. Reducing the cost of health care requires effectively dealing with the market clout issues raised by the Attorney General and the Division to ensure that payment reform does not lead to higher costs. Further, the Attorney General's reports have shown that price differences exist regardless of the way the provider is paid and any payment reform legislation should include efforts to mitigate these payment disparities.

Today, 98 percent of Massachusetts residents have coverage, but cost control remains the challenge, and small businesses and working families need meaningful relief from rising health care costs. Ensuring the long-term sustainability of the state's health care reform law and fulfilling payment reform's goals of better integration of care, better alignment of incentives, and lower costs requires addressing the dynamics and distortions of the current marketplace.

Policymaker Profile: Mary Beckman

By Merritt Dattel McGowan

Quiet, unassuming intelligence and endless curiosity for knowledge—as I sat riveted by the career trajectory of Mary Beckman, currently Chief of the Non-Profit Organizations/Public Charities Division of the Massachusetts Office of the Attorney General—this is what struck me as the unifying theme to her career accomplishments over the last 24 years. Her career presents interesting lessons for all attorneys, but especially for newer attorneys starting out in health law and policy.

Mary started her career wanting to pursue theology and philosophy, with a degree in comparative religion and German from Dartmouth College followed by a year-long fellowship in theology in Tübingen, Germany. She says what intrigued her most about theology and philosophy was deciphering how religion and ethics motivate human behavior in social and political relationships—which naturally led her to practice law.

Her Early Career

While at Yale Law School, Mary was drawn to experiences where she could utilize her legal skills to improve access to justice for disadvantaged populations. She advocated for individuals with disabilities and people with HIV in the Yale Legal Services Clinic; researched women's health care in prisons; and attended Congressional hearings on Medicare payments to physicians in the early days of the Resource Based Relative Value Scale—further solidifying her interest in health care.

Mary's introduction to the health care industry and its direct effects on everyday people began when she worked during college summers at a family-operated manufacturing plant in Erie, Pennsylvania. While working in the human resources department, she participated in evaluation of different health benefit plan options and was introduced to HMOs and PPOs in the mid-1980s. In addition, prior to law school, Mary assisted patients and families with adjustment to illness, discharge planning, and management of benefits as a member of the Social Work Department at Massachusetts General Hospital. Mary remembers heart-wrenching experiences of families coping with the loss or disability of a loved one and frantic searches for an open rehabilitation or skilled nursing bed or cobbling together a patchwork of home supports for patients who were ready for discharge from the hospital.

Observing the struggles many people face navigating the complex health care system, the desire to design a better system loomed in Mary's mind. Logically, she wanted her next step to be working in health care policy, but upon graduating from law school, a wise confidante gave her the advice to obtain practical experience in the law first. So she clerked for a year for the Honorable H. Lee Sarokin, then of the United States District Court, and afterward she practiced as an Associate in the Health Law Practice in Ropes & Gray's Boston office. In Mary's words, "Ropes was *the* place to practice health care law in the mid-1990s." She spent a very intense three years "in the trenches" there shaping all aspects of her future career.

History Always Repeats Itself

Finally fulfilling her dream of working on both law and public policy, Mary left Ropes & Gray to serve first as Deputy Legal Counsel under Governor William Weld (1997) and then for Governor Paul Cellucci (1997-1999). Under her purview were a wide variety of legal issues including health and human services, housing and community development, elder affairs, constitutional issues, campaign finance law and state ethics law (which tied into her earlier philosophy interest). Next, Mary served as Assistant Secretary for Health Policy at the Massachusetts Executive Office of Health & Human Services (EOHHS).

When asked about the hot topics for Massachusetts policymakers at the time, Mary responded with the Managed Care Reform Law of 2000, which she helped implement during her time at EOHHS. She also advised the Secretary and Governor on the Harvard Pilgrim Health Care receivership (preparing her for her current role). Most fascinating though, was her role supporting the Massachusetts Health Care

Task Force, which met over a two year period from 2000 to 2002. Membership in the Task Force consisted of representatives from hospitals, health maintenance organizations, health care providers, consumer advocates, business, labor, and all three branches of state government—in fact, many of the same players that are around today. The Task Force's purpose was to perform a comprehensive review of the Massachusetts health care system. Reportedly, this was the first time such a Task Force had ever been created—where top state officials sat around the table with stakeholders and other prominent leaders in health care to analyze, debate, and decide on the path Massachusetts should take to better the health care system. Highlights of some of the recommendations embraced by the Task Force include: increase state monitoring and data collection; redistribute care to lower-cost settings; consider expanding MassHealth; consider mandating insurance coverage; design financial incentives to encourage patient-centered quality improvement; review adequacy of public payments; explore new capitation models with adequate data to support quality and effective management of care; and consider increasing oversight of risk-sharing arrangements and risk-bearing entities, among others. Those of us who dabble in health policymaking know that these topics are still being bandied about now—10 years later.

Mary's next career move was to become Director of Compliance for Children's Hospital Boston, the first full-time compliance officer in the hospital's history. This was also a brand new area for Mary, where she was able to learn about hospital operations, implement new systems and coordinate the development of hospital policy to comply with required reporting, confidentiality and security of information, clinical documentation systems, and other areas. Finally, after nearly ten years at Children's Hospital Boston, Mary decided to go back into public service.

Her Current Charge

In August of 2011, Attorney General Martha Coakley appointed Mary to Chief of the Non-Profit Organizations/Public Charities Division of the Massachusetts Office of the Attorney General. Mary thoroughly enjoys her second stint in public service—in her words "supporting the non-profit sector of over 22,000 charities operating in Massachusetts as well as overseeing it for the public good." Indeed, Mary has already made a difference as Chief recently overseeing several transactions involving non-profits. Several notable recent matters concerned for-profit Steward Health Care System acquiring non-profit Morton Hospital and Quincy Medical Center in Massachusetts.

Undeniably, Mary's quiet, unassuming intelligence and endless curiosity for knowledge have so far helped her develop many lofty talents and led her to interesting jaunts through life.

This article represents the opinions of its author and not necessarily those of the Office of the Attorney General. However, the author and Ms. Beckman are colleagues in the Massachusetts Office of the Attorney General. This article should not be considered an official Opinion of the Attorney General rendered pursuant to her specific statutory authority.

Health Law Brief: Ryo Cigar Association, Inc. v. Boston Public Health Commission, 79 Mass.App.Ct. 822 (2011)

by Amy Kaufman

The Massachusetts Appeals Court ("Appeals Court") affirmed a judgment by the Superior Court denying Ryo Cigar Association, Inc., a trade association of cigar wrap manufacturers, and New Image Global, Inc., a cigar wrap manufacturer, injunctive and declaratory relief against the enforcement of a regulation banning the sale of cigar wraps in the city of Boston. The Appeals Court also dismissed the manufacturers' arguments that the regulation is unreasonable, violates principles of equal protection, and conflicts with State and Federal laws.

The Boston Public Health Commission ("Commission") was created by the Boston Public Health Act of 1995 and was given broad powers to regulate health and certain health care providers in Boston. The Commission enacted the regulation at issue after it held a number of hearings about the implications of tobacco use, especially by Boston residents. During these hearings, the Commission found that tobacco use leads to lung cancer, a primary cause of cancer death in Boston. Additionally, the Commission determined that "there are certain tobacco products such as [cigar wraps] that are frequently marketed and sold to the youth and are also known to be used as drug paraphernalia" *Ryo Cigar* at 824. Therefore, it concluded that enacting a regulation banning the sale of cigar wraps in Boston was justified and furthered its mission to "protect, promote, and preserve the health and well-being of Boston citizens."

In their complaint, the manufacturers argued that the regulatory ban violates principles of equal protection, took their property without just compensation, and is arbitrary and capricious. They also demanded injunctive and declaratory relief. Following a two-day trial, however, the Superior Court judge reached conclusions about the use of cigar wraps similar to those of the Commission. The court also found that cigar wraps come in a variety of colors and flavors, are used to create custom marijuana cigarettes, and are a preferred means of smoking marijuana by young people. Based on his findings, the judge determined that "reasonable public officials in a reasonable legislative body, like the Boston Public Health Commission" *Ryo Cigar* at 826, could conclude that the use of cigar wraps presented legitimate health concerns for the Commission to address. Therefore, he rejected the manufacturers' arguments and dismissed their complaint.

The manufacturers presented three main arguments in their appeal: (1) the regulation is arbitrary and capricious and outside the scope of the Commission's power; (2) the regulation violates the equal protection rights of young African-American males; and (3) the regulation conflicts with State and Federal laws. The Appeals Court rejected all three arguments.

Argument 1: The regulation is arbitrary and capricious.

The Appeals Court began its analysis by noting that the Commission has statutory authority to promulgate reasonable health regulations not inconsistent with other laws. Acknowledging its tendency to give the same deference to health regulations promulgated by local health boards, such as the Commission, as it would give to statutes, the court cited past cases that have upheld State and local tobacco regulations and emphasized that the present regulation "fits comfortably within the zone delineated by prior tobacco regulations." Thus, the Appeals Court concluded that the regulation is reasonable, rationally related to a legitimate health-related purpose and clearly within the scope of power awarded to the Commission.

Argument 2: The regulation violates principles of equal protection.

The Superior Court dismissed the manufacturers' argument that the regulation violates equal

protection by treating them differently than other cigar makers. That court determined that it was appropriate to evaluate the regulation under the rational basis test because "it neither burden[s] a fundamental right nor discriminate[s] on the basis of a suspect classification."

On appeal, the manufacturers added a new layer to this argument by claiming that the regulation did in fact discriminate on the basis of race, particularly against African-American males. According to the Appeals Court, the manufacturers could not raise the issue here since it they had not done so below. The court nevertheless pointed out that, even if the manufacturers *could* raise the issue, their argument would fail since they did not show that the facially neutral law actually had a discriminatory purpose and effect. Instead, the manufacturers merely noted the Commission's observations that cigar wrap manufacturers' marketing campaigns were targeted toward young African-American males and the use of cigar wraps had increased among that population. They did *not* present evidence that these observations amounted to racial discrimination or that the impact of the regulation on the African-American population was disproportionate to the impact of the regulation on other populations.

Argument 3: The regulation conflicts with State and Federal laws.

In their final argument, the manufacturers claimed that the regulation conflicts with State and Federal laws concerning controlled substances. They stated that the preamble of the regulation at hand asserts that cigar wraps "often are used as drug paraphernalia," bringing the regulation into the controlled substances arena which is exclusively governed by comprehensive State and Federal legislation. The Appeals Court responded to this argument by noting a key distinction: that the Commission's findings only provided that cigar wraps "often are used as drug paraphernalia," and never that they are in fact drug paraphernalia; therefore, the regulation remains separate from those in the controlled substance arena. The manufacturers also argued that the regulation is inconsistent with the Commonwealth's intent to allow unfettered sale of tobacco products to adults, as well as with statutes governing the taxation of tobacco products in the Commonwealth. However, the Appeals Court suggested that the regulation at issue operates simultaneously with those schemes, rather than in conflict with them.

The Appeals Court affirmed the Superior Court's judgment.

Health Law Brief: State of New York, et al. v. Amgen, Inc., et al., 652 F. 3d 103 (1st Cir. 2011)

by Alexis Bortniker

In *State of New York, et al. v. Amgen, Inc., et al*., the First Circuit reversed a Massachusetts District Court's dismissal of a whistleblower action against Amgen, Inc. and certain affiliated entities (collectively, "Amgen") alleging that Amgen violated the False Claims Acts ("FCAs") of six states by causing providers to present false Medicaid claims to the government without disclosing that they had received kickbacks, and that Amgen had encouraged providers to submit false claims to the government regarding reimbursements for the dispensing of Aranesp, a drug used to treat anemia.

Relying on its decision in *United Stated ex rel. Hutcheson v. Blackstone Medical, Inc.,* No. 10-1505, 2011 WL 2150191 (1st Cir. June 1, 2011), the First Circuit held that in California, Illinois, Indiana, Massachusetts, New Mexico and New York (the "States"), compliance with the applicable anti-kickback statute is a precondition to receiving payments from Medicaid and therefore failure to comply with anti-kickback statutes can raise claims under the States' FCAs. Further, the First Circuit held that the FCAs of the States are not substantially different from the federal FCA provisions.

Additionally, the First Circuit affirmed the Massachusetts District Court's dismissal of the claims under the Georgia FCA, finding that the Georgia FCA does not refer to kickbacks, but instead is concerned with schemes to bill the state Medicaid program for unnecessary drug tests at inflated prices, and that therefore the relator did not state a legitimate claim against Amgen under Georgia's FCA.

The matter began with a complaint filed by Kassie Westmoreland (the "Relator") on June 5, 2006 in the Massachusetts District Court. The Relator was an employee of Amgen, the company that manufactured Aranesp, from September 2002 to March 2005. On September 1, 2009, the U.S. government declined to intervene in the matter, but fifteen states and the District of Columbia decided to intervene by filing a multi-state complaint on October 30, 2009. The Massachusetts District Court dismissed the claims in 2010 stating that the plaintiffs could not survive a 12(b)(6) motion to dismiss because they had failed to identify a false or fraudulent claim for Medicaid payment within the meaning of those states' FCAs. During the District Court proceedings, six states voluntarily dismissed their claims. Additionally, the District of Columbia and four states did not appeal the Massachusetts District Court's decision. As a result, the Relator, the States, and Georgia brought the appeal to the First Circuit.

The Plaintiffs alleged two types of kickbacks in the case. The first alleged kickback was due to overbilling for excess product included in Aranesp vials. Aranesp is an injectable drug sold in single dose vials. The United States Pharmacopeia ("USP")[1] requires that single dose vials contain an amount of the drug in slight excess of the labeled volume to allow withdrawal and administration of the labeled amount. Aranesp vials contained roughly 16-19% overfill between 2002 and 2008. Per the Plaintiff, the USP recommends overfill be up to 10% of the dosage. Medical providers generally are allowed to receive reimbursement from state Medicaid programs for administered overfill. The Plaintiffs, however, alleged that Amgen intentionally overfilled the vials more than was required and actively encouraged providers to bill such excess overfill, therefore resulting in kickbacks. The second group of alleged kickbacks took the form of free weekend retreats, lavish advisory board meetings, sham honoraria, consulting fees and other benefits offered to induce medical providers to prescribe Aranesp over other anemia drugs.

The Plaintiffs argued that by paying these kickbacks, the Defendants knowingly caused the providers to violate the FCAs of the States.

The District Court granted the Defendants' motion to dismiss, finding that the Plaintiffs failed to identify "a false claim for pay-

ments" under an express or implied certification theory.

The First Circuit reversed the dismissal as to claims in the States and affirmed as to Georgia.

The First Circuit held that like the federal FCA, the States' FCAs impose liability on any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment of approval to a state, (2) knowingly makes, or causes to be made or used, a false record or statements to get a false or fraudulent claim paid or approved by the state, or (3) conspires to defraud the state by getting a false claim allowed or paid. The States' FCAs provide that a defendant acts "knowingly" if he has "actual knowledge" of a claim or statement's truth or falsity, or "acts in deliberate ignorance" or "reckless disregard" to its truth or falsity. The First Circuit held that these statutes may be construed consistently with the federal FCA.

The Federal Circuit rejected the District Court's holding that a claim can only be impliedly false or fraudulent for non-compliance with a legal condition of payment if that condition is expressly stated in a statute or regulation.

To survive the motion to dismiss, the First Circuit held, the Relator and Georgia and the other State interveners must show (1) that the claims at issue misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent, and (2) that the Defendants knowingly caused the submission of false or fraudulent claims. The Defendants did not contest that the Relator and the state interveners had met the second requirement, so only the first question remained. In answering this question, the First Circuit looked to determine whether or not the claims submitted to the States misrepresented compliance with a precondition of payment recognized by those particular programs.

The First Circuit held that the FCAs in Illinois, Indiana, Massachusetts, and New York made clear that claims tainted by kickbacks of the kind alleged by Plaintiffs are not eligible for Medicaid payments in those states. The First Circuit also concluded that the provider agreements of New Mexico and California also made clear that claims submitted to the Medicaid programs of those states cannot be paid if they are tainted by kickbacks.

With respect to Georgia, the First Circuit held that, although the Georgia Medicaid program may have a precondition of payment that claims not be influenced by kickbacks, the plaintiffs failed to identify a legal authority to support their point. The First Circuit emphasized that Georgia, unlike the other States, does not have a corresponding state law to the federal anti-kickback statute.

(Endnotes)
1 The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration.

Health Law Brief: Sisson v. Lhowe

by Lynn M. Squillace

In October 2011, the Supreme Judicial Court held that a plaintiff may, after the running of the statute of repose, amend a medical malpractice complaint to add a wrongful death claim when the underlying complaint alleged injuries including expected premature death.[1] This matter of first impression examined the limits of the seven year statute of repose in M.G.L. c. 260 § 4.

Husband and wife plaintiffs, Dawn and Richard Sisson, Jr., filed a medical malpractice complaint on February 27, 2006 alleging that defendant Lhowe and others had provided negligent medical care to Dawn between January 26, 1999 and November 16, 1999. The complaint alleged that the defendants' medical negligence was a direct and proximate cause of Dawn's claimed injuries, "including, but not limited to, expected premature death from metastic osteosarcoma." Dawn died from osteosarcoma on March 29, 2007, prior to trial but more than seven years after the last medical treatment. On March 28, 2008, the plaintiffs amended their complaint to add wrongful death claims and also to add Richard as the administrator of Dawn's estate. Defendants moved in limine to preclude the wrongful death claims based on the statute of repose, which had run on November 16, 2006 (prior to Dawn's death, but seven years after the last incident of alleged negligence). The motion in limine was allowed and the wrongful death claims were eventually dismissed by the Superior Court.

The Supreme Judicial Court transferred the case from the Appeals Court on its own initiative, reviewing the allowance of the motion to dismiss *de novo* and considering whether, as a matter of law, the wrongful death claim was barred by the applicable statute of repose. The Court noted that chapter 260 §4 is both a statute of limitations and repose for medical malpractice, providing that "'[a]ctions . . . for . . . malpractice shall be commenced only within three years after the cause of action accrues' . . . [and] 'in no event shall any such action be commenced more than seven years after the occurrence of the act or omission which is the alleged cause of the injury upon which such action is based.'"[2] In contrast to a statute of limitations which runs from the accrual of the claim, the date on which the injury occurs or when the plaintiff should have reasonably known of the injury resulting from medical negligence, a statute of repose focuses on the date the cause of action arises, which is "the date a defendant's negligent acts or omissions were alleged to have occurred 'regardless of whether a cause of action has accrued or whether any injury has resulted.'"[3]

The Court first interpreted the statutory language providing that "in no event shall any such action be commenced more than seven years" after the occurence "according to [its] 'ordinary and approved usage.'"[4] The Court further interpreted the meaning of the word "action," seeing it, in this context, as referring to the operative facts giving rise to the medical malpractice complaint essentially finding that the amendment to a complaint to add a count for wrongful death was not a new action precluded by the statute of repose when the count arises out of the same "constellation of facts as the original complaint."[5] Therefore, related claims that are based on injuries resulting from the same alleged acts of medical malpractice are not required to have been plead with the original complaint, but must be made while the action is pending, as they are not distinct causes of action, but rather relate to the initial claim. The Court explained, "[T]hat various remedial claims may be made as a result of the negligent act is not the concern of the statute of repose, so long as the original malpractice complaint (or action) was filed within the seven-year period that begins to run from the date of the negligent acts or omissions."[6]

In considering the legislative history and intent behind the enactment of the statute of repose, the Court noted that the statute was passed as part of a broader attempt to restrain the costs of medical malpractice insurance. The statue of repose seeks to eliminate stale claims where the passage of time makes such medical malpractice claims difficult to defend.[7] In support of this conclusion, the Court offered the fact that foreign body claims are excepted from the statute, as such claims are considered no

more costly to defend after the passage of time.[8]

In the case at hand, the Court concluded that none of the purposes of the statute of repose are furthered by the dismissal of the plaintiffs' wrongful death claim for several reasons. Where a named plaintiff dies before the resolution of a malpractice suit, the additional costs the legislature was concerned about do not arise where the parties simply proceed to trial on the wrongful death claim, rather than the personal injury claim. The Court noted that the liability issues and any problems of proof are the same where both claims arise out of the same facts. Further, because the underlying malpractice complaint alleged that Dawn's death was imminent and the alleged damages were substantially similar, there was no concern that insurers would be required to defend unanticipated lawsuits as they were already on notice of the claim, no funds had been disbursed, additional discovery of evidence needed to defend the wrongful death claim would not be difficult, and there were no issues of finality to contend with as the underlying malpractice suit had not yet been tried.[9]

Based on this analysis the Court held that "a wrongful death claim may be substituted for a personal injury claim only where (1) trial has not commenced; (2) the original complaint alleging malpractice was filed within the statutes of limitation and repose; and (3) the allegations of liability supporting the personal injury claim are the same as those supporting the wrongful death claim."[10]

Justice Spina offered a strongly worded dissent arguing that the wrongful death action had been abolished by the statute of repose before it could have been brought, since Dawn died after the seven year repose period expired.[11] Therefore, the result should be the same as a case where a death occurs more then seven years after the alleged negligent act: the plaintiffs' wrongful death action ceases to exist and cannot be brought.[12] The dissent criticized the Court's opinion for creating an exception to the statute of repose where one had not been written by the legislature, and for relying on an unidentified ambiguity in the statute leading to an unfounded conclusion that an action for medical malpractice and one for wrongful death are a single action for the purpose of a statute of repose analysis.[13]

The dissent further pointed out that the Court had essentially undertaken a "relation back" to the original filing of the plaintiffs' complaint, but avoided a relation back discussion as the principle cannot apply to a statue of repose, lest the Court "'reactivat[e] a cause of action that the Legislature obviously intended to eliminate.'"[14] Moreover, in this particular case, a true relation back to the original filing of the complaint would mean that Dawn filed her estate's wrongful death claim before she actually died.[15]

Dismissing the majority's policy arguments, the dissent pointed out that the Court's holding makes it difficult to reconcile dismissing a case filed one day after the running of the repose period, but allowing the same case filed one day earlier to continue. There would not be much, if any, difference in the costs of defending either case or the staleness of the evidence. However, as the dissent's persuasive argument goes, absent a legislated modification of the statute of repose, there comes a point when stale claims must be eliminated, no matter the harshness of the result.[16]

(Endnotes)
1 *See Sisson v. Lhowe*, 460 Mass. 705 (2011).
2 M.G.L. c. 260 §4.
3 *Sisson* 460 Mass. at 709.
4 *Id*. at 708.
5 *Id*. at 709-10.
6 *Id*. at 709-10.
7 *Id*. at 713.
8 "'The later discovery of the foreign object is, for all practical purposes, proof of some earlier negligence on the part of a health care provider.'" *Id*. at 714 (internal citations omitted).
9 *Id*. at 714-15.
10 *Id*. at 716.
11 *Id*. at 716-17.
12 *Id*. at 719.
13 *Id*. at 717-18.
14 *Id*. at 721 (internal citations omitted).
15 *Id*.
16 *Id*. at 720.

Health Law Brief: Gargiulo v. Baystate Health, Inc., et al.

by Torrey Young

Debra Gargiulo ("Gargiulo"), a former medical resident at Baystate Medical Center (collectively, with Baystate Health, Inc. "Baystate"), brought State and Federal discrimination claims against Baystate.[1] The case came before Magistrate Judge Neiman of the United States District Court of Massachusetts (the "Court") on a motion to compel discovery. The basis of the discrimination claims were for her age and disability. Gargiulo also claimed retaliation for engaging in protected conduct.

Gargiulo sought access to records, evaluations, and reports, as well as those documents of physicians who were similarly situated in her residency program. Baystate opposed discovery of these documents, asserting that the documents are protected by the Massachusetts medical peer review privilege and therefore not discoverable (G.L., c 111, §§ 203-205).

The Massachusetts medical peer review privilege mandates that the proceedings, reports, and records of a medical peer review committee are confidential and are not subject to subpoena, discovery, or introduction into evidence in any judicial or administrative proceeding.[2] Judge Neiman acknowledged Massachusetts' case law, which recognizes that the purpose of the statutory medical privilege is to promote candor, confidentiality, aggressive critiquing, and self-regulation of the medical profession.[3]

Federal Rule of Evidence 501 provides that, in general, "the privilege of a witness, person, government, State or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State or political subdivision thereof shall be determined in accordance with State law."[4]

The Court accepted that Gargiulo invoked only diversity jurisdiction in the jurisdictional section of her complaint, and Baystate therefore argued that the Massachusetts peer review privilege applied to all claims. However, the Court rejected this argument, because Gargiulo's complaint also raised claims under the Americans with Disabilities Act ("ADA") and the Age Discrimination in Employment Act ("ADEA"). Claims under the ADA and the ADEA support Federal jurisdiction. Thus, the Court was "disinclined to promote form over substance" since viable Federal claims were apparent on the face of the complaint. Notably, the Court highlighted the fact that neither the Supreme Court nor the First Circuit has annunciated a rule for situations like this, where both bases for jurisdiction are present and where State and Federal law provide competing answers regarding discovery of medically peer reviewed materials.

Baystate also argued in the alternative, asking the Court to recognize a new Federal common law privilege for medical peer review documents, despite the fact that no court in the First Circuit or District of Massachusetts has recognized such a privilege. Baystate contended that accepting a privilege at the Federal level would promote uniformity since there is near national agreement for having a medical peer review privilege at the State level.

The First Circuit has developed a two-prong test for determining whether to recognize a State privilege under Federal common law: first, whether Massachusetts' courts would recognize such a privilege; and second, whether the asserted privilege is intrinsically meritorious. Assuming *arguendo* that Massachusetts would consider the documents in question as privileged, the Court proceeded to analyze the intrinsic merit of the privilege. According to prior First Circuit and Massachusetts District case law, to determine whether the medical peer review privilege is intrinsi-

cally meritorious, the Court usually evaluates the following four factors, in no particular order: 1) whether the communications originated in a confidence that they would not be disclosed; 2) whether this confidentiality is essential to the full and satisfactory maintenance of the relationship between the parties; 3) whether this relationship ought to be sedulously preserved; and 4) whether the injury of disclosure to the relation would be greater than the benefit gained for the correct disposal of litigation. Upon a finding in favor of disclosure for any one of these factors, the privilege is not recognized.

Here, the Court began with the fourth factor, which it described as essentially a balancing test of the Federal interest against the State interest, and viewed the result as being determinative. Offering three reasons, the Court found that the Federal interest was "quite strong, particularly as it applies to the types of claims pursued by [Gargiulo]."[5] First, the few Federal courts that have recognized medical peer review privileges have done so in the context of medical malpractice claims, but in this case Gargiulo asserted civil rights and employment discrimination claims, instances in which other courts in the First Circuit have refused to create a medical peer review privilege. Second, the Supreme Court has cautioned against recognizing privileges broadly, because of the negative impact on the fundamental principle that the public and each party has a right to the other side's evidence. Here, the Court believed that the privilege, if adopted, insofar as it would go far beyond the medical malpractice context, would "cut too broad a swath."[6] Third, the Supreme Court has specifically discouraged Federal Courts from recognizing a privilege where Congress has considered the privilege and elected to not provide it. The Court observed that such appeared to be the very situation when Congress enacted the Health Care Quality Improvement Act of 1986 ("HCQIA").[7] HCQIA extends qualified immunity to medical professionals involved in a defined medical peer review process, but Congress declined to create a federal evidentiary privilege for the documents produced during such reviews. The Court quoted prior Massachusetts District case law regarding Congress's "silence" in not including a privilege against discovery of medical peer review materials.[8]

The Court believed that the federal interest in fighting discrimination weighed in favor of disclosure, and noted that HCQIA specifically waived immunity for peer reviewers in cases arising out of violations for civil rights. The Court concluded: "This carve out, in conjunction with [HCQIA]'s silence on medical peer review privilege, and the general federal interest in battling discrimination, tips the scale in favor of disclosure."[9] Gargiulo's Motion to Compel Production of Discovery was allowed. The Court, however, permitted the parties to enter a protective order to maintain the confidentiality of the peer reviewers and any patients mentioned in the documents.

(Endnotes)
1 *Gargiulo v. Baystate Health, Inc.*, No. 11-30017-MAP, 2011 WL 3627549 (D. Mass. Jul. 15,2011).
2 Mass. Gen. Laws ch. 111, § 204(a).
3 *Gargiulo,* at *1.
4 Fed R. Evid. 501.
5 *Gargiulo,* at *4.
6 *Id*.
7 *Id*.
8 *Id*.
9 *Id*. at *5.

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