A Public Policy Discussion: Taking the Measure of the Stark Law

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I. INTRODUCTION

The Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a "Convener on Stark Law" (Convener Session) held on April 24 and June 30, 2009 in Washington D.C. AHLA's public interest activities are intended to promote a better understanding of healthcare issues and to encourage a constructive dialogue among members of the industry, all branches of government, academics, patients, and consumers. Over the past few years, the AHLA Public Interest Committee has addressed a range of significant issues, including emergency preparedness, corporate compliance, corporate governance, and healthcare quality.

The purpose of the Convener Session was to provide a forum for a candid discussion of the efficacy of the federal physician self-referral statute or "Stark Law" (also referred to as "Law" throughout this paper) and to consider what, if any, changes to the Law might be beneficial in light of both the current structure of the healthcare delivery system and pending healthcare reform proposals. Participants endeavored to consider the issues from both an industry and government perspective.

In brief, the Stark Law prohibits a physician from referring Medicare patients for certain designated health services to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies.[1] In addition, the Law prohibits the entity from billing the Medicare program for services provided pursuant to a tainted referral. Through its regulation of physician financial relationships, the Stark Law has a significant influence on the structure and operation of the healthcare delivery system.

The Convener Session participants represented a broad range of viewpoints, including in-house counsel, attorneys in private practice who work primarily with hospitals and/or physicians, lawyers who represent *qui tam* relators, academics, and attorneys now in the private sector who were formerly involved in government service on behalf of both regulatory and enforcement agencies. Representatives from the Centers for Medicare and Medicaid Services (CMS), the Office of the Inspector General (OIG) for the Department of Health and Human Services, and the Department of Justice (DOJ) attended the Convener Session to listen to the discussion but did not participate. In advance of the Session, each participant was asked to consider three issues: (1) whether the Stark Law is working as intended; (2) the practical impact of the Stark Law and the

[1] 42 U.S.C. §1395nn(a)

benefits, challenges, and unintended consequences arising from it; and (3) possible improvements to the Law and its enforcement.[2]

The Convener Session prompted a vigorous discussion of both policy issues and practical considerations. The purpose of this White Paper is to provide a summary of that discussion and the resulting proposals for changing either the Stark Law or the manner in which it is administered or enforced. To put the discussion in context, this White Paper includes a brief overview of the Stark Law and its regulatory history.[3]

II. EXECUTIVE SUMMARY

The federal Stark Law is an effort to limit the influence of financial relationships on physician referrals. The Law prohibits a physician's referral of Medicare patients for certain services to an entity with which the physician has a financial relationship, unless the relationship meets a statutory or regulatory exception. The Stark Law also prohibits the entity from billing for any services provided pursuant to a tainted referral. The strict liability provisions of the Stark Law combined with its breadth have yielded both positive and negative results:

Pros:

- *Encouraged Compliance Programs*. The Stark Law has encouraged the development of both corporate compliance programs and contract management systems. The structure of the statute and its broad application has heightened the healthcare industry's scrutiny of physician financial relationships, particularly with hospitals.

- *Restricted Investment*. For those who believe that physician ownership of ancillary services should be discouraged, the Stark Law has been effective in restricting physician investment in free-standing imaging centers and other providers of ancillary services.

- *Aided Enforcement*. When the Stark Law serves as the basis for an action under the False Claims Act (FCA), a relator or the government avoid the intent requirements that otherwise would apply to FCA cases based upon the federal Anti-kickback statute. In addition, the Stark Law's complexity and technical nature make it relatively easy to establish a violation as the predicate for an FCA action.

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[2] The agenda for the Convener Sessions Parts I & II and a list of the participants are attached as Exhibits A and respectively.

[3] *See* 42 C.F.R. § 411.350 (2007), 72 Fed. Reg. 51012 (Sept. 5, 2007) and 42 U.S.C. §1395nn (2008). Stark II Phase III can also be downloaded at http://edocket.access.gpo.gov/2007/pdf/07-4252.pdf.

Cons:

- *Increased Complexity and Unintended Consequences*. The Stark Law was intended to provide a bright line test limiting physician self-referral. As applied, the Law's structure, breadth, and complexity have yielded few bright lines. A vast array of exceptions (that some characterize as loopholes) have driven the restructuring of the healthcare delivery system and in some cases created either an unlevel playing field or unclear boundaries**.**

- *Impediment to Changes in Healthcare Delivery and Payment.* The Stark Law's requirement that any financial relationship between an entity and a physician fit within an exception can serve as an impediment to the development of new delivery and payment systems. Arrangements such as pay-for-performance, shared savings and bundled payments are frequently problematic under the Stark Law because they may not fit squarely within any existing exception.

- *Non-Compliance Inevitable*. Compliance with the Stark Law is difficult even for the best intentioned providers in light of the Law's complexity and strict liability provisions. Moreover, providers currently have no clear direction on how they should disclose a Stark violation.

- *Disproportional Consequences*. As a result of the Stark Law's prohibition on billing for services provided pursuant to impermissible referrals, technical violations that cause no harm to the federal program can trigger huge penalties. Even when the Stark violation is less innocent, the resulting liability can be grossly disproportional to the nature of the conduct giving rise to the violation.

Changes to the Law: The Convener Session participants identified a series of potential changes to the Stark Law to address areas where the Law may have either diverged from its initial purpose or triggered unintended consequences. These proposals ranged from structural changes to the Law, to more technical changes, to regulatory exceptions. While there were varying degrees of support for different proposals, the participants agreed that, overall, the purposes of the Stark Law would be well served by simplification of the Law and by a statutory change granting CMS broader discretion in crafting regulatory exceptions.

Enforcement Issues: With respect to enforcement, the Convener Session participants noted that the Stark Law has been enforced almost exclusively through the FCA, including its *qui tam* provisions. Participants voiced concern that the recent amendments to the FCA would increase exposure significantly if simply the retention of payments received for services provided pursuant to a referral prohibited by the Stark Law is sufficient basis for an FCA claim. There was general consensus that a Stark self-disclosure protocol would be beneficial to the healthcare industry and that CMS should be given explicit authority to compromise the overpayment liability attendant to a Stark violation. In addition, participants discussed imposing fines for technical Stark violations (as opposed to triggering the prohibition on billing) and giving CMS the discretion whether to prohibit reimbursement for services provided pursuant to a prohibited referral.

III. THE STARK LAW: AN OVERVIEW

The Ethics in Patient Referrals Act of 1989 (Stark I) prohibited a physician from making a referral to an entity for the furnishing of clinical laboratory services (for which Medicare might otherwise pay) if the physician (or an immediate family member) had a financial relationship with the entity, unless an exception applied. Stark I also prohibited a clinical laboratory from presenting a claim for payment for any clinical laboratory services rendered pursuant to the tainted referral. Stark I became effective January 1, 1992.

Congress amended the Stark Law in the Omnibus Budget Reconciliation Act of 1993 (Stark II).[4] These amendments significantly broadened the scope of the Stark Law by expanding the Law's referral prohibitions from clinical laboratory services to ten (10) additional "designated health services."[5] Stark II also modified certain existing exceptions, added new exceptions, and extended the Stark Law's prohibitions to Medicaid referrals by giving the government the power to deny federal financial participation for services rendered to Medicaid patients pursuant to a prohibited referral.

CMS has published a series of regulations implementing the Stark Law. Significant regulatory events include:

- Stark I proposed regulations. Published March 11, 1992.

- Stark I final regulations. Published August 14, 1995, these final rules incorporated those provisions of Stark II that relate to clinical laboratory referrals and revised the proposed rule based on public comment.

- Stark II proposed regulations. Published January 9, 1998, these proposed regulations (1) applied many of the provisions of Stark I to the additional designated health services contained in Stark II, (2) proposed numerous new and revised definitions that explained key provisions of the Law, and (3) added several new regulatory exceptions.

- Stark II Phase I Final Regulations. Published January 4, 2001, the Phase I interim final rule marked a change in direction from the Stark II proposed regulations. Phase I (1) addressed the general referral prohibition and the exceptions

[4] Stark II went into effect on January 1, 1995.

[5] The ten additional "designated health services" (DHS) include: (1) physical therapy services, (2) occupational therapy services, (3) certain radiology services, (4) radiation therapy services and supplies, (5) durable medical equipment and supplies, (6) parenteral and enteral nutrients, equipment, and supplies, (7) prosthetics, orthotics, and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs, and (10) inpatient and outpatient hospital services.

applicable to both ownership and compensation arrangements, (2) defined key terms, and (3) created a number of new regulatory exceptions.

- Stark II Phase II Final Regulations. Published March 26, 2004, the Phase II interim final rule addressed (1) the statutory exceptions related to ownership and investment interests, (2) the statutory exceptions for certain compensation arrangements, and (3) reporting requirements.

- Stark II Phase III Final Regulations. Published September 5, 2007, the Phase III regulations clarified aspects of the Phase I and Phase II regulations based on public comments. The Phase III final regulations also (1) established the rules under which a physician will be deemed to "stand in the shoes" of a physician organization and (2) clarified and expanded the physician recruitment exception.

- 2009 Inpatient Prospective Payment System (IPPS) Final Rule. Published August 19, 2008, the 2009 IPPS final rule introduced significant changes, including (1) limiting the physician "stand in the shoes" provision to physician owners/investors, (2) amending the definition of "entity", effectively limiting the ability of physician-owned entities to provide services "under arrangements" to a hospital, and (3) limiting the use of percentage-based and per-click compensation arrangements for office space and equipment leases.

IV. BRIEFING PAPERS: THEMES

In advance of the Convener Session, participants submitted briefing papers addressing (1) whether the Stark Law is working as intended, (2) the practical impact of the Stark Law and the benefits, challenges, and unintended consequences arising from it, and (3) possible improvements to the Stark Law and its enforcement. Certain themes emerged from these papers:

Effect on Industry Practices: Many participants acknowledged that the Stark Law has changed some behaviors and encouraged the development of both corporate compliance programs and contract management systems. The structure of the statute and its broad application may cause practical problems but the Law has heightened the healthcare industry's scrutiny of physician relationships. These compliance-focused behavior changes, however, have occurred predominantly among hospitals and other institutional providers, not physicians. Although the Law targets physician financial relationships and physician referrals, the penalties and attendant enforcement activities fall predominantly on institutional providers.

Enhanced Government Enforcement: The strict prohibition on billing for services provided pursuant to a referral from a physician who has an impermissible financial relationship with an entity has made the Stark Law a very useful predicate for the government and *qui tam* relators in federal FCA cases. By using the Stark Law, the relator and the government avoid the intent requirements under the federal Anti-kickback statute. Moreover, the Stark Law's

complexity and technical nature make it much easier for the government to establish a violation. Potential or actual FCA exposure has heightened the industry's concerns over Stark compliance.

Intent Drift: The Stark Law was intended to provide a bright line test limiting physician self-referral. As applied, the Law's structure, breadth, and complexity have yielded few bright lines. A vast array of exceptions (that some characterize as loopholes) have driven the restructuring of the delivery system and in some cases, created an unlevel playing field. The expansion of services provided by physician groups through the in-office ancillary services exception was highlighted as an unintended and perhaps pernicious consequence of the Law.

Structural Problems: The Stark Law created an extremely broad prohibition on physician referrals. If a financial relationship exists between a physician and an entity, referrals by the physician to that entity are prohibited unless one is able to fit the financial relationship within one or more exceptions. This structure drives the need for an exception for each and every financial relationship that one wishes to permit. Some argue that this structure has made the Law unworkable given the dynamics of the healthcare industry.

Complexity: Virtually everyone acknowledges the complexity of the Stark Law. The statute itself includes a broad prohibition and exceptions with multiple elements. CMS' rulemaking efforts have added detailed definitions, new exceptions, special rules on compensation, and a number of clarifying provisions. The result is an interconnected set of technical rules governing physician referrals that are challenging to apply and difficult to explain. Several participants suggested that compliance with the Stark Law is exceedingly difficult even for the best intentioned providers.

Disproportionality: Given the structure of the Law, innocent or highly technical violations can result in ruinous liability. For example, an administrator's oversight in securing a physician's signature can trigger the referral prohibition. The unlucky hospital is consequently prohibited from billing Medicare for all services ordered by that physician and if bills have been submitted, any amounts collected from the Medicare program are subject to recoupment. If the omission is not discovered for months or years, the hospital's recoupment exposure mounts with each patient admitted and service ordered by the physician. CMS' inability to compromise the amount of the overpayment liability, combined with the lack of any established procedure for self-reporting Stark violations to the government, exacerbates the problem. The disproportionate consequences of a technical Stark violation are viewed by many as unfair and as undermining respect for the Law.

V. THE STARK LAW'S UNDERLYING ASSUMPTIONS

The Convener Session started with a discussion of the purposes of the Stark Law and the assumptions underlying its enactment. Most agreed that the Stark Law was enacted based on the assumption that financial incentives skew a physician's judgment, increasing utilization, undermining competition, and potentially compromising quality. The Law reflects an effort by the government to control the use of resources by reducing what were assumed to be

inappropriate influences on a physician's judgment. The studies that prompted the enactment of the Stark Law suggested that when a physician owns an imaging modality, he or she will use more imaging services. Participants pointed out, however, that no studies have demonstrated that the increase in utilization was, in fact, "overutilization."

The premise that financial incentives influence physician behavior was generally accepted by the Convener Session participants, but all agreed no one has proven whether the resulting care is optimal or not. Moreover, some participants noted that while financial incentives may correlate with an increase in utilization, there are other factors at work. For example, physicians who believe in the efficacy of a particular technology will be more willing to invest in and use that technology. Thus, physicians may invest in a modality because they are true believers in the benefits that it will provide to their patients.

On the other hand, participants acknowledged that physicians are in a position of trust and that patients themselves cannot be expected to safeguard against overutilization or the other purported dangers of self-referral.

Several participants criticized the Stark Law's in-office ancillary services exception as inconsistent with the articulated purposes of the legislation. It was noted that physicians have the greatest financial interest in those services provided through their own group practices. The Stark Law expressly permits such relationships, leaving some open questions as to Congress' intent and the political realities of enacting legislation.

VI. THE STARK LAW IN CONTEXT

The Available Tools: The Convener Session participants considered the role of the Stark Law in the context of the other regulatory and enforcement devices that the government has at its disposal for addressing physician self-referral practices:

- *The Stark Law's Efficacy*. The participants generally agreed that the Stark Law has been a key factor in the government's attempts to regulate physician self-referral. The Stark Law is credited with eliminating physician ownership of freestanding diagnostic centers and blamed for encouraging physicians to provide an ever growing range of services through their group practices. The Law has made it more difficult for physicians to have an ownership interest in a provider of designated health services but prompted an expansion of leasing and management services arrangements. Some participants acknowledged that the threat of Stark exposure has led to positive changes in physician contracting and physician recruitment practices. Others maintained that Stark has "re-routed" rather than eliminated pernicious behavior.

- *False Claims Act*. For the past several years, the FCA has served as the primary mechanism for enforcement of the Stark Law. While the Law restricts a physician from making a referral to an entity based on the existence of a non-compliant

financial relationship, from an FCA perspective, the key provision is the prohibition on billing for services furnished pursuant to a prohibited referral. The billing prohibition creates FCA exposure if the claims were submitted with the requisite intent (reckless disregard or deliberate ignorance of their truth or falsity). The amendments to the FCA included in the Fraud Enforcement and Recovery Act of 2009 appear to significantly increase entities' Stark Law exposure by effectively expanding the definition of a claim to include the knowing and improper retention of an overpayment. In practical terms, this could mean that an entity that submits a claim with no knowledge that it may be prohibited by the Stark Law may face FCA exposure if it later discovers the Stark violation and fails to timely return the reimbursement received for claims submitted based on services provided pursuant to prohibited referrals.

- *Reimbursement.* There was a general consensus among the Convener Session participants that modification of the reimbursement rules would be among the most effective means for controlling utilization and costs. Suggested reimbursement reforms that could control utilization include (1) decreasing reimbursement for all ancillary services provided through a physician's group practice; (2) adopting a declining reimbursement formula for particular modalities tied to volume on the theory that the provider's margin increases dramatically above a certain volume threshold; (3) decreasing payments for high margin services (and service lines); (4) limiting the number of entities that are eligible to bill for certain lucrative services by implementing more stringent credentialing requirements; (5) bundling the payment for physician office visits and ancillary services; and (6) adopting bundled payment plans that promote shared risk among providers involved in an episode of care.

- *The Anti-kickback Statute*. At the time the Stark Law was enacted, the government's ability to use the Anti-kickback statute to regulate inappropriate influences on a physician's referrals was limited by several factors. At that time, there was no civil liability for Anti-kickback violations under the Civil Money Penalty (CMP) statute, and the government was not sure that it could use an Anti-kickback violation as a predicate for a federal False Claims Act case. Government enforcement agencies were looking for a non-intent based statute and the Stark Law filled that need.

  Convener Session participants noted the evolution of the federal Anti-kickback statute. Over the past twenty years, the scope and application of this statute have been expanded, making it a more flexible and effective enforcement tool. The Anti-kickback statute can now be enforced in a civil context through both the federal False Claims Act and the CMP statute. This civil enforcement capacity has made the Anti-kickback statute far more "user friendly" for the government. Enforcement actions, corporate integrity agreements, and advisory opinions have raised industry awareness and created a far more robust enforcement environment.

In light of the Anti-kickback statute's current parameters, several participants suggested that today, there is less need for the Stark Law to support the government's enforcement efforts. Others voiced disagreement with the suggestion that the Stark Law was no longer needed, arguing that for many in the industry, the Anti-kickback risks raised by a particular relationship are considered only as an afterthought.

One participant noted that there is a clear tension between the Stark Law and the Anti-kickback statute. Many relationships that are permissible under the Stark Law may run afoul of the Anti-kickback statute. This can create confusion and make it more difficult for the government to prosecute kickbacks when they occur in a context that fits within a Stark exception. The net result is that the Stark Law occasionally undermines the enforcement of the Anti-kickback statute.

- *Utilization Review.* The participants briefly discussed utilization review and most agreed that it is not an effective means of controlling overutilization. Although things may change in the future, most agreed that utilization review processes are not currently supported by an adequate infrastructure of either evidence-based outcomes data or accepted standards of care.

Healthcare Reform: The Convener Session participants discussed how healthcare reform may affect the role and efficacy of the Stark Law. If the reforms to the system include either pay-for-performance, gain sharing, bundled payment or outcomes measures, the Stark Law could be a significant impediment, preventing hospitals and other providers from aligning incentives with physicians. Although the Hospital Physician Incentive Plan Prohibition, which is part of the CMP statute, may be the most direct impediment to gain sharing or pay-for-performance programs, the Stark Law imposes substantial limits on the ability of providers to implement such arrangements. The key problem is that these types of programs inevitably link physician payments to the volume or value of physician referrals. This type of payment formula generally will not pass muster under the compensation arrangement exceptions to the Stark Law.

If the reform initiatives focus on managed care options, the Stark Law may become much less relevant. In this type of system, the problems of "stinting" and patient steering would be the likely areas of abuse rather than overutilization arising out of self-referral.

VII. STARK LAW STRUCTURE AND ITS IMPLICATIONS

The Stark Law starts with an extremely broad prohibition. All physician referrals to an entity are prohibited unless the physician's financial relationships with that entity fit within one or more exceptions. Given the equally broad definition of financial relationships, the Stark Law has virtually ubiquitous application in the healthcare delivery system. The practical implications of the Law are greatly magnified by the fact that where the entity has a non-excepted financial relationship with a physician, the entity is prohibited from billing for any designated health

services referred to it by that physician. In addition, the Stark Law is a strict liability statute in that the referral prohibition and the prohibition on billing are not dependent on the parties' intent.

The Convener Session participants characterized Stark's unusual structure and broad application as creating both strengths and weaknesses. The proscriptive structure of the Stark Law requires the creation of an exception for each and every permissible financial relationship. Given the dynamics of the healthcare industry, the Law is destined to impede changes that involve relationships that do not fit within existing exceptions. This, in turn, creates pressure for an ever increasing number of exceptions, enhancing the complexity of the law and undermining the industry's ability to understand and comply with its provisions. The mechanical application of the Stark Law can also result in overpayment liabilities that are highly disproportionate to the conduct giving rise to the offense.

On the other hand, the Stark Law's broad prohibition and lack of an intent element make it easier for CMS and government enforcement agencies to use. In one context, Stark is a payment rule: if you don't comply, you don't get paid. In the False Claims Act context, Stark Law violations may be characterized as false claims. The Stark Law may thus enable the government and/or the relator to avoid the intent requirements under the federal Anti-kickback statute. Moreover, the technical nature of the Stark Law makes it much easier to establish a violation. The sharp rise in the number of Stark-based False Claims Act cases is a testament to the utility of the statute.

The Convener Session's discussion of the Stark Law's structure also addressed the following issues:

Hospitals in the Crosshairs: The Stark Law prohibits *physicians* from making referrals but the statutory penalties attach to the submission of claims for services provided pursuant to the prohibited referrals. Consequently, the hospitals submitting claims for such services have by far the greatest exposure under the Stark Law and highest likelihood of incurring disproportional penalties for submission of "tainted" claims. The Stark-based FCA cases have been primarily filed against hospitals and such claims are generally far more lucrative than those involving other providers. Stark enforcement against physicians is almost nonexistent and there is little reason to believe that will change. Given this, it is not surprising that physicians often view Stark compliance as the *hospital's* problem.

The Dangers of Disproportionality: The risk that a Stark violation might result in a level of exposure that could effectively bankrupt a hospital is a scenario that haunts administrators. For example, assume that in 2001, a hospital enters into a medical director agreement with its most productive cardiac surgeon. The terms of the agreement are commercially reasonable and the compensation is set at fair market value. In 2002, the medical director agreement expires but the hospital mistakenly assumes that the agreement automatically renewed and continues to pay the surgeon. The surgeon also thinks the written agreement is still in place and continues to provide the services and submits weekly timesheets documenting the hours devoted to his medical director duties. In 2009, the hospital discovers that the medical director agreement expired in 2002. Under the Stark Law, the hospital has had a non-excepted financial relationship with the cardiac surgeon for the past seven years and *all* reimbursement that the hospital received

during that period for services provided to Medicare patients pursuant to referrals from that cardiac surgeon are subject to recoupment by the government. The repayment liability in this instance could be millions of dollars. If the hospital made the same type of faulty assumption with respect to five agreements, the potential exposure grows accordingly. If this Stark violation is used as the basis for a False Claims Act case, civil penalties and treble damages could also be recovered. In short, the hospital's total exposure flowing from an expired medical director agreement could well be ruinous.

While the potential exposure for a Stark violation is enormous, historically the likelihood of enforcement has been low. CMS has not been actively seeking recoupment based on violations of the Stark Law. Enforcement of Stark through the False Claims Act is random and often not the sole or even primary focus of the government's case. The risk of a hospital facing disproportional penalties for an innocent Stark violation, however, is exacerbated to the extent that prosecutorial discretion has been effectively abdicated to whistleblowers under the *qui tam* provisions of the FCA. Given all these factors, the industry has viewed Stark enforcement as akin to lightning striking - unpredictable but deadly.

It should be noted, however, that the amendments to the FCA in the Fraud Enforcement and Recovery Act of 2009 could lead to much more aggressive *qui tam* enforcement of the Stark Law. A large number of providers may be vulnerable to FCA actions based upon the knowing and improper retention of Medicare reimbursement received for services furnished pursuant to a prohibited referral.

The disproportional penalties attendant to a Stark violation can create a problem for the government. When the application of the Stark Law threatens the financial viability of a community hospital, the possibility of either judicial nullification or political backlash is real. These dangers are reduced by the fact that most hospitals, even when faced with a claim with little merit, will settle rather than roll the dice in a government enforcement action.

Some Convener Session participants argued that the draconian consequences of a Stark violation have not been more controversial only because enforcement has been both scant and unpredictable. If the Law were actually enforced, there would be many more concrete examples of its disproportional penalties. These participants maintain that it would only take a few high profile examples to prompt changes in the Stark Law.

VIII. RESTRUCTURING OPTIONS

The Convener Session participants explored how the Stark Law might be restructured and what effect the proposed changes might have. The discussion addressed the following topics:

Reverse the Premise: The participants discussed whether the Stark Law should be amended so that it prohibits only specific types of financial relationships. Under this approach the focus would shift from fitting all financial relationships within exceptions to defining a list of prohibited financial relationships that physicians must avoid. Several participants expressed

skepticism about the ability of Congress or CMS to define the list of illegal arrangements in a manner that could effectively control industry behavior. Others opined that it would be fairer and more effective for the Law to define the relationships deemed to be abusive and specifically prohibit those relationships.

Add an Intent Requirement: The participants discussed the possibility of incorporating an intent requirement into the Stark Law. Under this approach, a physician referral or the submission of a claim by an entity would not be prohibited unless the action was taken with the knowledge that it was prohibited. Such an amendment would avoid exposing innocent parties to significant sanctions for inadvertent or technical Stark violations. Some participants objected to this approach contending that adding an intent requirement would fundamentally undermine the efficacy of the Stark Law. Many voiced the opinion that Stark with an intent element would be duplicative of the Anti-kickback statute. Stark would no longer be a payment rule, but more akin to a kickback prohibition.

Focus on Ownership: Several participants suggested amending the Stark Law to limit the financial relationships that would trigger the referral prohibition to ownership interests. Passive ownership interests - arrangements where the owner physician does nothing more than refer patients and collect a check - were identified as the most susceptible to abuse. Participants generally acknowledged that focusing on ownership interests and eliminating compensation arrangements would greatly simplify the statute's scope and application. The federal Anti-kickback statute would still be available to address truly abusive compensation arrangements.

Some suggested that, in conjunction with the elimination of compensation relationships from the Stark Law, the definition of ownership could be expanded to include ownership of medical equipment leasing companies and other enterprises that derive substantial revenues from entities involved in the delivery of designated health services.

Concerns were expressed that eliminating compensation relationships from the Stark Law would eviscerate the statute. The ability of the industry to design compensation arrangements that replicate the benefits (and consequently the dangers) of ownership was acknowledged. Other participants noted that the Stark Law was enacted at a time when the government was litigating whether an Anti-kickback statute violation could form the basis for a False Claims Act case. Given the evolution of the FCA case law, as described above, there is less need for the compensation provisions in the Stark Law.

The participants also considered whether physician ownership is intrinsically bad. The whole hospital exception and the in-office ancillary services exception were cited as policy determinations that some types of physician ownership are appropriate. Other participants disagreed, taking the position that both of these exceptions reflect political compromises rather than policy determinations. A discussion ensued regarding physician ownership of specialty hospitals, ambulatory surgery centers and other facilities. There was general consensus that it is *not* the function of the Stark Law to limit physician ownership for political reasons.

Narrow the Scope of Prohibited Compensation Arrangements: In lieu of completely eliminating compensation arrangements from the purview of the Stark Law, several participants

urged that the scope of the compensation arrangements covered by the Law be limited. One suggestion was that the Stark prohibitions apply only to those compensation arrangements where the payments vary with the volume or value of referrals. Many agreed that this limitation focuses the Stark Law on the compensation arrangements most likely to be abusive and eliminates many of the problems created by the broader prohibition.

Some suggested that the Stark prohibition should also apply to compensation arrangements where the payments are not at fair market value. This would provide greater protection against abusive relationships and enable regulators to use the Stark Law to go after arrangements where the compensation paid to the physician is excessive. Other participants argued that a fair market value requirement would generate considerably more complexity and inherent uncertainty with little substantive benefit. Moreover, including a fair market value requirement is problematic because some relationships simply are not premised on a fair market value exchange. Recruitment arrangements, incidental medical staff benefits, and volunteer activities/benefits were cited as examples.

The difficulty of establishing and documenting fair market value was another concern raised by the participants. For example, it is unclear what type of data one should use to determine the fair market value of a physician's participation in a pay-for-performance program. Call coverage arrangements generally suffer from the same foible. Other participants noted that determining fair market value in the healthcare industry in a manner that is not influenced by potential referrals can be very difficult given the central role of physicians in the provision and ordering of healthcare services. Several participants expressed the view that valuation consultants have been the primary beneficiaries of the existing fair market value requirements in the Stark Law exceptions. Participants complained that the current emphasis on the need to prove fair market value encourages providers to hire consultants who frequently "make up a value," thereby undermining respect for the law.

Several participants argued that the Stark Law compensation provisions do not need a fair market value requirement because the Anti-kickback and CMP statutes are available to address excessive compensation and other abusive relationships.

Give CMS Broader Rulemaking Discretion: The Stark Law permits CMS to create additional regulatory exceptions to the referral and billing prohibitions for financial relationships that the Secretary determines do "not pose a risk of program or patient abuse."[6] Guided by this standard, CMS has taken a cautious approach in crafting new Stark exceptions. Participants suggested the regulatory exceptions are often too narrow, too elaborate and, consequently, impractical. It was suggested that CMS should be given broader discretion to enact exceptions that are consistent with broader policy objectives, such as increasing efficiency and quality and decreasing costs. This approach would enable CMS to enact broader, less complicated exceptions and the agency could expressly consider an exception's practical application.

[6] 42 U.S.C §1395nn (b)(4).

Simplify: As noted above, there is general consensus that the Stark Law is exceedingly complex and highly technical. Many of the participants suggested that everyone would benefit if the Law's definitions and exceptions could be simplified. The specific suggestions included:

- Signature. Perhaps the classic example of a "technical" Stark violation is a failure to secure a physician's signature when all other elements of the relevant exception are satisfied. Elimination of the signature requirement from all of the applicable Stark exceptions would enhance the industry's ability to comply and decrease the number of technical violations leading to disproportionate sanctions. The downside to eliminating the signature requirement is that it is helpful in establishing the scope and terms of the parties' arrangement.

- Written Agreement. Elimination of the written agreement requirement from all applicable Stark exceptions was also suggested. This change would further enhance the industry's ability to comply with the Law and decrease the number of technical violations leading to disproportionate sanctions. Many argued that the expiration of a written agreement alone should not trigger liability under the statute. Some participants, however, opposed eliminating the writing requirement, pointing out that it provides law enforcement with an easy benchmark, thereby promoting enforcement. A writing clarifies the scope, terms, and rationale underlying an arrangement and enhances transparency. Some participants suggested a middle ground whereby the failure to comply with the writing requirement would result in a civil penalty but not trigger the Stark referral or billing prohibitions.

- Commercial Reasonableness. Several participants characterized the commercial reasonableness requirement as a mystery and suggested that it be eliminated. If an arrangement is a sham, it can be addressed by the Anti-kickback statute. Supporters of the commercial reasonableness standard argued that it was a good "back stop" to fair market value that focuses on the practical realities of the arrangement.

- Reduce Complexity of Exceptions, Streamline Definitions, Stop Writing Exceptions to Exceptions, etc. Some participants noted that the complexity of the Stark Law arises in part from its history of "reactive" rulemaking. According to this perspective, the cycle has been that (1) the agency promulgates an exception or a rule, (2) following implementation, someone identifies a potentially abusive practice in the industry; and (3) the agency reacts, not by taking a different tact, but by either amending the existing rule or creating "an exception to the exception" to address the perceived concern. Although this cycle may seem logical, it has resulted in a maze of regulatory definitions, special rules, and exceptions.

  It was also suggested that either Congress or CMS streamline the Stark Law by eliminating cumbersome or unnecessary elements in the various exceptions, streamlining definitions and, in some instances, starting from scratch on specific

concepts (*i.e.*, the definition of remuneration). Other Convener Session participants criticized this approach as unworkable, pointing out that the complexity of the regulations has been driven by either demands for guidance or abusive practices.

- *De Minimis* and/or Technical Violation Exceptions. Both carving out small dollar arrangements through a broad *de minimis* exception and adopting a technical violation exception were suggested. These exceptions would simplify compliance with the Law by eliminating from its scope technical violations, run-of-the-mill expense reimbursements, minor courtesies, and perhaps even modest medical director fees. Opponents pointed out that there is a tension between the Stark Law and the Anti-kickback statute that makes it difficult for the government to accept a broad *de minimis* exception under the Stark Law without undercutting its ability to pursue Anti-kickback claims. It was also noted that if Stark compensation arrangements are limited to those where compensation varies with the volume or value of referrals, then there should not be a need for a broad *de minimis* exception. With respect to the technical violation exception, most agreed that it would be difficult to define what constitutes a "technical violation" and that, like the *de minimis* exception, a technical violation exception could adversely affect enforcement of the Anti-kickback statute.

IX. STARK ENFORCEMENT AND COMPLIANCE

The Stark Law prohibits physicians from making certain referrals and entities from billing for services provided pursuant to prohibited referrals. Reimbursement received by such entities is subject to recoupment. In addition, some authorities suggest that providers have an affirmative duty to disclose and repay the government once a Stark violation is identified. As noted above, the potential repayment obligation can be vastly disproportional to the nature of conduct giving rise to the violation. The challenges posed by this disproportional exposure are exacerbated by the rules governing CMS' ability (or more accurately, inability) to compromise an overpayment obligation arising out of a Stark violation. Under existing law the agency believes that it lacks the authority to seek less than a complete repayment of the reimbursement paid for services provided pursuant to a prohibited referral. At the same time, there are few reports of CMS seeking recoupment under the Stark Law. In fact, the agency has not established a process for providers to self disclose Stark problems.

Several participants in the Convener Session noted that when confronted with evidence of a Stark violation, providers are thrust into a vacuum with little practical guidance on how best to address the situation. A provider's options when it discovers a Stark violation were described by one participant as follows:

- Do nothing.
- Fix the problem and don't look back.

- Fix the problem and return the entire "overpayment."

- Identify a government agency, make a disclosure and attempt to negotiate a compromise.

All options pose substantial risks. The participants generally agreed that if one chooses to disclose a Stark violation, there are no good choices. CMS has stated that it does not have the discretion to compromise the amount of the overpayment. The OIG's voluntary self-disclosure protocol, which previously permitted disclosure of potential Stark infractions, is generally no longer available as a means of disclosing and compromising Stark violations, unless the conduct also implicates the Anti-kickback Statute. Disclosure to the Department of Justice or local US Attorney's Office could be viewed as an admission of wrongdoing and neither the DOJ nor the US Attorneys are known for their willingness to compromise claims for less than the face amount of the repayment obligation.

It is also relevant that to date, virtually all Stark enforcement has been accomplished through cases filed under the federal False Claims Act. Initially driven by creative *qui tam* relators and more recently by Department of Justice initiatives, the FCA has been the government's sole means of affirmatively pursuing violations of the Stark Law. The combination of the Stark Law and the FCA often yields astronomical exposure for the defendants (recoupment, plus treble damages, attorneys' fees and civil penalties of $5,500 to $11,000 per claim). The recently enacted amendments to the FCA significantly expand the circumstances under which providers could face such exposure, including FCA claims arising out of a provider's retention of Medicare payments for services provided pursuant to referrals prohibited by the Stark Law.[7] The potential impact of these FCA amendments on the risk created by the discovery of an historical Stark Law violation should not be underestimated. Healthcare reform legislation may further increase providers' FCA exposure depending on whether Congress enacts certain proposed changes, including an expanded definition of "obligation."

Given the backdrop of potentially ruinous liability under the FCA, the inability to take advantage of the OIG's voluntary disclosure protocol and CMS' stance on its lack of discretion, the industry has been casting about for a practical means of addressing Stark violations once they are identified.

The Convener Session participants discussed a number of ways in which the enforcement and resolution of Stark violations might be handled. The topics addressed included:

Technical Violations: One participant suggested that "technical" violations, such as those violations that are not linked to the volume or value of referrals, should be subject to a separate set of sanctions. The idea is that a technical violation should not give rise to either FCA exposure or huge repayment liabilities. One of the challenges to this approach would be defining what constitutes a "technical violation."

[7] *See* Fraud Enforcement and Recovery Act of 2009.

Make the Prohibition on Billing Discretionary: The problem of grossly disproportional penalties could be addressed by making the billing prohibition discretionary. In other words the entity that provides services pursuant to a tainted referral could submit claims for services but CMS would have the discretion to disallow the claims and seek recoupment. This option would eliminate FCA claims based on Stark violations because the mere submission of the claims would not be prohibited. Some participants objected to this approach because it would require a fundamental change in the statute and impair enforcement activities, particularly those involving the FCA.

Give CMS the Discretion to Compromise Stark Repayment Obligations: There was general consensus that CMS should be able to compromise a Stark repayment obligation. There was some disagreement as to the meaning of existing regulations but all agreed that giving CMS broader explicit authority to compromise the amount of a provider's repayment obligation would be beneficial. Along with the authority to compromise, several participants suggested that CMS establish a Stark self-disclosure protocol to give the industry a practical means of addressing Stark violations once they are identified.

EXHIBIT A

CONVENER ON STARK LAW – PART I

April 24, 2009
Georgetown University, Public Policy Institute
Washington, DC

AGENDA

TIME	EVENT	SPEAKER
8:00 – 8:30	Registration and Breakfast	
8:30 – 8:45	Welcome, Goals and Guidelines for the Session	Beth Schermer, Joel M. Hamme
8:45 – 9:00	Introduction of Participants	All
9:00 – 9:30	Stark Law in the Starting Blocks ▪ Statutory Purpose ▪ Briefing Paper Themes	Beth Schermer
9:30 – 10:30	Stark Law in Context ▪ Laws and other measures addressing self-referral and related program fraud & abuse ▪ Looking forward: self referral concerns now and in the future ▪ Role of the Stark Law and other measures in addressing self referral concerns now and in the future	All
10:30 – 10:45	Break	
10:45 – 12:00	Stark Law Structure ▪ Advantages and disadvantages to the structure of the Stark Law ▪ How does the structure of the Stark Law impact its effectiveness?	All
12:00 – 1:15	Lunch (provided)	
1:15 – 2:15	Stark Law and Potential Changes ▪ What changes would improve the Stark Law's effectiveness for both providers and the government? ▪ Statutory vs. regulatory changes	All
2:15 – 2:30	Break	
2:30 – 3:30	Stark Law Enforcement and Compliance ▪ Government enforcement issues, penalties ▪ Provider compliance and correction issues	All

3:30 – 4:00	Summation, Next Steps, Adjournment	Beth Schermer
4:00 – 5:30	Reception	

CONVENER ON STARK LAW – PART II

June 30, 2009
Marriott Wardman Park Hotel
Hoover Room – Mezzanine Level
Washington, DC

AGENDA

I. Introduction

II. Confirming Consensus on Significant Elements of the White Paper

A. THE STARK LAW IN CONTEXT WITH OTHER LAWS AND PROCESSES

1. Areas of Consensus

a. General Impact of the Law

Participants agreed that the Stark Law has been effective in limiting physician ownership in freestanding diagnostic centers and has encouraged better management of physician contracting. The group also agreed that the Stark Law has spawned an expansion of leasing and management services arrangements that rerouted rather than eliminated pernicious behavior.

b. Reimbursement

Participants agreed that modification of reimbursement rules would be one of the most effective means of addressing utilization and cost issues that are often cited as the goals of the Stark Law. Suggested reimbursement changes included decreased reimbursement for ancillary services provided through group practices, declining reimbursement for high volume procedures, bundled payments that promote shared risk, among others.

c. Utilization Review

Participants agreed that utilization review is not an effective means of controlling the volume or cost of the services provided.

d. The Stark Law and Health Reform

Participants agreed that if health reform embraces aligned incentives between physicians and hospitals as a significant means of controlling costs and reducing utilization, the Stark Law in its current form may limit the ability of providers to implement these arrangements. Participants also agreed that if health care reform focused on bundled payment alternatives, the Stark Law's focus on stemming overutilization may make the law less relevant.

2. Agreements to Disagree

a. The Invigorated Anti-Kickback Statute

Participants could not reach consensus on whether there was still a need for to preserve the Stark Law's current strict liability structure in light of the availability of civil enforcement of the Anti-Kickback Statute under both the False Claims Act and Civil Money Penalty Statute, although many felt that there was still an important role for the Stark Law.

B. STARK LAW STRUCTURAL ISSUES

1. Areas of Consensus

a. Enforcement Benefits

Participants agreed that the Stark Law's broad prohibition and lack of intent make it a strong tool for CMS and government enforcement authorities.

b. Hospitals vs. Physicians

Participants agreed that while the law is intended to prohibit physicians from making referrals, enforcement has and will continue to focus on hospitals, resulting in physicians being less invested in Stark compliance efforts.

c. Disproportionate Penalties

Participants agreed that the penalties that may attach to "technical" or "de minimis" violations can be disproportionate

to the harm, and this potential for disproportionate penalties makes enforcement unpredictable and undermines respect for the law.

C. RESTRUCTURING OPTIONS

1. Areas of Consensus

a. Give CMS Broader Rulemaking Discretion

Participants agreed that CMS should be given broader discretion to craft regulatory exceptions that are consistent with broader policy objectives, such as increasing efficiency and quality and decreasing costs.

b. Give CMS Discretion to Compromise Stark Claims

Participants agreed that the Stark Law should be amended to give CMS broader authority to compromise a provider's repayment obligation.

c. Simplify the Stark Law

Participants agreed that the Stark Law is exceedingly complex and highly technical and is in need of simplification. Specific suggestions, including eliminating the requirements for signatures, written agreements, and commercial reasonableness, had general support, with concerns noted on specific items.

d. Apply a Different Set of Sanctions for "Technical Violations"

Participants agreed that the Stark Law could be improved by applying different sanctions to "technical violations." They also agreed that it would be difficult to reach consensus on the definition of a "technical violation."

2. Agreements to Disagree

The participants discussed many other restructuring options, and identified both the benefits and difficulties with each approach without reaching complete consensus. These options included:

a. Reversing the Premise of the Law

Participants discussed whether the Stark Law should be amended to permit all financial relationships except those specifically prohibited, rather than prohibiting all relationships unless they fall into specific exceptions.

b. Adding an Intent Requirement

Participants discussed whether the addition of an intent element to the Stark Law would help avoid liability based upon inadvertent or technical violations or whether it would instead gut the statute and make it duplicative of the Anti-kickback Statute.

c. Focusing on Ownership

Participants discussed whether limiting the Stark Law's applicability to ownership interests would simplify and clarify the statute or would undermine its efficacy by allowing compensation arrangements that effectively mirror ownership interests.

d. Narrow the Scope of Prohibited Compensation Arrangements

Participants discussed amending the Stark Law to narrow the scope of the prohibition on compensation arrangements to those arrangements where payments vary with the volume or value of referrals. Most participants felt that this change would achieve simplification and still target those compensation arrangements most likely to be abusive.

e. Focusing the Compensation Prohibition on Payments Not at Fair Market Value

Participants discussed whether the Stark Law's prohibition on compensation arrangements should apply only to compensation arrangements where the payments are not at fair market value (in addition to applying to those arrangements that vary with the volume or value of referrals). Some participants felt this approach would focus on and deter excessive payment relationships. Others thought it would generate considerably more complexity and primarily benefit consultants.

f. CMS Discretion

Participants discussed the impact of amending the Stark Law to give CMS the discretion to deny payment for services provided pursuant to a prohibited referral rather than automatically disallowing payment for such services. While some supported this approach, others felt it would impair enforcement activities substantially.

III. Conclusion, Next Steps, Wrap Up and Thanks

EXHIBIT B

Convener on Stark Law
Washington, DC

ROSTER OF PARTICIPANTS

***** *Convener Session Task Force*

S. Allan Adelman
Partner
Adelman Sheff & Smith, LLC
180 Admiral Cochrane Drive, Suite 370
Annapolis, MD 21401
Tel: 301/340-1140
Fax: 301/294-6406
Email: aadelman@hospitallaw.com

John T. Brennan
Partner
Crowell & Moring, LLP
1001 Pennsylvania Ave NW
Washington, DC 20004
Tel: 202/624-2760
Fax: 202/628-5116
Email: jbrennan@crowell.com

Jonathan L. Diesenhaus
Partner
Hogan & Hartson
555 13th Street NW
Washington, DC 20004
Tel: 202/637-5416
Fax: 202/637-5910
Email: jldiesenhaus@hhlaw.com

Robert G. Homchick
Partner
Chair, Health Law Practice
Davis Wright Tremaine, LLP
1201 3rd Avenue, Suite 2200
Seattle, WA 98101
Tel: 206/757-8063
Fax: 206/757-7063
Email: roberthomchick@dwt.com
Andrea M. Kahn-Kothman

Associate Counsel and Special Counsel
JMC Faculty/Medical Staff Affairs and Payment Initiatives
Thomas Jefferson University
1020 Walnut Street
Philadelphia, PA 19107
Tel: 215/503-5887
Fax: 215/923-3613
Email: andrea.kahn-kothmann@jefferson.edu

David E. Matyas
Partner
Epstein Becker & Green, PC
1227 25th Street NW, Suite 700
Washington, DC 20037
Tel: 202/861-1833
Fax: 202/861-3533
Email: dmatyas@ebglaw.com

Kevin G. McAnaney
Law Offices of Kevin McAnaney
1800 K Street NW, Suite 720
Washington, DC 20006
Tel: 202/457-0494
Fax: 202/457-6636
Email: kevin@mcananeylaw.com

Jean M. Mitchell
Professor
Georgetown Public Policy Institute
Georgetown University
3520 Prospect Street NW
Washington, DC 20007
Tel: 202/687-7038
Fax: 202/687-5544
Email: mitchejm@georgetown.edu

Marc S. Raspanti
Partner
Pietragallo Gordon Alfano Bosick & Raspanti, LLP
1818 Market Street, Suite 3402
Philadelphia, PA 19103
Tel: 215/320-6200
Fax: 215/981-0082
Email: msr@pietragallo.com

Cynthia Y. Reisz
Partner
Bass Berry & Sims, PLC
315 Deaderick Street, Suite 2700
Nashville, TN 37238
Tel: 615/742-6283
Fax: 615/742-2783
Email: creisz@bassberry.com

Donald H. Romano
Partner
Arent Fox, LLP
1050 Connecticut Avenue NW
Washington, DC 20036-5339
Tel: 202/715-8407
Fax: 202/857-6395
Email: romano.donald@arentfox.com

Beth Schermer (Moderator)*
Partner
Coppersmith Schermer & Brockelman, PLC
2800 N Central Avenue, Suite 1200
Phoenix, AZ 85004
Tel: 602/381-5462
Fax: 602/224-6020
Email: bschermer@csblaw.com

Albert W. Shay
Partner
Morgan Lewis & Bockius, LLP
1111 Pennsylvania Avenue NW
Washington, DC 20004
Tel: 202/739-5291
Fax: 202/739-3001
Email: ashay@morganlewis.com

Sanford V. Teplitzky
Principal
OBER | KALER
120 East Baltimore Street, Floor 10
Baltimore, MD 21202
Tel: 410/347-7364
Fax: 443-263-7564
Email: teplitzky@ober.com

Cynthia F. Wisner
Assistant General Counsel
Trinity Health
34605 Twelve Mile Road, Suite 250
Farmington Hills, MI 48331
Tel: 248/489-6471
Fax: 248/489-6775
Email: wisnerc@trinity-health.org

GOVERNMENT OBSERVERS (*Individuals in attendance only, not reflective of all who were invited)*

Daniel R. Anderson
Deputy Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

Troy Barsky
Director
Technical Payment Policy Division
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Carol Bennett
Deputy Associate General Counsel for Program Integrity
Office of the General Counsel, Centers for Medicare and Medicaid Services Division
United States Department of Health and Human Services

Dara A. Corrigan
Associate Deputy Assistant Secretary
Office of Health Policy
Office of the Assistant Secretary for Planning and Evaluation
United States Department of Health and Human Services

Joan P. Dailey
Senior Attorney
CMS Division
Office of the General Counsel
United States Department of Health and Human Services

Rhonda F. Ford
Deputy Director
Technical Payment Policy Division
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Joy McGlaun
Senior Policy Advisor
Special Committee on Aging
United States Senate

Karen Milgate
Director
Office of Policy
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Anne Montgomery
Senior Policy Advisor
Special Committee on Aging
United States Senate

Lewis Morris*
Chief Counsel to the Inspector General
Office of Counsel to Inspector General
United States Department of Health and Human Services

Vicki Robinson
Industry Guidance Branch Chief
Office of Counsel to the Inspector General
United States Department of Health and Human Services

SCRIBES

Kristin Cilento Carter
Associate
OBER|KALER
120 East Baltimore Street, Suite 800
Baltimore, MD 21202
Tel: 410/347-7309
Fax: 443/263-7509
Email: kccilento@ober.com

Samuel C. Cohen
Associate
Arent Fox, LLP
1050 Connecticut Avenue NW
Washington, DC 20036
Tel: 202/857-6322
Fax: 202/857-6395
Email: cohen.samuel@arentfox.com

Matthew T. Fornataro
Associate
Crowell & Moring, LLP
1001 Pennsylvania Avenue NW
Washington, DC 20004
Tel: 202/624-2874
Fax: 202/628-5116
Email: mfornataro@crowell.com

Amy F. Lerman
Associate
Epstein Becker & Green, PC
1227 25th Street NW, Suite 700
Washington, DC 20037
Tel: 202/861-1832
Fax: 202/861-3532
Email: alerman@ebglaw.com

AHLA PUBLIC INTEREST COMMITTEE

Thomas W. Coons (Committee Chair)*
Principal
OBER|KALER
120 East Baltimore Street
Baltimore, MD 21202
Tel: 410/347-7389
Fax: 410/547-0699
Email: twcoons@ober.com

Elisabeth Belmont (Immediate Past President, AHLA)
Corporate Counsel
MaineHealth
465 Congress Street, Suite 600
Portland, ME 04101
Tel: 207/775-7010
Fax: 207/775-7029
Email: belmoe@mmc.org

Arthur N. Lerner*
Partner
Crowell & Moring, LLP
1001 Pennsylvania Avenue NW
Washington, DC 20004
Tel: 202/624-2820
Fax: 202/628-5116
Email: alerner@crowell.com

Lewis Morris*
Chief Counsel to the Inspector General
Office of Counsel to Inspector General
United States Department of Health and Human Services

Philip L. Pomerance
Chief Operating Officer and General Counsel
Best Practices Inpatient Care, Inc.
3880 Salem Lake Drive
Long Grove, IL 60047
Tel: 847/235-3070
Fax: 847/719-2265
Email: ppomerance@bestpracticesinpatientcare.com

Michael L. Silhol
Senior Vice President and General Counsel
Parkland Health and Hospital System
5201 Harry Hines Boulevard
Dallas, TX 75235
Tel: 214/590-4686
Fax: 214/590-4580
Email: mlsilh@parknet.pmh.org

Lisa D. Vandecaveye
Corporate Vice President of Legal Affairs
Botsford Health Care Continuum
28050 Grand River
Farmington Hills, MI 48336
Tel: 248/471-8528
Fax: 248/471-8896
Email: lvandecaveye@botsford.org

John R. Washlick
Partner
Cozen O'Connor, PC
1900 Market Street
Philadelphia, PA 19103
Tel: 215/665-2134
Fax: 215/701-2234
Email: jwashlick@cozen.com

AHLA LEADERSHIP

Joel M. Hamme (AHLA President)
Principal
Power Pyles Sutter & Verville, PC
1501 M Street NW, 7th Floor
Washington, DC 20005
Tel: 202/872-6761
Fax: 202/785-1756
Email: joel.hamme@ppsv.com

Peter M. Leibold *
Vice President and Chief Executive Officer
American Health Lawyers Association
1025 Connecticut Avenue NW, Suite 600
Washington, DC 20036
Tel: 202/833-0777
Fax: 202/833-1105
Email: pleibold@healthlawyers.org