



# FINANCIAL INCENTIVES FROM THE STIMULUS PACKAGE FOR PROVIDERS

By Michele Madison



Adoption of electronic health records is one of the rare bi-partisan goals of the federal government. In 2004, President Bush set a federal government goal to ensure all American citizens have access to electronic health records. In 2009, President Obama restated the goal. Congress, through the American Reinvestment and Recovery Act of 2009 ("ARRA"), provided approximately nineteen billion

dollars to incentivize mass adoption of electronic health records. The ARRA provides direct funding to physicians and hospitals to support the adoption and implementation of electronic health records.

## PHYSICIANS.

The Medicare funding for physicians may be as high as \$44,000. Specifically, physicians that participate in Medicare may receive financial incentives starting in 2011 if specific requirements are satisfied. First, the physician must "meaningfully use" certified electronic health records. Meaningful use means that the physician has obtained and implemented an electronic health record that (1) includes e-prescribing; (2) exchanges health information for care coordination; and (3) reports to the Centers for Medicare and Medicaid Services (CMS) specific measurements required by CMS.

The second requirement is that the electronic health record must be certified. However, the certification requirements have not been established. The ARRA established the National Coordinator of Health Information Technology and the HIT Policy Committee and the HIT Standards Committee to develop policies, certification standards and implementation specifications. Electronic health record systems must be certified and in compliance with the requirements set by the federal agencies in order to permit physicians to obtain the funding.

If the physician adopts a certified electronic health record and meaningfully uses it, the physician may receive incentive payments commencing with 2011 through 2016. The calculation of incentive payments is seventy-five percent (75%) of the Secretary of Department of Health and Human Services (DHHS) estimate of the Medicare charges for the physician during the payment year, which shall be calculated within two months of the expiration of the payment year. The payments will be made to the physician or his or her employer or a facility where the physician reassigns his or her Medicare billings and may be split

between multiple locations if the physician works for multiple facilities. The payments will commence with maximum amounts of \$18,000 per year if the electronic health record is meaningfully used prior to 2011 and \$15,000 if the electronic health record is adopted after 2012. The maximum incentive payments will then decrease each year from \$18,000 to \$12,000 to \$8,000 to \$4,000 to \$2,000 in 2016.

On the other hand, if a physician does not adopt and meaningfully use electronic health records by 2015, commencing in 2015, the physician's reimbursement from Medicare will decrease by one percent (1%) to two percent (2%) each year until 2018, provided the decrease will not exceed a cumulative decrease of five percent (5%). Accordingly, physicians have an incentive for quick adoption and meaningful use of certified electronic health records and a disincentive for failing to begin using electronic health records.

## HOSPITALS.

Similar to physicians, the ARRA uses a carrot and stick approach to



promote the adoption of electronic health records. Hospitals that meaningfully use certified electronic health records may receive additional funding based upon a specific formula. A hospital's meaningful use of electronic health records differs slightly from physicians because hospital electronic health records do not need to include e-prescribing functions. Instead, the hospital must adopt and use a certified medical record by ensuring that it can exchange health information for care coordination and report

required data related to quality healthcare to CMS. If a hospital complies with the ARRA requirements, CMS has allocated the following formula for hospital incentive payments:

$$\begin{aligned} & \$2,000,000 \times (\text{Discharge ratio}) \times \\ & \quad (\text{Medicare Share}) \times \\ & \quad (\text{Transition Factor}) = \text{Financial Incentive} \end{aligned}$$



In order to evaluate this formula, the hospital must calculate each component of the formula. The specific components are as follows:

The discharge ratio is determined by taking the total number of discharges for the payment year between 1,150 to 23,000 discharges (not to exceed 23,000) and multiply the answer by \$200.00.

The Medicare Share is determined through the following calculation: (((Total estimate number of inpatient beds during the payment year attributable to patients who hospital received payment from Medicare Part A) plus (the estimated number of beds attributable to the Medicare Advantage plans Part C)) divided by ((the total number of inpatient beds) multiplied by ((the total eligible charges received by Hospital during the payment year minus charity care or estimated uncompensated care) divided by (the hospital's total charges during the payment year))).

The transition factor is set as one (1) for the first payment year,  $\frac{3}{4}$  for the second payment year and  $\frac{1}{2}$  for the third payment year and 0 for the fourth payment year. If a hospital fails to adopt electronic health records in 2015, the hospital will not be eligible for payments. Moreover, if a hospital starts meaningfully using electronic health records in 2013, the transition factor will be ratcheted down each year to reduce the incentive payments.

The ARRA also sets forth a different calculation for Critical Access Hospitals (CAH) which will commence payments in 2011. The CAH formula is dependent upon the specific CAH reasonable costs for the payment year or from previous cost reports that have not been depreciated. In addition, the Medicare Share utilized is the CAH Medicare Share, plus twenty percentage points (20%) and capped at one hundred percent (100%). Therefore, depending upon how the CAH is paid, the specific formula and actual costs must be analyzed in accordance with the regulations. Further, any payments to CAHs are limited to four years and will not apply to cost reporting periods after five (5) years. Accordingly, each hospital must evaluate the potential benefit available from Medicare based upon its specific characteristics and factors.

It is also important to note that Medicaid also provides financial incentives to eligible professionals, which exceeds merely physicians, for adoption and meaningful use of electronic health records. Medicaid financial incentives cannot be duplicative and are also based upon the specific characteristics and factors unique to the eligible professional's practice. Additional information will be provided through separate publications regarding Medicaid financial incentives. □

*Michele P. Madison is a partner in the firm's Healthcare and Healthcare Information Technology Practices, where she provides general legal advice to health systems in various regulatory and business matters. Ms. Madison received her bachelor's degree from Georgia State University and her law degree from the University of Georgia.*



# IMPORTANT FEDERAL CIRCUIT DECISION RAISES STARK LAW AND ANTI-KICKBACK CONCERNS FOR HOSPITAL BASED PHYSICIAN SERVICES

By Robert C. Threlkeld, Esq.



Recently, the Third Circuit Court of Appeals issued a decision that raises important issues under the Stark law and the federal anti-kickback statute. Because the hospital physician arrangement at issue involved the provision of anesthesiology – a hospital based service that typically is not viewed as involving the referral or the possibility of referral

of patients by physicians to a hospital for designated health services – the decision bears attention by both physicians and hospitals.

In *Kosenske v. HMA, et al.*, (3<sup>rd</sup> Cir. 2009) a whistleblower alleged that an exclusive service arrangement between a group of anesthesiologists and an HMA hospital executed in 1992, followed by the provision of pain management services at an HMA outpatient clinic, triggered the restrictions of the Stark law, 42 U.S.C. 1395nn and the Anti-Kickback statute, 42 U.S.C. 1320a-7b. The whistleblower also alleged that the arrangement did not satisfy the personal services exception to the Stark Act or the related safe harbor provision to the Anti-Kickback statute.

The facts of the case as outlined by the Third Circuit opinion were as follows. An anesthesiology group, BMAA, negotiated an exclusive agreement for anesthesia services with Carlisle Hospital in December 1992. Under the exclusive agreement, BMAA would provide exclusive anesthesia coverage for Carlisle patients on a 24/7 basis, the hospital would provide the space, equipment and supplies for BMAA to use for anesthesia purposes, the hospital would provide personnel, space, equipment and supplies for anesthesia *as well as pain management*, and BMAA would not contract with hospitals other than Carlisle or such other facilities that Carlisle might own in the future. The agreement also provided that if Carlisle opened any other facilities, it would offer an exclusivity arrangement at such facility for anesthesia services, but did not require BMAA to accept it. Of further note, BMAA did not commit to provide pain management services to the hospital's patients, although Carlisle would offer space, equipment and supplies for same. Nonetheless, in 1994 Dr. Kosenske, a member of BMAA (and the whistleblower in the case) began to provide pain management services at Carlisle, using space in the hospital that was typically used for other purposes because there was no dedicated pain management clinic there.

In 1998, Carlisle built an outpatient ambulatory surgery center and pain

clinic. From the outset, BMAA provided pain management services to patients in the pain clinic, but did not pay for any space, equipment or personnel that Carlisle provided for its pain clinic patients. BMAA, notably, was the only physician group providing pain management services there. BMAA submitted claims for professional services at the pain clinic, Carlisle submitted claims for the technical fee, just as in the hospital arrangement. In 2001, HMA purchased the assets of Carlisle (the Court treated the contract with BMAA as if it had been assigned, even though there was no formal assignment).

Dr. Kosenske asserted in his suit that the False Claims Act was implicated because of Stark law and Anti-Kickback violations that he alleged.

At the district court level, the court granted summary judgment to BMAA. While recognizing that BMAA received numerous benefits under the arrangement, that BMAA had thus received “remuneration” that established a “compensation arrangement” and “financial relationship” between BMAA and Carlisle for purposes of Stark, the district court also found that the arrangement satisfied the personal services exception under Stark (42 U.S.C. 1395nn(e)(3)(A)) and the related safe harbor under the Anti-Kickback statute. Among other things, the court found that the 1992 agreement satisfied the requirement of a writing, and further found that the services were exchanged for fair market value. The district court made this fair market value finding even though there was no appraisal or expert testimony as to the value of the services or remuneration; rather, the court held that because the services agreement reflected an arms length transaction it, by definition, reflected fair market value.

The Third Circuit, however, disagreed. The Court's opinion recognizes that for Stark purposes, hospital based services such as anesthesia typically do not raise the concern of referrals from a hospital based physician to a hospital; instead, the concern is that *physicians will directly or indirectly pay a hospital* to obtain such an exclusive arrangement. However, as to pain management services, the Court stated that there is a significant risk of referrals for patients to the hospital for surgical and other services that constitute designated health services. Thus, the Stark Act and Anti-Kickback statute were implicated. Further, the Third Circuit found that the personal services exception was not met.

The Court offered several reasons for this decision. First, the Court held that the exclusive services contract did not bind BMAA to provide services at other facilities and did not cover the arrangement at the pain



management clinic following its opening in 1998. Further, even if the agreement could be read to obligate BMAA to provide such services, it said nothing about the remuneration BMAA was receiving in exchange for such services, such as free space, equipment and staffing.

Second, the court held that the district court's notion that an arms-length transaction ipso facto sets fair market value was incorrect, and further held that the 1992 contract could not set a market price for a transaction six years later when the ambulatory surgical center opened. Thus, the court reversed the grant of summary judgment.

This decision is important for several reasons. First, it suggests that a written exclusivity agreement that covers hospital-based services will not protect an arrangement between hospital-based physician providers (such as anesthesiologists, radiologists and pathologists) that implicates other services by such physicians unless the agreement covers such services with particularity. Second, it reinforces the desirability of having a fair market value assessment for any such arrangement. Third, it reinforces the need to have specific contracts governing both hospital-based services and other physician-hospital arrangements that is broad enough to cover future arrangements that are specifically contemplated or, in the alternative, for new written agreements to be executed whenever such new exclusivity or other arrangements are set at new facilities. □

*Robert C. Threlkeld is a partner in the firm's Healthcare, Litigation and Exempt Organizations Practices. Mr. Threlkeld actively represents hospital systems, physician practice groups and other healthcare providers in a range of regulatory matters, and regulatory and business disputes. Mr. Threlkeld received his bachelor's degree from Emory University, his master's degree from Harvard University, and his law degree from Georgetown University.*



# ADVAMED ISSUES REVISED CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

By Amita A. Sanghvi



On December 18, 2008, the Advance Medical Technology Association (“AdvaMed”), a medical device manufacturer trade association, issued a revised Code of Ethics on Interactions with Health Care Professionals (the “Revised Code”), which becomes effective July 1, 2009. In addition to the Revised Code, AdvaMed published a list of Frequently Asked Questions that aid in understanding the guidelines. This article examines some of the key revisions of the Revised Code.

## BROADER SCOPE

The Revised Code broadens the scope of affected persons and entities under the revision. First, the Revised Code now applies to any “Company” that develops, produces, manufactures, and markets medical technologies, not just companies that are members of AdvaMed. Second, the Revised Code has broadened the definition of Health Care Professionals (“HCPs”) to include any individuals or entities “involved in the provision of health care services and/or items to patients.” This includes not just health care practitioners but also persons who are involved in the decision to purchase, lease, or recommend medical technology, such as a practice manager.

## ROYALTY ARRANGEMENTS

The Revised Code now allows for companies to enter into royalty arrangements with HCPs in exchange for novel, significant, or innovative contributions that will improve medical technologies. The calculation of royalty payments should be based on factors that avoid improper influence. The Revised Code sets out examples of improper royalty payments: royalty payments should not be conditioned on a requirement that the HCP purchase, order, or recommend the technology or another product developed by the company offering the royalty payments. Further, the payments should not require the HCP to market the technology upon commercialization.

## LIMITATIONS ON GIFTS AND ENTERTAINMENT

The Revised Code prohibits a company from providing any gifts that do not have a genuine educational function to HCPs. This includes gifts

that have a minimal value such as pens and notepads branded with the company’s name. Although the Revised Code allows for Companies to provide HCPs with gifts that benefit a patient or have some educational value, such gifts, excluding textbooks or anatomical models, may not exceed \$100. Additionally, a company may not provide or pay for any entertainment or recreational activities, even when the company engages HCPs as speakers or consultants.

## MODEST MEALS

The Revised Code allows for Companies to provide modest meals to HCPs incidental to a bona fide presentation of scientific, educational, or business information rather than part of an entertainment or recreational event. These modest meals must take place in a setting that is conducive to such informational presentations. Moreover, the meals may only be provided for those who attend the presentation and have a bona fide interest in the presentation. Thus, friends or spouses of attendees would have to pay for any meal served if they attend such a presentation.

## EVALUATION AND DEMONSTRATION PROJECTS

AdvaMed recognizes that allowing HCPs to evaluate devices at no charge can be beneficial to patients and to the practitioners using the technology. Evaluation and demonstration devices can be either single-use devices or multi-use capital equipment. For single-use products, companies should limit the number of products provided free of charge to the amount reasonably necessary for the adequate evaluation of the products. This number may vary depending on such factors as the length of time necessary to evaluate the product and the number of HCPs being trained. Similarly multi-use equipment should only be furnished for a reasonable period of time necessary to evaluate the equipment.

Compliance with the Revised Code is discretionary. Nevertheless, AdvaMed strongly encourages all companies to annually certify that they have adopted the Revised Code and implemented an effective compliance program. Moreover, best practices from a regulatory perspective strongly encourage all vendors and practitioners to comply with the Revised Code. To encourage compliance, AdvaMed will publish on its website a list of those companies that have submitted this annual



certification. In order to effectively avoid ethical and legal concerns, health care providers that interact with medical technology companies should review the guidelines that AdvaMed sets forth and develop safeguards to prevent potentially inappropriate behavior.

### **Seven Steps to Success**

AdvaMed suggests that Companies take the following steps to help translate the Code into reality:

- (1) Implement written policies and procedures.
- (2) Designate a compliance officer and committee.
- (3) Conduct effective training and education programs.
- (4) Develop effective lines of communication such as anonymous reporting systems.
- (5) Conduct internal monitoring and auditing.
- (6) Enforce standards through well-publicized disciplinary guidelines.
- (7) Respond promptly to detected problems and undertake corrective action.



*Amita A. Sanghvi is an associate in the firm's Healthcare Practice. Ms. Sanghvi recently worked as a public policy extern for a major pharmaceutical company where she analyzed federal and state legislation to determine the impact on the company's business and developed position papers, reports and talking points on issues affecting electronic prescribing and evidence-based medicine for use by the company's state and federal lobbyists. Ms. Sanghvi received her bachelor's degree from the University of Rochester and both her law degree and master of health administration from the University of North Carolina at Chapel Hill.*



# THE CHANGING FACE OF FEDERAL SELF DISCLOSURE: STARK VIOLATORS NEED NOT APPLY!

By Holly Pierson



## I. INTRODUCTION

Scrutiny from the federal and state governments on waste and potential fraud in the healthcare system remains intense. Indeed, providers can find themselves being prodded and poked from a virtually unlimited number of sources — RACs, MACs, federal and/or state OIG, United States

Attorney's Offices, State Attorney Generals, whistleblowers, and the like. Against this back drop, many providers are bolstering their compliance plans, particularly the internal auditing component, in an effort to preemptively identify and address their own areas of potential weakness and exposure.

Once a provider identifies an area in which it has potential or actual exposure, the next step is often to determine what can or must be done with that information. Since 1998, one such consideration has been the federal OIG Self Disclosure Protocol. Under this framework, the OIG does not grant the disclosing entity immunity from fines and other penalties, but it has expressed a willingness to allow the fact of the voluntary disclosure to mitigate the severity of the sanctions imposed.

The OIG has periodically tweaked and refined the Self Disclosure Protocol over the years. Last month, it issued the 2009 Open Letter to Health Care Providers ("2009 Open Letter")<sup>1</sup> in which the OIG made two changes to the Self Disclosure Protocol that are viewed by many in the health care community as relatively dramatic. In this environment, providers need to have a firm grasp on the changes made by the 2009 Open Letter and how it has changed the landscape of self disclosures in the industry.

## II. THE 2009 OPEN LETTER TO HEALTH CARE PROVIDERS.

The 2009 Open Letter announced two noteworthy changes to the Self Disclosure Protocol: (1) the OIG will no longer accept self disclosure for violations of the Stark Law (governing physician self referrals) unless a "colorable" violation of the federal anti-kickback statute is also present, and (2) the minimum settlement amount to resolve self-disclosed

anti-kickback matters is \$50,000<sup>2</sup>. These changes mark a significant departure from prior OIG guidance.

## A. REVERSAL OF OIG'S PRIOR POSITION.

Just three years ago, in April 2006, the OIG issued an Open Letter to providers in which it actually encouraged providers to use the Self Disclosure Protocol to resolve Stark Law violations.<sup>3</sup> In reversing this position and focusing only on Stark violations that also involve anti-kickback violations, the OIG apparently recognized that the unexpectedly high number of Stark Law-only violations being self disclosed pursuant to the protocol were draining the OIG's resources.

## B. POTENTIAL IMPACT OF 2009 OPEN LETTER ON PROVIDERS.

The OIG's change in position with regard to Stark-only claims perhaps raises more questions than it answers. First, what does this change in policy mean with regard to the government's level of attention to pure Stark violations under \$50,000? Although the 2009 Open Letter itself cautions providers not to make inferences about the government's enforcement of the Stark Law, the letter also plainly states that the OIG is narrowing the scope of the Self Disclosure Protocol in order to more efficiently manage its resources and that "detering kickbacks remains a high priority for OIG." See 2009 Open Letter (emphasis added).

Second, what options remain for providers who wish to self disclose Stark-only issues? With the federal OIG off the table, providers appear to be relegated to Medicare MACs, the local U.S. Attorney's Office, Main Justice or — for matters that involve Medicaid — Georgia's OIG. Of the remaining options, only the Georgia OIG currently has to date established its own self-disclosure protocol.

## III. GEORGIA OIG'S SELF DISCLOSURE PROTOCOL.

Georgia's Self Disclosure Protocol is found in *Part I, Policies and*

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<sup>2</sup> *Id.*

<sup>3</sup> See Open Letter to Health Care Providers, April 24, 2006, available at <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>.

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<sup>1</sup> See 2009 Open Letter to Health Care Providers, available at <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.



*Procedures for Medicaid*, Section 402.10. An in-depth discussion of this protocol is beyond the scope of this article, but a key distinction between the Georgia protocol and the federal one merits mention: Georgia's self-disclosure provision is written in mandatory rather than permissive terms. Thus, while the Georgia protocol encourages but does not require providers to self audit, once errors or overpayments are identified, "providers **must** alert the Department and work toward a resolution or refund."

#### IV. CONCLUSION

The self disclosure process has long been a source of angst for health care providers, requiring a rigorous analysis of each matter's distinct facts and attendant risks. The landscape in this important area has once again shifted, and providers and their counsel must work collaboratively to assess the meaning and practical effect of these changes. □

*Holly A. Pierson is Of Counsel in the firm's Healthcare, Fraud & Abuse Defense, and Commercial Litigation Practices, where she concentrates on internal investigations, white collar defense and special litigation, including healthcare fraud, whistleblower actions, identity theft, mortgage and banking fraud, environmental issues, and public corruption. Ms. Pierson received her bachelor's degree from the University of North Carolina and her law degree from the University of Georgia.*





# FEDERAL REQUIREMENTS FOR DISCLOSURE OF PAYMENTS TO PHYSICIANS ON THE HORIZON

By Brynne Rachel Goncher, JD, MPH



Numerous physicians consult for medical device, pharmaceutical and medical supply manufacturers, receive training in the use of products, receive other medical education, or have other types of relationships in which some form of payment or other remuneration is received from these companies. Many people have concerns that these types of relationships and payments create a conflict of interest for physicians, causing physicians to prescribe, utilize, or recommend products they would not otherwise endorse, which in turn increases the cost of care. Others argue that such payments fund research that may not otherwise be available, and regulation of these payments may slow medical advancement. Regardless, physicians, hospitals, as well as pharmaceutical, medical device and medical supply manufacturers must be aware of federally mandated disclosure requirements on the horizon.

In October 2008, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress establish a national database to publicly reveal financial relationships between physicians and the pharmaceutical industry. On January 22, 2009 Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced the Physician Payments Sunshine Act of 2009 as a follow-up to a bill they originally introduced in 2007<sup>1</sup>. The 2009 bill requires certain drug, device, and medical supply manufacturers to disclose anything of value given to doctors, including compensation, gifts, honorarium, speaking fees, consulting fees, travel, services, dividends, profit distributions, stocks or stock option grants, or ownership or investment interests. Companies would be required to submit information to the Department of Health and Human Services regarding (i) the name of the physician receiving payment; (ii) the business address of the physician; (iii) the value of payment; (iv) the dates on which payments were made; (v) a description of the type of payment; (vi) the reason for the payment; and (vii) the name of the drug, device, biological, or medical supply the payment was related to. Information would be reported online beginning in March 2011 and quarterly thereafter. As introduced, the bill requires manufacturers to disclose information relating to payments greater than \$100. Penalties for failure to report include civil monetary penalties ranging from \$1,000 to \$10,000, with a cap of \$150,000 per year. Those who knowingly fail to report may be faced with increased fines of \$10,000 to \$100,000,

<sup>1</sup> S. 301, 111th Cong. (2009).

with a cap of \$1,000,000. Information would be searchable by the public on an internet website. The bill would pre-empt any state laws requiring disclosure of payments to physicians. Similar efforts to pass a disclosure bill in the House of Representatives are underway.

Although the 2009 Senate bill is only in the first step of the legislative process, on March 2, 2009 MedPAC reiterated its prior recommendations regarding the benefits of reporting. On April 28, 2009 the Institute of Medicine published a report specifically encouraging Congress to create a national reporting program. Industry groups including PhRMA and the Advanced Medical Technology Association (AdvaMed), as well as several large medical device and pharmaceutical manufacturers believe that a physician disclosure bill is imminent and are lobbying hard to make sure that any legislation passed is favorable to their industries. Upon the effectiveness of such disclosure requirements, all payments to physicians will be under increased scrutiny. Physicians must be aware that the details of any relationships they enter into with medical device, pharmaceutical and medical supplies manufacturers, as well as any gifts or other remuneration they receive from such companies may soon be available for public scrutiny, and should enter into such relationships or receive such remuneration accordingly. Manufacturing companies must be aware that they may soon have the obligation to publicly disclose these relationships and payments and act accordingly. Hospitals must be aware of these changes as they will affect hospital medical staffs. All parties should continue to monitor the proposed federal legislation. □

*Brynne R. Goncher is an associate in the firm's Healthcare Practice. Ms. Goncher concentrates in representing healthcare providers in various business and regulatory matters. Ms. Goncher received her bachelor's degree from the University of Pennsylvania and both her law degree and master of public health administration from Emory University.*