



GEORGIA HEALTH LAW DEVELOPMENTS

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Health Law Section

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MESSAGE FROM THE CHAIR

Greetings Health Law Section Members,

The Executive Committee has been busy planning our activities on behalf of the section this year and are excited about our upcoming events.

The Health Law Section recently sponsored the Georgia ICLE Fundamentals of Health Law Program. Thanks again to program chair Rob Meadows along with everyone who participated for another successful program.

The section will also be sponsoring the annual Advanced Health Law Program on November 21, 2014, at the Four Seasons in Atlanta. We hope that you will be able to join us. The Executive Committee is currently planning the program and is excited to include a wide range of current topics.

We would like to thank all of the authors who contributed to this addition of the Health Law Section Newsletter. In this most recent edition, Kevin Little provides commentary on the financial ramifications for physician compensation under the Affordable Care Act. Also, Sarah Browning provides an update of fair market value analysis in Stark Compliant Physician Compensation Arrangements. I’m also grateful for the contribution of my law partner, Tony Cochran, who provides his insight on government investigations of physicians. Finally, we appreciate the contribution from Georgia State University College of Law student Christian Dennis as well as an article on the Two Midnight Rule by Deonys de Cardenas. We also would like to thank Dan Mohan for his assistance editing and publishing the newsletter.

The Executive Committee strives to prepare meaningful, substantive programs for our section and provide you with information relevant to the practice of health care. We invite our members to submit articles, reports, and proposals for presentations that would be informative to the membership.

It is an honor to serve as Chair of the section this year. Please let me know if you have any ideas or suggestions that might help us better serve you.

Best regards,

Brian M. McEvoy
Chair, Health Law Section

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Financial Ramifications for Physician Practices of ACA Deductibles: Getting Paid for “Affordable Care”

By Kevin S. Little
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Absent in the noisy political rhetoric for and against The Patient Protection and Affordable Care Act (ACA),¹ popularly known as “Obamacare,” is analysis of the potential financial impact of the ACA’s significantly high deductibles upon physician practices. In a third-party payer system where consumers are inclined to think that if covered by insurance the doctor’s bill is paid by the insurer, adapting to high ACA deductibles may be painful for patients and treating doctors alike.

The New Day: Shifting Health Care Costs From Payer to Patient

Laudable objectives of the ACA include slowing the growth of health care costs, improving quality of health care and, perhaps the law’s hallmark feature, expanding health insurance to cover to everyone. Proponents of the ACA tout new “access” to health care by way of health insurance coverage for all, irrespective of pre-existing health conditions. This policy objective is advanced in part by the ACA’s play-or-pay mandates. So insurers are not left insure only high-cost patients, the ACA mandates that everyone (including, notably, the young and healthy) to obtain coverage and pay insurance premiums if not covered under an employer or government insurance plan. The alternative -- a penalty tax to the government -- is intended to incentivize a decision to pay insurance premiums. To avoid wide-spread abandonment by businesses of employer-sponsored health insurance based on the new costs of providing health insurance with “essential benefits” required by the ACA, employers with fifty or more employees that decide against offering ACA health insurance coverage must pay significant penalty taxes to the government.

Even with the government’s much publicized website problems, multiple delays in implementing certain ACA provisions and ongoing political wrangling about whether the ACA is good or bad, millions of Americans have already enrolled *via* the ACA’s Health Insurance Exchange in and are now covered by ACA health insurance plans. Millions more will. In an industry where medical practice models heavily depend upon third-party payer revenue, more insured patients should be all good for doctors -- right?

The economic reality is that there is no free lunch for those insured under the ACA and this reality will impact physician practices. The significant new costs of insuring greater risks (pre-existing health conditions, no life time limits or annual caps, required essential benefits, etc.) of course must be passed on to consumers. One way insured individuals and families will shoulder the increased costs is by high deductibles. The ACA strongly advances an existing trend toward high deductible insurance plans.² It authorizes deductibles of up to \$6,350 for an individual and \$12,700 for a family. The ACA’s online marketplace, www.healthcare.gov, presents bronze, silver, gold or platinum plan options, which, in addition to some differences in benefits, involves choice of higher premiums or higher deductibles. Due to the impression conveyed by the ACA that all plans now must include “essential” health benefits, many consumers are expected to shop based on premium alone. To avoid higher premiums, consumers are expected to gravitate toward the higher deductible bronze plans.

The average individual deductible for the lower-priced bronze plans is \$5,081 a year for an individual, which is 42 percent higher than the average deductible for an individually purchased plan last year (\$3,589).³ While limited preventive care is exempt from the ACA deductibles, most treatment is not. Absent very significant cumulative or big-ticket medical expense (rare for most patients), the typical patient insured by an ACA bronze plan will pay out-of-pocket most or all of his or her annual health care costs.

Doctors and their insured patients are accustomed to the usual mechanics of our third-party-payer system, involving presentation of an insurance card to the doctor’s receptionist, small co-pays, submission of a claim to an insurer and an insurer’s payment. Patients are not used to paying the full costs of their health care, especially if they write checks (or have deductions from their pay) for insurance premiums. And physician practices are set up to depend upon claim processing and payment by third party payers, with limited patient billing only after claims are processed by the insurer.

This model is not well suited to high deductible insurance plans, however. No one likes a surprise bill, especially for medical tests or procedures a

patient thought the insurer might pay. Payment of an unexpected doctor bill received weeks after treatment has been obtained can easily be relegated in priority behind the more pressing car payment, cable bill, or cell phone bill, and may be delayed or avoided altogether as a result.

So what should physician practices do?

Get Paid Upfront

This strategy seems obvious for any business. However, payment up front is not as straightforward a proposition for physicians as it is for a plumber, grocery store, or lawyer, at least where insured patients are involved. Physicians are subject to provider agreements with third party payers that dictate what charges are “allowed,” irrespective of what the doctor may otherwise charge. As a matter of well-established routine in physician practices, insurer processing of claims reveals the “allowed” amounts for a health care provider’s charges. So, where deductibles are so high that the insurer’s role is mostly a moot point yet the provider agreement nonetheless binds the doctor to collect only what is “allowed,” how can the doctor determine and collect the proper amount from the patient at the time of service?

The allowed amounts are stated in the third party payer’s fee schedule. The payer’s fee schedule is part of its provider agreement with the doctor or medical practice and, if not attached to the contract, should be obtainable by a request to the payer.⁴ Because physicians are contractually bound to charge only an “allowed amount” stated in the fee schedule for a particular service, the allowed amount is what can be collected from the insured patient at the time services are rendered.

For many physician practices, important adjustments to office procedures can facilitate collecting full payment of the allowed amount for charges directly from high deductible patients at the time of service. Trusted office personnel may be delegated to obtain, save and carefully organize on an ongoing basis all payer fee schedules so that allowed amounts for anticipated services can be determined before services are rendered. Front-of-the-office intake functions could include a determination that a deductible has or has not been met, preferably before the patient arrives. If a deductible has not been met, requiring full payment of the allowed amount of all charges for the anticipated service will avoid the risk of delayed or no payment for the services rendered.⁵

Educate Patients

Part of the challenge for physician practices in trying to obtain full payment by insured patients at the time of service will involve training patient expectations. Physician practices will benefit from educating insured patients with high ACA deductibles *in advance* of their doctor’s appointment about the payment expectations of the doctor.⁶ Advance communication of payment responsibilities will allow patients to plan and make payment necessary arrangements, which will reduce the likelihood of unpleasant misunderstandings where high deductibles have not been met. Getting in front of payment issues that will stem from higher deductible health insurance plans in this way should help contain any increase in receivables or uncollectible patient accounts that might otherwise attend the new high deductible insurance plans.

Disclaimer: Thoughts shared here do not constitute legal advice.

¹ The Patient Protection and Affordable Care Act, 2010 HR3590, March 23, 2010.

² The number of Americans insured under high deductible plans rose from about 1 million in 2005 to 15.5 million in 2013. *January 2013 Census Shows 15.5 Million People Covered by Health Savings Account/High-Deductible Health Plans*, America’s Health Insurance Plans, June 2013.

³ Deductibles, *Out-Of-Pocket Costs, and the Affordable Care Act*, HealthPocket, December 12, 2013.

⁴ In some states, like Georgia, state law requires health plans to provide their fee schedules to physicians upon request. See O.C.G.A. § 33-30-23; *Medical Association of Georgia v. Blue Cross & Blue Shield of Georgia*, 244 Ga. App. 801, 536 S.E.2d 184 (Ga. App. 2000).

⁵ Acceptable payment methods are cash and credit cards. New retail credit options designed specifically for health care expenditures (e.g., www.carecredit.com) are emerging and may afford patients greater credit options.

⁶ There are many options that may, depending upon the circumstances of a medical practice, be useful in this process and warrant consideration, including post cards before appointments, printed brochures, an online payment portal, telephone calls before appointments and office signage at the front desk.

What's Fair in Stark-Compliant Physician Compensation Arrangements: The Role of FMV Appraisals in Developing Stark Case Law

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As hospitals expand their contractual arrangements with referring physicians through direct employment, service agreements or “under arrangement” arrangements, hospitals increase their risk that whistleblowers will attack these arrangements as illegal financial relationships under the federal Stark prohibition on physician self-referrals (the “Stark Law”).

Missteps can be costly. The latest installment of the *Tuomey* saga ended last October to the tune of \$237.5 million dollars.¹ *Halifax* settled out of court earlier this month for \$85 million, only after government actors backtracked on original demands for a billion dollar recovery and a *qui tam* suit which spanned the better part of a decade.² These catastrophic results are only exacerbated by the strict liability component of the Stark Law.

Recent Stark Law cases illuminate which legal issues have become key battlegrounds in Stark litigation in the context of the federal False Claims Act: primarily whether compensation is “fair market value,” “commercially reasonable,” or “takes into account the volume or value of referrals.” To address these issues and as a first line of defense, players in the health care industry have historically turned to independent fair market appraisals from recognized health care evaluators. However, developing Stark case law suggests that industry players may need to reassess their treatment of such independent fair market appraisals.

This article reviews four of the most notable Stark Law cases, *Villafane*,³ *Bradford*,⁴ *Tuomey*⁵ and *Halifax*,⁶ discusses the role of fair market appraisals in each case, and suggests a few fair market appraisal strategies that health care providers may adopt to further reduce Stark risk.

The Regulatory Framework: *Fair Market Value, Commercial Reasonableness, and Volume and Value of Referrals*

The Stark Law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare or Medicaid to an entity with which he or she (or an immediate family

member) has a financial relationship (ownership or compensation), unless an enumerated exception applies.⁷ The federal False Claims Act⁸ prohibits Medicare payments for services when those services are “tainted” by a Stark Law violation.⁹ Many cases alleging violation of the federal Stark Law are brought under the False Claims Act, following submission of claims to Medicare or Medicaid that have been “tainted” by the referrals from physicians with which the hospital had financial relationships that allegedly violated the Stark Law.

Depending upon the circumstances and the applicable exception, Stark Law exceptions generally require compensation in financial arrangements be “fair market value” (FMV), “commercially reasonable,” and compensation cannot take into account the “volume or value of referrals or other business generated between the parties.” These three Stark Law concepts are separate and distinct, though each concept must be considered in the context of the others when considering Stark Law exceptions.

Fair Market Value is defined by the Stark Law statute as the value in an arm’s-length transaction, consistent with the general market value.¹⁰ Stark regulations define “general market value” as

[T]he price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.¹¹

Fair Market Value is an element of ten different Stark Law exceptions.

“Commercial reasonableness” is also a specific requirement of most of the Stark law exceptions that require FMV compensation,¹² but is substantially different from FMV. Stark regulations do not specifically define “commercial reasonableness,” however the Centers for Medicare & Medicaid (CMS) have provided some guidance. In Phase I rules, CMS states that it is “interpreting commercially reasonable to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.”¹³ CMS’s Phase II commentary provides:

An arrangement will be considered ‘commercially reasonable’ in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential DHS referrals.¹⁴

Essentially, “commercially reasonable” means that a financial relationship must make commercial sense, even if no referrals are made between the parties of the agreement.

Stark regulations also fail to explicitly define “volume or value of referrals or other business generated” even though the concept is a requirement of twenty different Stark Law exceptions. By way of explanation, CMS states that an “arrangement does not take into account the volume or value of referrals or other business generated if compensation is (i) fixed in advance and results in FMV compensation; and (ii) does not vary over the term in a manner that takes into account referrals or other business generated.”¹⁵

Grasping and appropriately applying each of these key Stark Law concepts can be a difficult task, as is seen in the following Stark Law cases. Additionally, as courts continue to grapple with the Stark Law it becomes clear that viable FMV appraisals must consider all three Stark Law concepts when evaluating the appropriateness of payments made to a physician or physician group.

Villafane

In April 2008, the United States District Court for the District of Kentucky issued one of the earliest decisions to shed light on the Stark Law in the dismissal of *United States ex rel. Villafane v.*

Solinger, 543 F.Supp. 2d 678 (W.D. Ky. 2008). In *Villafane*, the plaintiff and relator was a pediatric cardiologist who filed a *qui tam* action against affiliates of the University of Louisville Medical School, including Kosair Children’s Hospital, the medical school’s research foundation and several doctors from his former practice group.¹⁶

The heart of the Stark issue in *Villafane* involved the flow of money between Kosair Children’s Hospital and several physicians who were full-time members of the Louisville Medical School faculty who participated in the school’s professional practice plan. The practice plan required these physicians to pay a percentage of their private practice revenues to the medical school’s fund, which then channeled money to the school’s research foundation. Kosair Children’s Hospital was one of several hospitals that contributed to the medical school’s research foundation, which was used, among other things, to support the physicians’ salaries. The relator claimed that this flow of money between Kosair Children’s Hospital and the defending physicians created a financial relationship, and as a result, any referrals for DHS made by these physicians to the hospital violated the Stark Law.

The *Villafane* Court applied a “goal-and-purpose-oriented perspective,” rather than a “hyper-technical” approach when analyzing each element of the Stark Law’s Academic Medical Center (AMC) exception. The court then dismissed the case, holding that the financial relationship fell within the Stark Law’s AMC exception, which required that a physician’s total compensation be both (1) FMV and (2) determined in a manner that did not take into account the volume or value of any referrals or other business generated.¹⁷

As a threshold matter on the issue of FMV, the *Villafane* Court refused to consider both a physician’s compensation by an academic medical center in the form of a faculty salary and compensation from the physician’s own private practice when determining whether the faculty compensation was FMV. With respect to the defendant physicians’ faculty salaries, the defendants offered evidence that the faculty salaries were in line with national salary data compiled in the Association of Administrators in Academic Pediatrics’ Medical School Pediatric Faculty Compensation Surveys. The court was persuaded by this evidence, and even though the same evidence showed that Kosair Children’s Center’s Medical Chief’s salary was consistently above the 90th percentile for neonatologists, refused to find an issue with the

medical chief's salary. The court reasoned that the chief was also paid for chief duties and responsibilities at the medical school and, in the court's words, to compare ordinary neonatologists to the medical chief at Kosair was to compare "apples and oranges." Finally, because the physicians' salaries were fixed at FMV and on their face did not vary during a given fiscal year based on referrals, salaries did not reflect the volume or value of referrals.

The *Villafane* Court separately considered whether faculty compensation took into account the volume or value of referrals from the defending physicians. Plaintiffs alleged that payments from Kosair Children's Hospital to the medical school's research foundation reflected the volume or value of referrals because the hospital would not have contributed to the research foundation *at all* if such payments did not fund physician referrals to the hospital. The court held this argument was "contrary to the clear statutory and regulatory purpose" of the Stark Law's AMC exception. Turning to CMS's Stark commentary, the court found that the physicians' faculty salaries did not take into account the volume or value of referrals because they were fixed at FMV on their face and did not vary during a given fiscal year based on referrals. Again, the medical chief's salary was separately addressed, but the court noted that the chief's salary was "hardly surprising given his greater responsibilities" at the medical school.

The defendants in *Villafane* did not obtain a FMV appraisal prior to entering into the contested physician compensation arrangements. However, the defendants were able to offer specific evidence to support their compensation decisions. Further, in the case of the medical chief, Kosair Children's Hospital could firmly defend the decision to compensate a physician well above the national average. While *Villafane* shows that FMV appraisals are not necessary to defend Stark litigation, the case also shows that expert documentation discussing the physician's compensation may be extremely useful in a Stark Law defense.

Bradford

In *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F.Supp.2d 602, the District Court for the Western District of Pennsylvania returned to the Stark Law in another *qui tam* suit. This time, the court examined a sublease agreement between Bradford Regional Medical Center (BRMC) and a physician practice for the use of nuclear imaging equipment.

In 2001 BRMC discovered that two physicians, who were significant BRMC referral sources for nuclear imaging services, intended to lease a nuclear camera for use in their own physician practice. The nuclear camera would allow the physicians to perform diagnostic testing within their own facilities without referring these tests to the hospital. BRMC determined that such a drop in nuclear medicine referrals would have a significantly detrimental impact on BRMC's nuclear medicine revenues.

After a period of strained communications and attempts by BRMC to revoke or suspend the physician's privileges, BRMC and the physician practice entered into a sublease agreement for the practice's nuclear camera. Under the terms of the agreement, the physician practice agreed not to compete with the hospital with respect to nuclear cardiology services during the sublease's term. The hospital paid the physician practice a monthly amount that was equivalent to the amount the physician practice paid to originally lease the equipment, an additional amount for the physician's covenant not to compete, and a billing fee equal to 10% of all collections of tests performed with the camera.¹⁸

Prior to executing the sublease, BRMC engaged an accountant to provide a FMV appraisal. After comparing the revenues the hospital would generate with the sublease in place to the revenues the hospital expected to receive without the lease in place, the accountant concluded that the amounts to be paid were FMV. Importantly, the projected hospital revenues were based on the expectation that the physician practice would refer patients to the hospital if the sublease arrangement was approved, and the hospital would lose benefits should the privileges of the physician practices' doctors be terminated.

At trial, the relators argued the court must determine, as a threshold matter, whether an indirect compensation agreement existed between BRMC and the physicians, which required the court to determine whether the arrangement took into account the volume or value of referrals. Further, the relators argued that the defendants must assert a Stark Law exception prior to addressing FMV issues, and that the defendant carried the burden of proving an exception applied. The defendants argued that because the physician's compensation under the sublease was fixed, the arrangement did not take into account the volume or value of referrals generated.¹⁹ Further, the defendants argued that the relators must

prove, as a threshold matter, the arrangement was not FMV and therefore an indirect compensation arrangement.

In reviewing the Stark Law, the *Villafane* decision, Stark regulations and CMS commentary, the *Bradford* Court agreed with the relators' position that whether a fixed compensation agreement is FMV is not considered until defendants raise an exception. The court then separately discussed FMV, commercial reasonableness and the volume or value of referrals concepts. Turning to the defendant's position that the lease payments paid to the physicians were FMV, the court then dissected BRMC's FMV appraisal.

Despite the conclusions of BRMC's valuation consultant, the *Bradford* Court held that the compensation received by the physician practice was in excess of FMV because it was determined in a manner that "takes into account the volume or value of referrals." The court was particularly disturbed that the defendants did "little more than generally cite to the report in support of their argument." The court found that compensation paid to the physician practice was "inflated" to compensate the physicians' ability to generate other revenues, making the compensation in excess of FMV and indicating an indirect compensation existed. Further, a Stark Law exception did not apply because the arrangement was not FMV, because compensation was determined in a manner that took into account the volume or value of referrals.

Bradford provides the perfect example of how the Stark Law FMV, commercial reasonableness and volume or value of referrals concepts can quickly become confused and why any appraiser completing a FMV analysis should be well acquainted with each concept. Further, *Bradford* clarifies that FMV appraisals are not infallible, and should a health care provider obtain a FMV appraisal prior to executing a transaction, the provider should know and understand the contents of the appraisal.

Tuomey

The most infamous (and ongoing) Stark Law case to date is *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, which began in 2003 when several local specialty groups informed Tuomey Healthcare System (Tuomey) that they were considering performing their outpatient surgical procedures at another facility. To avoid a drastic reduction in surgical case volume, the hospital began negotiating with the specialists. Ultimately, Tuomey

and the specialists entered into new, "part-time" agreements with essentially the following terms:

- The specialists were deemed "part time employees."
- The specialists were required to provide outpatient procedures exclusively at Tuomey or other facilities in the same system.
- The specialists reassigned all billing rights to Tuomey.
- Tuomey agreed to pay each specialist an annual base salary that would fluctuate based on Tuomey's net cash collections for outpatient procedures.
- Each specialist was eligible for a "productivity bonus" equal to 80% of the net collections plus a potential "incentive bonus" that could total up to 7% of the productivity bonus, leading to a total of 119% of the collections.
- Each contract would last for a 10 year term.
- The specialists were barred from competing with Tuomey for outpatient services during the agreement and for two years thereafter.

The relator in this case (Drakeford) was one of the specialists, who expressed concerns over the legality of these terms and engaged his own attorney to review the proposed arrangement. When Drakeford's attorney and Tuomey's attorneys could not agree on the legality of the agreements, a third, nationally recognized Stark expert was engaged as a "tie breaker." The Stark expert expressed significant reservations regarding legality of the agreements, and so Tuomey engaged yet *another* lawyer who eventually issued an opinion that the arrangements were not prohibited by the Stark Law.

Tuomey claimed that the contested "part-time" employment arrangements did not violate the Stark Law because they met the Indirect Compensation Arrangement exception, which provides that certain enumerated compensation arrangements do not qualify as a "financial relationship." Specifically, an indirect compensation arrangement does not constitute a financial relationship if the compensation received by the referring physician is: (1) FMV; (2) not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the hospital; and (3) commercially reasonable.²⁰ At trial, the Department of Justice (DOJ) was able to show a one-to-one correlation between each Tuomey physician's aggregate compensation and the volume or value of the physician's referrals to the hospital. Because the

court understood this to prove the compensation took into account the volume or value of referrals, the Indirect Compensation Exception was inapplicable to the Tuomey arrangements.

Tuomey also argued, with respect to the FCA, that requisite scienter did not exist because of the hospital's reliance on the advice of counsel in the obtained FMV appraisals.²¹ On this point, the court was particularly unimpressed by Tuomey's actions in obtaining a favorable FMV appraisal after receiving multiple unfavorable opinions. On a motion for summary judgment, U.S. District Judge Seymour ordered Tuomey to pay more than \$237 million in civil penalties. Tuomey's attorneys have already filed their notice to appeal the financial judgment to the 4th U.S. Circuit Court of Appeals.

Tuomey illustrates how FMV appraisals can harm a health care provider's case, should Stark litigation occur. To avoid a similar situation, providers may want to contemplate the necessity of a FMV appraisal prior to executing a transaction, and further, avoid opinion shopping for a favorable FMV opinion.

Halifax

The most recent Stark Law case, *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002-Orl-31DAB (M.D. Fla. Mar. 19, 2012), is yet another *qui tam* action originally filed in June, 2009. The relator was a member of the compliance department of a corporate affiliate of Halifax Hospital Medical Center (Halifax).²²

In this case, Halifax entered into contracts with several medical oncologists that provided payment of incentive bonuses from a pool that was equal to 15% of the operating margin for the medical oncology program. Each oncologist's bonus would be based on the physician's personally performed services. The DOJ argued that these bonuses constituted compensation that took into account the volume or value of referrals, creating a financial relationship between the physicians and Halifax, and subsequently, referrals from these physicians for DHS violated the Stark Law.

The DOJ also argued that Halifax violated the Stark Law when the hospital accepted referrals from three neurosurgeons who were paid in excess of FMV. Apparently, the relator raised concerns as to the FMV of the neurosurgeon's compensation at a meeting in 2009 and suggested Halifax administrators obtain an independent FMV appraisal.

The DOJ also pointed to arrangements between Halifax and multiple psychiatrists which provided that, in addition to a fixed salary, they would receive incentive payments equal to 100% of the hospital's gross collections, minus the amount of their salary and the hospital's costs for billing and collection. According to the DOJ, the compensation paid to these psychiatrists took into account the volume or value of referrals, constituted a prohibited financial relationship, and therefore any following referrals for DHS from the psychiatrists to the hospital violated the Stark Law.

In all three cases, Halifax argued that compensation paid to physicians was protected by the Bona Fide Employment exception, which requires that compensation be (1) FMV; (2) commercially reasonable; and (3) not take into account the volume or value of referrals, among other requirements. Last November, a court found that the Bona Fide Employment exception would not protect the arrangements between Halifax and the oncologists because the compensation took into account the volume or value of referrals. Specifically, "the fact that each oncologist could increase his or her share of the bonus pool by personally performing more services [could not] alter the fact that the size of the pool (and the size of each oncologist's bonus) could be increased by making more referrals."

This past January, *Halifax* defendants successfully argued that compensation paid pursuant to arrangements between Halifax and the two psychiatrists were FMV by providing multiple expert reports and other evidence while the Relators provided nothing on this exact issue. However, the court still found the relationships were not protected by the Bona Fide Employment exception because the arrangement allowed the psychiatrists to increase their incentive payments by making additional referrals for DHS to Halifax. Because the psychiatrists could increase their compensation by making additional referrals for DHS, the compensation took into account the volume or value of referrals, and the Bona Fide Employment exception did not apply.

Halifax demonstrates how a FMV appraisal can help a provider prove one element of a Stark Law exception, but also shows that FMV cannot exist in a vacuum. When reviewing a potential transaction, a FMV opinion may afford better protection if the appraiser is aware of all facts relating to a proposed transaction.

Additionally, *Halifax* also brings to light the benefits attorney-client privilege can provide to a FMV appraisal. The privileged nature of FMV opinions were the subject of several *Halifax* motions, demonstrating that health care providers may benefit greatly from working closely with an attorney in determining the appropriate compensation for physicians. Attorney-client privilege, when used appropriately, may reduce some risk in potential Stark litigation.

FMV Appraisal Suggestions

Following *Villafane*, *Bradford*, *Tuomey* and *Halifax*, health care providers should consider three questions when developing FMV appraisal strategies:

- (i) Does the arrangement need a FMV appraisal?
- (ii) Who should the appraiser be?
- (iii) What kind of appraisal is appropriate for the transaction?

First, as seen in *Villafane*, not all business arrangements require a FMV appraisal, and a Stark law case can be successfully defended without an appraisal. If the arrangement is fairly vanilla and involves limited parties, the anticipated arrangement may not require a FMV appraisal. Further, as seen in *Tuomey*, too many FMV opinions may raise a red flag for investigators. Note, however, that providers who decide not to commission an independent third party FMV appraisal should nevertheless engage in some process to confirm the FMV nature of the compensation or other payments made to the physicians; and, the file should be well-documented to support the FMV nature of the compensation.

Second, even though an appraiser may be highly qualified in certain lines of business, an appraiser for a health care transaction should be well acquainted with health care regulations. *Villafane*, *Bradford*, *Tuomey* and *Halifax* each highlight the complexity of a Stark exception analysis in Stark litigation. A health care provider can be best prepared and defended against Stark litigation by working closely with an appraiser who routinely works in the healthcare industry, and who therefore understands and can apply the concepts of “FMV,” “commercial reasonableness,” and “volume or value of referrals,” as those terms are defined in and contemplated by the Stark Law, to the proposed transaction. Further, as seen in *Halifax*, providers should consider working with an attorney to obtain protection under the attorney-client privilege.

Finally, if a provider does obtain a FMV appraisal, the providers should understand the working parts of an appraisal, and make sure the appraisal is appropriate for the situation. As seen in *Bradford*, a court will expect a health care provider to review and understand the parts of an appraisal before using the appraisal in any defense. A provider may use common sense to consider whether an appraisal is appropriate for the situation and determine whether a more robust opinion is needed.

¹ *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS (D.S.C., 2013).

² U.S. Department of Justice, Florida Hospital System Agrees to Pay the Government \$85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians (March 11, 2014), <http://www.justice.gov/opa/pr/2014/March/14-civ-252.html>

³ *United States ex rel. Villafane v. Solinger*, 543 F.Supp. 2d 678 (W.D. Ky. 2008).

⁴ *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F.Supp.2d 602 (W.D. Pa. Nov. 10, 2010).

⁵ *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394 (4th Cir. 2012).

⁶ *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002-Orl-31DAB, 2012 WL 91147 (M.D. Fla. Mar. 19, 2012).

⁷ 42 U.S.C. 1395nn.

⁸ 31 U.S.C. § 3729 *et seq.*

⁹ Falsely certifying compliance with the Stark Law in connection with a claim submitted to a federally funded program is actionable under the FCA. See *United States ex rel. Schmidt v. Simmer, Inc.*, 386 F.3d 235, 243 (3rd Cir. 2004) (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997)).

¹⁰ 42 U.S.C. 1395nn(h)(3).

¹¹ 42 C.F.R. § 411.351.

¹² Stark exceptions which require commercial reasonableness include (i) the office space rental exception (ii) the equipment rental exception, (iii) the bona fide employment relationship exception, and (iv) certain group practice arrangements with hospitals. The personal service arrangement exception arguably has a commercial reasonableness requirement by requiring the service be “reasonable and necessary for the legitimate business purposes.”

¹³ 63 FR 1700 (Jan. 9, 1998).

¹⁴ 69 FR 16107 (March 26, 2004).

¹⁵ 66 FR 877-878.

¹⁶ Villafane filed his complaint in August, 2003, and the government declined to intervene in June, 2005. In October, 2006, the Court dismissed the relator's False Claims Act claim and all state law claims brought against the medical school research foundation.

¹⁷ 42 C.F.R. § 411.355(e)(1)(ii).

¹⁸ The facts of *Bradford* are more complicated and convoluted than presented here, however for sake of brevity, only the questionable provisions of the BRMC nuclear camera sublease are briefly outlined.

¹⁹ The defendants relied on *Villafane* and the same "bright line rule" established by CMS regulations stating an "arrangement does not take into account the volume or value of referrals or other business generated if compensation is (i) fixed in advance and results in FMV compensation; and (ii) does not vary over the term in a manner that takes into account referrals or other business generated."

²⁰ 42 C.F.R. § 411.357(p).

²¹ Note that while the Stark Law is a strict liability statute, the FCA requires scienter.

²² *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002-Orl-31DAB (M.D. Fla., 2012).

Governmental Investigations of Physicians: The Perils of Parallel Proceedings

By: Anthony L. Cochran
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The term “parallel proceedings” is shorthand for describing simultaneous civil, administrative, regulatory, or criminal investigations or formal proceedings. Parallel proceedings in health care have become commonplace as a result of –

- (1) expansion of health care fraud initiatives at both the State and Federal levels;
- (2) the advent of Zone Program Integrity Contractors (“ZPICs”), with the ability to initiate a fraud investigation, and Recovery Audit Contractors (“RACs”), who were designed to protect Medicare by identifying improper payments and referring potential fraud to the Centers for Medicare & Medicaid Services (“CMS”);
- (3) the ever-expanding scope of whistleblower litigation at both the State and Federal level;
- (4) the ever-present regulation by State Medical Boards; and,
- (5) the risk of exclusion by the Office of Inspector General (“OIG”) of the Department of Health and Human Services.

It is not uncommon for a physician who becomes ensnared in a billing inquiry to face the potential of:

- (1) Whistleblower civil litigation, which can include multiple damages, penalties, and attorney’s fees;
- (2) Criminal prosecution by either State or Federal authorities, which can result in incarceration, restitution, and fines;
- (3) Probation, suspension or revocation of medical license;
- (4) Exclusion from Medicare and Medicaid;
- (5) Loss of clinical privileges at hospitals;
- (6) Loss of eligibility for insurance panels;
- (7) Adverse publicity, including a report to the National Practitioners Data Bank; and,
- (8) Payment of attorney’s fees to defend him/herself.

Parallel proceedings are challenging because what may be a good strategic move in one forum or setting may be ill-advised in another. When deciding

among difficult strategic choices, parallel proceedings require that counsel never lose sight of the client’s priorities.

- Typically, the first priority is to stay out of prison, *i.e.*, liberty.
- Retention of a professional license often is high on the list of priorities, if not at the top of the list. Loss of license can be the “economic death penalty.”
- Preservation of reputation is high on most client’s list of priorities.
- Preservation of one’s assets is important, but may not be the highest priority, particularly when compared with loss of liberty.

Priorities need to be discussed with the client and clearly understood. They should guide your advice and your client’s difficult choices.

Take for example the lawyer who represents a physician who is the subject of both a criminal prosecution and either a civil suit or an administrative proceeding before the state medical board or other licensing authority. If the physician is called upon to give a civil deposition or to testify at a board hearing, he or she may be faced with the dilemma of either waiving his or her Fifth Amendment privilege against self-incrimination, or invoking the privilege, which may, and often does, result in an adverse inference being drawn against him or her.¹ You and your client must discuss the consequences of both options.

Counsel for parties in parallel proceedings must be ever vigilant to ensure that the civil or administrative investigation is not used as a “Trojan horse for a parallel criminal investigation by gaining the cooperation of an unsuspecting criminal target, who would have otherwise invoked protections against self-incrimination.”²

With regard to the myriad implications of invoking the privilege, you should consider the following:

1. Will invocation of the privilege endanger your client's clinical privileges in hospitals where the physician is a member of the medical staff?

a. Will peer review proceedings be initiated against the physician?

b. Is the Hospital implicated by the physician's conduct, *e.g.*, is there a potential *Stark* or Anti-Kickback statute violation?

c. Will the Hospital enter into a common interest agreement concerning the investigation?³

2. Will invocation of the privilege endanger the physician's employment?

a. What are the events of default under his employment contract?

b. Will his colleagues enter into a common interest-joint defense agreement?

c. Will the physician's employer indemnify him? Do the practice's bylaws provide for indemnification? What are the State's corporate statutory requirements for indemnification/advancement of fees and expenses?⁴

d. Do any of his colleagues stand to profit by his elimination as a competitor?

3. Will invocation of the privilege endanger the physician's medical license with the State?

a. Will the State Medical Board initiate an investigation?

b. What happens if the physician refuses to be interviewed by an investigator with the State Medical Board?

4. Will invocation of the privilege endanger your client's eligibility as a provider in managed care companies?

a. What, if any, due process rights does the physician have under agreements with managed care groups?

5. Will invocation of the privilege endanger eligibility with Medicare or Medicaid?

a. Will there be an administrative audit or investigation?

b. Will administrative subpoenas or civil investigative demands ("CIDs") be issued?

c. How long is the potential exclusion from Medicare?

6. Will invocation of the privilege endanger your client's malpractice insurance coverage?

a. Does invocation of the privilege constitute failure to cooperate in the defense?

b. What exclusions are contained in the physician's insurance policy that could be implicated?

7. Will invocation of the privilege result in embarrassing media coverage?

a. Does anyone have an incentive to leak information to the media?

b. How will the physician's patients react?

c. How will the physician's referral sources react?

8. Will the privilege be waived if it is not asserted?⁵

Equally important are the possible implications of not invoking the privilege. In evaluating these, counsel must ask:

1. Why does your client insist on testifying, *e.g.*, paranoia that an invocation of the privilege will make the situation worse, anger the other side, or imply guilt?

2. Can you and your client make an intelligent waiver of the privilege?

a. Do you and your client have all of the documents and evidence, *e.g.*, witness statements, relevant to his or her involvement in the events in question?

b. Do you clearly understand what is being investigated?

c. Do you clearly understand what your client allegedly did?

3. How broad is the waiver of the privilege (should the physician decide to testify)?

a. Has the door been opened to future questioning in other settings?

4. Can the physician's testimony be used against him or her in the criminal investigation?

5. Can the physician's testimony be used against him or her by the Medical Board, Medicare, Medicaid, peer review committees at hospitals, insurance carriers, or managed care groups?

6. Can the physician agree with the opposing party to make confidential disclosures that

will not be disclosed to third parties and that cannot be obtained by third parties?

7. Is there a common interest privilege?⁶
8. Can a stay be obtained in order to avoid giving a deposition?
9. Is there any alternative to giving a deposition?
 - a. Can an interview be given instead?
 - b. Can written questions be answered in lieu of a deposition?
10. If the deposition does go forward:
 - a. Can topics on which criminal exposure might exist be avoided?
 - b. Can objections based on relevance be successfully asserted?
 - c. Will the testimony be videotaped?
 - d. Will the physician waive signature, or will he or she reserve the right to read and sign (to correct his or her testimony after having been afforded thirty days in which to read and study it)?
 - e. Are there any other technical, procedural objections that can be used to avoid having to testify on sensitive topics?

Whenever there is the potential of a criminal prosecution, you always need to know what your client's status is in the eyes of the prosecutor. Often, your client will receive a "target letter" from the Department of Justice. At other times, a Civil Investigation Demand⁷ or an investigative subpoena will be the first notice that there is an ongoing investigation. Beware that "[t]he tools available to the government for purposes of the civil investigation can have a tremendous impact on the criminal investigation."⁸ Lawyers representing clients in parallel investigations must take special care to ensure that their clients appreciate the likelihood that information developed by one party in one proceeding will be shared with and used in other proceedings. And, of course, false testimony could lead to criminal perjury charges, as well.

As with any criminal investigation, the investigators "follow the money." Thus, a critical question to your analysis is whether your client was significantly enriched by the conduct under investigation. The answer to that question can often be the difference between whether an investigation results in civil consequences or criminal prosecution.

This is just the beginning. At every step, in each parallel proceeding, counsel must be alert to the potential collateral damage or unintended consequences that might result from the selection of a strategic option. It is imperative that you explain these consequences to your client so that your client does not later ask you, "Why didn't you warn me about that?" With parallel proceedings, collateral consequences require constant vigilance.

Lest you have any doubt about the extent of the cooperation, please be aware that the United States Attorneys Manual states:

Health care fraud and abuse control is promoted when Federal, State, and local law enforcement entities share information about trends in health care fraud, emerging investigative and prosecutorial techniques, and other information necessary to achieve the common goal of controlling health care fraud.⁹

Finally, the close collaboration among whistleblower's counsel and government attorneys is also well publicized:

Each December, some of the nation's top health care lawyers gather to discuss developments in prosecuting and defending health care fraud cases at the Health Care Fraud Institute in Atlanta. ... One of the major developments ... was the increasing number of cases in which the Justice Department relies on private attorneys representing whistleblowers.... 10

¹ See *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976) ("The Fifth Amendment does not forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them.") An adverse inference may not, however, be drawn against a defendant in a criminal case due to a defendant's refusal to testify. See *Mitchell v. United States*, 526 U.S. 314, 327-28 (1995) ("The normal rule in a criminal case is that no negative inference from the defendant's failure to testify is permitted.")

² Hilder, Philip & Creech, Paul, *Texas Medicaid Fraud Control Unit, A Trojan Horse*, <http://www.hilderlaw.com/publications>. See also *Sterling Nat. Bank v. A-1 Hotels Intern., Inc.*, 175 F.Supp.2d 573, 579 (S.D.N.Y. 2001) (noting that where civil and criminal proceedings are conducted concurrently, “there is a special danger that the government can effectively undermine rights that would exist in a criminal investigation by conducting a *de facto* criminal investigation using nominally civil means”).

³ See *In re Grand Jury Subpoena*, 415 F.3d 333 (4th Cir. 2005) (Common interest agreement between corporation that was subject of SEC investigation and employee who was also subject of that investigation could not serve as basis for employee’s assertion of joint defense privilege against grand jury subpoenas seeking documents related to company’s earlier internal investigation because at the time of the internal investigation, during which employee was interviewed by inside and outside counsel, a common interest agreement was not yet in effect, and the interviews were not for the purpose of formulating a joint defense).

⁴ Georgia - O.C.G.A. § 14-2-851(a), § 14-2-857(a), (d), and § 14-2-853(a) : Generally speaking, a corporation may indemnify an individual who is a party to a proceeding because he or she is or was a director, officer or employee against liability incurred in the proceeding if: (1) Such individual conducted himself or herself in good faith; and (2) Such individual reasonably believed: (A) In the case of conduct in his or her official capacity, that such conduct was in the best interests of the corporation; (B) In all other cases, that such conduct was at least not opposed to the best interests of the corporation; and (C) In the case of any criminal proceeding, that the individual had no reasonable cause to believe such conduct was unlawful.”

⁵ See *Minnesota v. Murphy*, 465 U.S. 420, 428 (1984) (holding that the privilege is lost if not affirmatively invoked, even where defendant did not make knowing and intelligent waiver).

⁶ *McKesson Corp. v. Green*, 279 Ga. 95 (2005) (when a party discloses materials that are protected by the attorney work-product privilege to a government agency investigating allegations against it, party waives the protection, notwithstanding confidentiality agreement with government agency); See also *In re Columbia/HCA Healthcare Corp. Billing Practices Litigation*, 293 F.3d 289, 302 (6th Cir. 2002) (client may not selectively waive attorney-client privilege by releasing otherwise privileged documents to government agencies during investigation, but continue to assert privilege as to other parties).

⁷ The DOJ has authority to use Civil Investigative Demands, which “permit the civil prosecutors to compel both documents and sworn testimony, and then to share this information with criminal prosecutors and counsel for whistleblowers” in *qui tam* cases. *Id.* at 30; 31 U.S.C. § 3733(a)(1) (2010).

⁸ Pierson, *Here Come the Feds: The Significant Impact of Healthcare Reform on Government Investigations and Enforcement*,” *The Champion*, September/October 2010 at 29.

⁹
http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/crm00978.htm#1.

¹⁰
http://www.whistleblowerlawyerblog.com/2012/12/health_care_fraud_institute_di_1.html

Just The Essentials: A Guide To The Employer Shared Responsibility Provision Of The Patient Protection and Affordable Care Act

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Attorneys in the health and employment fields will likely be asked to provide guidance regarding the Patient Protection and Affordable Care Act (“PPACA”) and its requirements for employers. Although the Obama administration has delayed the “employer mandate” for large employers until 2015¹ and for mid-size employers (with 50-99 employees) until 2016,² enforcement of these employer requirements is coming. Following is a high-level summary of the Employer Shared Responsibility requirements that many employers will be forced to grapple with as they shift from a “wait and see” approach to their implementation of the PPACA requirements.

The PPACA Requirements for Large Employers

The PPACA adds a new section, 4980H, to the Internal Revenue Code, which requires large employers (those with more than 50 full-time employees or full-time equivalents (“FTEs”)) to either provide “minimum essential coverage” or pay a penalty.³ This section is informally known as the employer mandate and offhandedly as the “play or pay” provision.

The PPACA defines a “full-time” employee as an “employee who is employed on average at least 30 hours of service per week.”⁴ This definition may run counter to employers’ traditional understanding, where a forty-hour work week has been the standard for the classification of “full-time” employee. Additionally, the total monthly hours of the employer’s part-time employees will be aggregated and divided by 120 to calculate the number of full-time equivalent employees.⁵ As such, an employer may not necessarily avoid the mandate by reducing the number of full-time employees and increasing their part-time staff.

Example 1:

Company A has 35 full-time employees and 24 part-time employees. If each part-time employee works

20 hours a week, Company A will have 51 FTE employees for PPACA purposes, thus making it a large employer subject to the employer mandate.⁶

The employer mandate applies to federal employers, state employers, local government entities, private for-profit employers, tax-exempt entities, and Indian tribal government entities.⁷ Therefore, most employers will fall within the scope of the PPACA. Note, however, that these PPACA requirements will not apply to small employers with fewer than 50 full-time employees or full-time equivalents.

In order for an employer’s health coverage to meet the “minimum essential coverage” required by the Employer Shared Responsibility provision, the coverage must satisfy standards for affordability and adequacy of coverage (“minimum value”).⁸ Regarding affordability, if the employee’s required contribution⁹ exceeds 9.5% of the employee’s household income, the coverage is deemed unaffordable.¹⁰ Additionally, health coverage that covers less than 60% of the total allowed costs of benefits fails to meet the minimum value standard.¹¹ Both adequacy and affordability must be met to satisfy the minimum essential coverage requirement.¹²

Calculating Employer Penalties

A large employer that fails to provide minimum essential coverage may face penalties. These penalties are calculated in two ways.

First, if the employer fails to offer full-time employees (and their dependents)¹³ any opportunity to enroll in minimum essential coverage, the employer must pay a penalty of \$2,000 annually¹⁴ per full-time employee beginning with the thirty-first employee.¹⁵ The penalty is triggered when at least one employee obtains coverage from a Health Insurance Exchange, state or federal, and receives a premium tax credit or cost-sharing subsidy.¹⁶ Notably, the penalty is assessed against every full-time employee, minus

thirty, that is employed by the employer, regardless of whether all of the employees obtained subsidized coverage or cost-sharing subsidy.¹⁷

Example 2:

*Company B is a large employer that employs 130 full-time employees. If Company B does not offer minimum essential coverage to its full-time employees and one or more employees receives a subsidy when obtaining health insurance via the Exchange; Company B will face a penalty of \$200,000.*¹⁸

Under the second calculation, large employers may also face penalties if they offer coverage that fails to meet the minimum value and/or affordability standards. If coverage is unaffordable, or does not meet minimum value, an employee can go to the Exchange and receive tax subsidies to purchase coverage. In such instances, the employer will be penalized \$3,000 annually, per employee who receives a tax subsidy to purchase coverage on the Exchange.¹⁹

Example 3:

*Company C has 130 full-time employees and offers health care coverage. But, for 8 low-wage employees, the employee's share of premiums exceeds 9.5% of their household income (i.e. the health coverage fails to meet the affordability standard). If these 8 employees obtain tax subsidies to purchase coverage on the Exchange, Company C will face a penalty of \$24,000 annually.*²⁰

Final Note

The impact of the Employer Shared Responsibility provision on employers is not limited to the penalties imposed. The employer mandate will also cause increases in cost due to administrative and reporting requirements. For example, the number of employees considered "full-time" for purposes of calculating the tax penalty is calculated monthly. This calculation can be burdensome on companies; a fact that the IRS acknowledged in a Notice in which the IRS stated that "a determination of full-time employees...may cause practical difficulties...for employers, employees, and the State Exchanges."²¹

Administrative challenges may make it difficult for employers to identify full-time employees accurately, "and consequently to forecast or avoid potential § 4980H liability."²² In recognition of the administrative challenges presented, the IRS has offered simpler methods of calculation and

reporting.²³ But, employers should be aware that the simpler methods offered by the IRS may not be available when it matters the most, when the Employer Shared Responsibility provision becomes enforceable in 2015, and 2016 for mid-size companies.²⁴

Pocket Guide:

Employer Shared Responsibility

- Often referred to as "Employer Mandate," or "Pay or Play" provision.
- Applies to most employers types.
- Imposes an option for "large" employer to either offer *Minimum Essential Coverage* or pay a tax.

Large Employers:

- Employers that employ 50 or more full-time and / or full-time equivalent employees.
- *Full-time employees:* those that work on average at least 30 hours per week.
- *Full-time equivalents:* The aggregate monthly number of hours worked by part-time employees, divided by 120.
- Note there are special considerations for seasonal workers.²⁵

Minimum Essential Coverage:

- Health coverage must be (1) adequate and (2) affordable.
- Coverage is adequate if it covers at least 60% of health care expenses for a typical population.
- Coverage is affordable if the employee's share is less than 9.5% of household income.

Penalties

- Penalties will be assessed after 3 events occur:
 1. Employer fails to offer Minimum Essential Coverage;
 2. Employee obtains adequate coverage from the Exchange;

3. Employee qualifies and receives Tax credit when obtaining coverage.

Penalty Amount Assessed:

- If Employer does not offer coverage:
 - US \$2,000.00 per employee for all full-time employees of the company, less 30 employees.
- Employer offers coverage that does not meet the *Minimum Essential Coverage* standard:
 - US \$3,000.00 annually, per employee that actually receives subsidized coverage on the Exchange.

General Notes:

- The Employer Shared Responsibility provision has been postponed and will be enforced beginning January 1, 2015 for employers with 100 FTEs or more, and January 1, 2016 for employers with 50-99 FTEs.
- The PPACA amends the Fair Labor Standards Act to prohibit discrimination against low-income employees who may qualify for a premium tax credit or cost-sharing reduction.²⁶

⁹ See 26 U.S.C. § 5000A(e)(1)(B)(i) (2006 & Supp. V 2011) (defining “required contribution” as “the portion of the annual premium which would be paid by the individual (without regard to whether paid through salary reduction or otherwise) for self-only coverage,” so if premiums for family coverage exceeds 9.5% of income, it will not be deemed unaffordable).

¹⁰ 26 U.S.C. § 36B(c)(2)(C)(i) (2006 & Supp. IV 2011).

¹¹ *Id.* § 36B(c)(2)(C)(ii).

¹² 26 USC § 4980H(a)(1) (2012).

¹³ See 26 U.S.C. §§ 4980H(a)(1), (b)(1)(a) (2012); *see also*

Treas. Reg. § 54.4980H-1(a)(12) (2014) (defining dependent as “a child (as defined in section 152(f)(1) but excluding a stepson, stepdaughter or an eligible foster child (and excluding any individual who is excluded from the definition of dependent under section 152 by operation of section 152(b)(3))) of an employee who has not attained age 26...the term dependent does not include the spouse of an employee.”

¹⁴ For violations that occur less than 12 months the penalty assessed equals: \$2,000 (annual penalty) x (1/12) x Number of violating months.

¹⁵ See 26 U.S.C. § 4980H(c)(2)(D) (2012) (Stipulating that the first 30 employees are disregarded in administering the penalty for the failure to offer coverage).

¹⁶ *Id.* § 4980H(a)(2) (2012).

¹⁷ *Id.* § 4980H(a) (2012).

¹⁸ Calculation: 130 employees – 30 employees (automatically disregarded) = 100 employees for which Company A will be penalized. Penalty equates to \$2,000 x 100 employees = \$200,000 annually or \$200,000 x (1/12) = \$16,666.66 per violating month, assuming factors are constant).

¹⁹ 26 USC §4980H(b) (2012).

²⁰ Calculation: Coverage was unaffordable for 8 employees, who were then eligible for subsidies to purchase coverage. 8 employees obtained subsidized coverage on the Exchange. As such, 8 employees x \$3,000 penalty = \$24,000 total penalty for Company B.

²¹ I.R.S. Notice 2011-36, 2011-21 I.R.B. 792.

²² *Id.*

²³ *Id.*

²⁴ See *id.* (Stating Notice 2011-36 provides relief for 2014. Subsequent years have not been approved as of February 11, 2014.).

²⁵ See 26 U.S.C. § 4980H(c)(2)(B)(i) (2012) stipulating employers who are in excess 50 employees within a 120-day period, and whose excess employees are classified as “seasonal employees” shall be exempt from “large-employer” classification; *see also* 26 U.S.C. § 4980H(c)(2)(B)(ii) (2012) (defining seasonal worker as “a worker who performs labor or services on a seasonal basis as defined by the Secretary of Labor, including workers covered by section 500.20(s)(1) of title 29, Code of Federal Regulations and retail workers employed exclusively during holiday seasons”).

²⁶ 29 U.S.C. § 218c(a) (2006 & Supp. V 2011).

¹ Treas. Reg. § 54.4980H (2014); *see also* I.R.S. Notice 2013-45, 2013-31 I.R.B. 116.

² Treas. Reg. § 54.4980H (2014).

³ Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), 26 U.S.C. § 4980H(d)(2)(a) (2012).

⁴ 26 USC § 4980H(d)(4)(a) (2012).

⁵ *Id.* § 4980H(c)(2)(E).

⁶ Calculation: 24 part-time employees x 20 hours per week x 4 weeks = 1920 (aggregate number of hours worked); thus, 1920 hours / 120 = 16 (the number of full-time equivalents). Finally, 16 (number of full-time equivalents) + 35 (number of full-time employees that work 30 or more hours = 51).

⁷ See I.R.S., Questions and Answers on Employer Shared Responsibility Provisions Under the Affordable Care Act, <http://www.irs.gov/uac/Newsroom/Questions-and-Answers-on-Employer-Shared-Responsibility-Provisions-Under-the-Affordable-Care-Act#Which> (last visited Feb. 12, 2014).

⁸ 26 U.S.C. § 36B(c)(2)(C)(i) (2006 & Supp. IV 2011).

The Two-Midnight Rule: History and Recent Updates

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I. The Two-Midnight Rule: Background

Due to increasing concerns regarding hospitals' use of outpatient stays (lasting two nights or longer) and short inpatient stays (lasting fewer than two nights) and in an effort to provide more clarity to physicians regarding inpatient status orders, the Centers for Medicare and Medicaid Services ("CMS") issued a proposed rule (the "Two-Midnight Rule"), now finalized and impacting providers nationally.¹ In addition to clarifications regarding inpatient status orders, CMS's intent behind the Two-Midnight Rule and accompanying new time-frame guidance included an expectation that both the number of outpatient stays lasting two nights or longer and the number of "short" inpatient stays would be reduced.²

Prior CMS time-frame guidance directed physicians to use a 24-hour period as a benchmark (the "24-Hour Benchmark"), ordering an inpatient admission for patients expected to need hospital care for 24 hours or more, and treating other patients on an outpatient basis.³ However, the 24-Hour Benchmark was one of many other factors a physician considered when making the decision to admit a patient as an inpatient and, if used alone, it did not ensure coverage under Medicare Part A.⁴ CMS policy stated that the decision to admit or discharge a patient could be made within 24 hours and should rarely take longer than 48 hours.⁵

II. The Two-Midnight Rule: A New Policy

CMS issued the Inpatient Prospective Payment Systems ("IPPS") Fiscal Year ("FY") 2014 Final Rule (the "Final Rule") on August 2, 2013 with an effective date of October 1, 2013, providing a short time period for providers to comply with the Final Rule.⁶ In the Final Rule, CMS finalized its new time-frame policy, the Two-Midnight Rule, and clarified requirements for physician documentation of orders and certification of inpatient admissions, specifically requiring an inpatient admission order as a condition of payment.⁷ The Two-Midnight Rule establishes that inpatient hospital services spanning two midnights are generally deemed appropriate and reimbursable under Medicare Part A.⁸ In addition, the Two-Midnight Rule outlines the new process for Medicare contractor reviews of hospital inpatient claims and

the appropriateness of such claims for reimbursement under the new time-frame requirements.

Presumption vs. Benchmark: The New Process for Medicare Inpatient Claim Reviews

Under the "Two Midnight Presumption," an inpatient hospital claim with a length of stay greater than two midnights following a formal order for an inpatient admission is "presumed" generally appropriate for payment under Medicare Part A.⁹ For medical review purposes, inpatient hospital claims that meet the Two Midnight Presumption will not be the focus of medical reviews (although these claims may be reviewed for medical necessity generally).¹⁰ While inpatient hospital claims meeting the Two Midnight Presumption will not be the focus of medical reviews, if CMS finds "evidence of systematic gaming, abuse or delays in the provision of care" in an attempt to circumvent CMS's requirements and meet the qualifications for the Two Midnight Presumption, the provider will be subject to targeted review and may face greater scrutiny and liability for non-compliance. Now, CMS will concentrate medical reviews on inpatient hospital claims that fail to meet the Two Midnight Presumption. CMS contracted reviewers will apply criteria under the Two Midnight Benchmark to determine whether such claims are appropriate for payment under Medicare Part A.¹¹ The Two Midnight Benchmark review criteria are based upon a physician's expectation that a beneficiary will require medically necessary inpatient hospital services spanning at least two midnights. In determining whether the Two Midnight Benchmark is met, CMS contracted reviewers will consider both the duration of inpatient hospital services and the beneficiary's time spent receiving outpatient services within the hospital prior to the formal inpatient admission.¹² The time spent receiving outpatient services within the hospital prior to the formal inpatient admission may include services such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment areas.¹³ Regardless of which medical review process applies, providers must ensure compliance with the requirements for documentation of the inpatient order and accompanying physician certification, including adequate documentation

supporting the expected duration of the inpatient stay and medical necessity of such care.

III. Litigation History and Current Challenges to the Changing Inpatient Landscape

In connection with the adoption of the Two-Midnight Rule, CMS expected a shift from outpatient to inpatient stays with consequential increases in reimbursement. In order to offset this cost, CMS implemented an across the board 0.2 percent reduction in the standardized Medicare payment amounts for all inpatient stays with discharges occurring on or after October 1, 2013.¹⁴ The American Hospital Association (“AHA”) along with several state hospital associations and four hospitals filed a hearing request challenging CMS’s actions with the Provider Reimbursement Review Board (“PRRB”), taking the first steps to getting the 0.2 percent payment reduction issue before a federal court since the PRRB lacks the power to grant the requested relief.¹⁵

The parties then filed suit in the District of Columbia District Court on April 14, 2014 (the “Complaint”), attacking the reasoning behind CMS’s determination that Medicare payments to hospitals would increase due to the shift from outpatient to inpatient stays as a result of the Two-Midnight Rule.¹⁶

The Complaint states that CMS in “[u]sing the new two-midnights rule as a fig leaf [...] also decided to cut the payments hospitals receive for treating Medicare patients.”¹⁷ Continuing, the Complaint states that “CMS claimed--without setting forth its actuaries’ reasoning or calculations--that the two-midnights rule and other related policy changes would result in a net increase in the number of inpatient hospital stays that Medicare covers under Part A...cost[ing] the Medicare program \$220 million in fiscal year 2014.”¹⁸ The Complaint challenges CMS’s resulting 0.2 percent payment reduction “on the grounds that it is arbitrary and capricious [thereby alleging violations under the Administrative Procedure Act (“APA”) due to CMS’ reliance on indefensible assumptions and failure to explain its assumptions], invalid for failure to undergo adequate notice and comment [further alleging violations under the APA], and contrary to federal law [the 0.2 percent reduction was discussed in the preamble to the Final Rule, but not codified in the Code of Federal Regulations thereby raising allegations of violations under both the APA and the Medicare Act].”¹⁹

In a related lawsuit (the “Second Complaint”) also filed on April 14, 2014, AHA and the co-plaintiffs challenged CMS’s policy in the Final Rule requiring physicians to certify the expectation that an inpatient admission would span two midnights.²⁰ Specifically,

the lawsuit challenges three Medicare policies which the plaintiffs allege in the Second Complaint “burden hospitals with arbitrary standards and documentation requirements and deprive hospitals of Medicare reimbursement to which they are entitled.”²¹

The Second Complaint notes that the Medicare Act has never included a definition of “what it means to be an ‘inpatient.’” Instead, for more than 50 years, the Secretary of the U.S. Department of Health & Human Services, acting through CMS to administer the program, has committed the decision whether to admit a patient to the hospital to the expert judgment of the treating physician.²² Arguing that the Final Rule “unwisely permits the government to supplant treating physicians’ judgment[,]” the Second Complaint reiterates that the “question whether to admit a patient as an inpatient is fact-sensitive and a matter of judgment.”²³ The Second Complaint notes that the Final Rule ignores long-standing history of committing admission decisions to a particular patient’s treating physician, and that the Final Rule instead “applies regardless of the ‘level of care’ the physician expects the patient to need” and which “provides that a Medicare beneficiary is not an ‘inpatient’ unless the admitting physician expects that beneficiary to need...hospital [care]... spanning two midnights.”²⁴

IV. Legislative Attempts to Address the Two-Midnight Rule

The Two-Midnight Rule Delay Act of 2013 was introduced to delay the “enforcement of the Medicare two-midnight rule for short inpatient hospital stays until the implementation of a new Medicare payment methodology for short inpatient hospital stays,” thereby prohibiting the Secretary from enforcing the Two-Midnight Rule for admissions occurring before Oct. 1, 2014.²⁵ The bill also prohibits the Secretary from increasing the sample of “probe and educate” claims established as of November 4, 2013 and further prohibits Medicare review contractors from denying inpatient claims for discharges that meet certain criteria which occur before Oct. 1, 2014.

V. The Two-Midnight Rule: Ongoing Probe Audits Continue in the Midst of Proposed Legislation and Lawsuits

The Two-Midnight Rule became effective on October 1, 2013 with simultaneous commencement of the “probe and educate” audits (the “Probe Audits”); and, in the midst of legislative attempts and law suits challenging the recovery audit landscape and CMS’ alleged abuses of its authority in related rule-making, the Probe Audits continue. In recent guidance, CMS

reiterated that “CMS will direct Medicare review contractors to apply CMS-1599-F and the additional guidance CMS plans to issue in conducting patient status reviews for claims submitted by acute care inpatient hospital facilities, Long Term Care Hospitals (LTCHs), Critical Access Hospitals (CAHs) and Inpatient Psychiatric Facilities (IPFs) for dates of admission on or after [October 1, 2013].”²⁶ Per CMS-1599-F Inpatient Rehabilitation Facilities patient status reviews are specifically excluded from the 2-midnight inpatient admission and medical review guidelines.²⁷

During the Probe Audits, when reviewing inpatient claims with dates of admission on or after October 1, 2013, MACs will assess hospital compliance with admission order requirements, certification requirements, and the Two Midnight Benchmark.²⁸ MACs will also apply the Two Midnight payment policy when conducting prepayment reviews for inpatient claims where the surgical procedure is cancelled. Recently CMS announced that MACs will also re-review its denied claims under the Probe Audits “to ensure the claim decision and subsequent education is consistent with the most recent clarifications.”²⁹

MACs will also identify providers who need additional education if a MAC encounters high claim error rates, which can expand the Probe Audit universe of claims. MACs will send detailed results letters and will offer providers the option of a telephone call if moderate to major corrective action is indicated.

Finally, although Recovery Audit contractors will not be conducting post-payment reviews of inpatient claims with dates of admission on or after October 1, 2013 through March 31, 2015, RAs may continue audits of inpatient admissions with dates of service prior to October 1, 2013.³⁰

VI. Conclusion

Despite the continuing “full-impact delays” and the uncertainty regarding the outcome of ongoing legal challenges and legislative proposals, the Two-Midnight Rule is effective and Probe Audits are ongoing. Providers should be self-auditing to ensure accurate documentation and compliance with physician orders and certifications. Providers should ensure that they continue to protect both their legal and appeal rights as they work with their legal counsel in a proactive manner when implementing operational changes to maintain compliance with the requirements under the Final Rule.

¹See Hospital Outpatient Prospective Payment Final Rule (77 Federal Register 68210, 68427 (Nov. 15, 2012)) discussing that “[i]n

the proposed rule, [CMS] indicated that [it] heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting them as inpatients; *see also* the Medicare Part B Inpatient Billing Proposed Rule (78 Fed. Reg. 16632 (March 18, 2013)) addressing CMS’ concerns regarding hospitals’ use of outpatient stays; *see also* Inpatient Prospective Payment Systems (“IPPS”) Proposed Rule (78 Fed. Reg. 27486 (May 10, 2013)) and IPPS FY 2014 Final Rule (78 Fed. Reg. 50496 (August 19, 2013)); *see also* Hospitals’ Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, (OEI-02-12-00040 (July 29, 2013) issued after CMS proposed the Two-Midnight Rule, the Office of Inspector General (“OIG”) issued a Memorandum Report (the “Report”) discussing hospital use of observation stays and short inpatient stays in 2012. The Report noted that on average, short inpatient stays cost Medicare and beneficiaries more than observation stays.

² 78 Fed. Reg. at 27649-27650.

³ Medicare Benefit Policy Manual (“MBPM”) (CMS Pub. 100-02) Ch. 1, § 10.

⁴ *See* MBPM (CMS Pub. 100-02) Ch. 1, § 10 noting that the decision to admit a patient is a “complex medical judgment” and is considered with other factors; *see also* 78 Fed. Reg. at 50907, discussing CMS’ prior 24-Hour Benchmark; *see also* The Social Security Act §§ 226, 1811, 1812, 1831, and 1832, 42 U.S.C. §§ 426, 1395c, 1395d(a)(1), 1395j, and 1395k delineating entitlement and scope of benefits coverage under Medicare Part A and Medicare Part B. Generally, Medicare Part A, the hospital insurance program, covers inpatient hospital services and Medicare Part B, the supplemental medical insurance program, covers certain physician services, hospital outpatient services and “medical and other health services” that are not covered under Medicare Part A.

⁵ MBPM (CMS Pub. 100-02) Ch. 6, § 20.6.

⁶ 78 Fed. Reg. 27486.

⁷ 78 Fed. Reg. at 50938-50942; although not discussed fully herein, Inpatient-Only procedures are also generally deemed appropriate and reimbursable under Medicare Part A.

⁸ 78 Fed. Reg. at 50952; *see also* Reviewing Hospital Claims for Patient Status: Admissions On or After October 1, 2013, (Last Updated: March 12, 2014) available at: <http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html>) where CMS notes in Section E. that “[i]t is not necessary for a beneficiary to meet an inpatient ‘level of care,’ as may be defined by a commercial screening tool, in order for [a Medicare] Part A payment to be appropriate. In addition, meeting an inpatient ‘level of care,’ as may be defined by a commercial screening tool, does not make [Medicare] Part A payment appropriate in the absence of an expected length of stay of 2 or more midnights.” This further complicates providers’ current utilization management processes (i.e. where screening tools may be required or used as guidance when determining the appropriateness of inpatient admissions for other payers).

⁹ *Id.*

¹⁰ Id.

¹¹ Id. at 50950-50951.

¹² Id. at 50952.

¹³ Id.; *see also* Frequently Asked Questions: 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions On or After October 1, 2013, (Last updated March 12, 2014) *available at*: <http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html>).

¹⁴ 78 Fed. Reg. at 50952-50954.

¹⁵ The Hospital Associations include the following entities: Greater New York Hospital Association, Healthcare Association of New York State, New Jersey Hospital Association and The Hospital & Healthsystem Association of Pennsylvania; the Hospitals include the following entities: Banner Health (Arizona), Einstein Healthcare Network (Pennsylvania), Wake Forest Baptist Medical Center (North Carolina), and The Mount Sinai Hospital (New York).

¹⁶ AHA v. Sebelius, Case No. 1:14-cv-607 (D.D.C., filed April 14, 2014).

¹⁷ Id. at ¶ 5.

¹⁸ Id.

¹⁹ Id. at ¶¶5, and Counts I-V.

²⁰ AHA v. Sebelius, Case No. 1:14-cv-609 (D.D.C., filed April 14, 2014).

²¹ Id.

²² Id. at ¶ 1.

²³ Id. at ¶¶ 3 and 4.

²⁴ Id. at ¶ 3.

²⁵ (H.R. 3698) introduced by Representatives Jim Gerlach and Joseph Crowley, referred to Committee on Dec. 11, 2013 and has a 7% chance of getting past the committee and a 2% chance of being

enacted; *see also* related (S. 2082) Two-Midnight Rule Coordination and Improvement Act of 2014, sponsored by Senator Robert Menendez which provides “for the development of criteria under the Medicare program for medically necessary short inpatient hospital stays...” and has a 2% chance of getting past Committee and 0% chance of being enacted.

²⁶ *See* Reviewing Hospital Claims for Patient Status: Admissions On or After October 1, 2013, (Last Updated: March 12, 2014) *available at*: <http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html>).

²⁷ Id.

²⁸ Id.; *see also* Admission Order and Certification Requirements and 2-midnight Benchmark, *available at*: <http://www.cms.gov/Center/Provider-Type/Hospital-Center.html>); *see also* Hospital Inpatient Admission Order and Certification, (Last Updated: January 30, 2014) *available at*: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf>.

²⁹ *See* Reopenings and Appeals of Inpatient Probe and Educate Claims, (Last Updated: February, 24, 2014) *available at*:

<http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html>. CMS is urging providers to work with their MACs to determine if a claim has been re-reviewed prior to submitting an appeal request. “To ensure that the re-review process does not affect the ability of a provider to file a timely appeal of a denied claim, CMS will waive the 120 day timeframe for filing redetermination requests received before September 30, 2014 for claim denials under the Probe & Educate process that occurred on or before January 30, 2014. Claim denials under the Probe & Educate process that occurred on or before January 30, 2014 for which an appeal has been filed will also be subject to re-review. Claims determined payable following re-review will be adjusted accordingly. Claims for which the denial is affirmed following re-review will be transferred to appeals automatically for a redetermination.”

³⁰ *See* (H.R. 4302) signed into law on April 1, 2014 by President Barack Obama, specifically Sec. 111, delaying yet again the “full-impact” of the Two-Midnight Rule by excluding RAs from the auditing window as noted supra, “unless there is evidence of systematic gaming, fraud, abuse or delays in the provision of care by a service provider.”