Recommendations on Due Diligence Findings:

Transaction Between Pearson & Caring Health Systems

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Executive Summary

This memorandum is designed to provide Pearson University Health System's ("Pearson") management with the requisite information to take appropriate action to secure the health system's financial future and address the legal and business implications of due diligence findings. This memorandum will analyze the various challenges faced by Pearson and will present counsel's recommendations on how Pearson should proceed in light of recent due diligence findings.

Introduction

Pearson is located in Beazley, Loyola. Pearson is an urban non-profit, tax-exempt health system. It is the sole corporate member of a 500-bed tertiary level hospital ("PMC") and a 150-bed rehabilitation and skilled nursing facility ("PSNF"). Pearson also has an academic affiliation with Magis Medical School ("Magis"), which provides residencies in a number of medical specialties. Through its relationship with Magis, Pearson conducts pharmaceutical and medical device clinical research. PMC is one of five hospitals that serve the Beazley metropolitan area. Of PMC's 650 physicians, 150 are employed by Pearson through Pearson Medical Associates ("PMA"), a wholly owned non-profit, tax-exempt subsidiary of Pearson.

I. Financial Assessment of Pearson University Health System and Caring Health System

Although PMC has a strong reputation in the Beazley community, it ranks second or third behind other hospital systems. Its facilities are dated, making it much more difficult to attract the younger, more affluent population that has flocked to competitor hospital systems in recent years. PMC also carries a high debt load ($400 Million), creating a number of problems for the

health system and impacting the system's ability to invest in new equipment. Its costs continue to be much higher and its quality lower than that of its competitors.

These challenges have caused PMC to fall behind its Beazley competitors. In addition, even though it has attempted to become more "physician friendly," PMC has failed to develop an integrated delivery model with its doctors. PMC is also challenged by its poor payor mix and significant leadership turnover in the past decade, placing a great deal of financial stress on the system. PMC has gone through a series of "right-sizing" within the past 18 months its bond rating has dropped to "A" with a negative outlook.

On the other hand, Caring Health System ("CHS") has managed to overcome many of the challenges that still confront PMC. CHS is also a large, non-profit/tax exempt multistate system that operates two hospitals in Beazley. Between its two hospitals, CHS is responsible for over 500 beds and is a clear leader in Beazley. CHS is nationally renowned and highly regarded for its superior quality and sophisticated leadership. Its facilities have strong partnerships with physicians in the Beazley community. It offers a market-leading ACO and narrow network insurance product. CHS is viewed as an "essential provider" by insurance companies, resulting in higher rates of reimbursement from private payors as compared to other systems.

CHS has traditionally staffed its facilities with independent contractor physicians. With the tightening of the Beazley physician market and Pearson's increase in physician employment, CHS has begun increasing its employment of physicians. Currently, CHS employs approximately 115 physicians, but has indicated that it intends to offer the largest employed medical group in the Beazley market within five years. CHS dominates the market in size and strength, as well as reputation, and Pearson has initiated a transaction with Caring in order to infuse new capital, embrace more efficient business practices, and usher a new generation of

sophisticated leadership that will preserve its place in the Beazley market as a leading health care provider.

II. The Transaction with Caring Health System

The transaction will be structured as a membership transaction with CHS as sole corporate member of Pearson. This structure is one of the most common for hospital transactions with both a non-profit buyer and seller.[1] These are traditionally non-cash deals in which the larger hospital takes on the liabilities of the smaller, target hospital. Usually in such a transaction, one of the parties will become the sole corporate member of the other.[2] There are a number of benefits associated with structuring a transaction in this way. One such benefit is that the smaller hospital will have increased access to clinical resources.[3] In addition to taking on the liabilities of the target hospital, the larger hospital may also take over its bond obligations.[4]

Pearson's articles of incorporation and bylaws will be amended to provide that all strategic, operational policy and financial decision-making will be reserved to CHS ("reserved powers"). In addition, PMC and PSNF's articles of incorporation and bylaws will be amended so that all such powers will be reserved to Pearson.

III. Summary and Analysis of Due Diligence Findings

A. Arrangements with Physicians Could Implicate False Claims Act Liability

The False Claims Act ("FCA") is a Federal Law that imposes liability on entities who contract with government programs.[5] It is the Federal Government's primary litigation tool to combat fraud. The FCA provides, in pertinent part, that:

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[1] Helen Adamopoulos, *4 Transaction Models for Community Hospitals*, Becker's Hospital
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] 31 U.S.C. §§ 3729–3733

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;. . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.[6]

The FCA imposes liability on any person or entity that submits a claim to the federal government that is known (or should be known) to be false.[7] Health care providers who are subject to the Stark Law and the Anti-Kickback Statute ("AKS") can face significant penalties for noncompliant arrangements.

A claim that results from a kickback or is made in violation of Stark Law may render it "false or fraudulent," creating liability under the FCA as well as under the AKS or Stark Law.[8] In *Tuomey Healthcare System, Inc*, a hospital, concerned with physicians shifting outpatient procedures to other venues outside their network, offered ten-year employment contracts to nineteen specialists in exchange for performing all outpatient procedures at the Hospital or its other facilities.[9] Compensation was based off of net collections for outpatient procedures and a productivity bonus that was found to be above fair market value ("FMV"). The compensation scheme was found to violate the Stark Law, which turned the hospital's claims for Medicare

[6] *Id.*
[7] *Id.*
[8] Office of the Inspector General: A Roadmap for New Physicians. Fraud & Abuse Laws. *Available at*: http://oig.hhs.gov/compliance/physician-education/01laws.asp. (Last visited, Feb. 17, 2017)
[9] *United States of America ex rel Michael L. Drakeford, M.D., v. Tuomey d/b/a Tuomey Healthcare System, Inc*., 976 F.Supp.2d 776, (D.S.C. October 2, 2013).

services by the nineteen physicians into false claims and the healthcare system was ordered to pay over $237 million for violating FCA and Stark Law.[10]

According to the American Health Law Association Physicians and Hospitals Law Institute, "FCA cases based on alleged violations of Stark or the AKS are particularly complex and expensive to defend because the claimed violation is alleged to have tainted all resulting claims, regardless of whether or not the services were actually rendered, were medically necessary, or were billed properly."[11] Thus, Pearson should make every effort to ensure its contracts and arrangements conform to the applicable AKS safe harbors and Stark Law exceptions to avoid exposure to excessive liability.

If a provider discovers a potentially noncompliant arrangement, it may choose to self-disclose the arrangement to government officials in order to limit its liability. Potential Stark Law violations are often disclosed to the Centers for Medicare & Medicaid Services ("CMS") using the Voluntary Self-Referral Disclosure Protocol ("SRDP") and potential violations of the AKS or a combination of the AKS and the Stark Law are often disclosed to the Office of Inspector General ("OIG") using the Provider Self-Disclosure Protocol ("SDP").[12] Where a person or entity in violation self-reports to the government under certain conditions, the FCA provides that the liability may be reduced to two times the government's losses.[13] However,

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[10] United States Dep't of Justice. Press Release, (Friday, May 10, 2013). *Available at*: http://www.justice.gov/usao-ednc/pr/jury-returns-39-million-verdict-against-hospital-violating-stark-law-false-claims-act. (Last visited, February 11, 2017).

[11] False Claim Act Matters Today: *Best Practices for Projecting Protecting Providers and Securing Insurance Coverage* (2015). *Available at:* https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHS15/bb_may.pdf

[12] Hall Render, Health Law News. (October 20, 2016). *Available at*: http://www.hallrender.com/2016/10/20/oig-data-confirms-that-non-compliant-real-estate-arrangements-are-costly/. (Last viewed Feb 11, 2017).

[13] Department of Justice. The False Claims Act, A Primer. (*Hereinafter,* FCA Primer). *Available at:*http://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf. (Last viewed Jan 25, 2017).

Pearson will need to satisfy three conditions to meet the requirements of the voluntary disclosures qualify for reduced damages under § 3729 of the FCA:

> (A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information; (B) such person fully cooperated with any Government investigation of such violation; and (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation, the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.[14]

Although self-reporting has the potential to reduce damages, it does not eliminate liability and the system can still incur significant penalties. Thus, self-disclosure should only be used after careful consideration.

1. Anti-Kickback Statute Considerations

The AKS[15] was originally created "to prevent financial incentives from influencing where a beneficiary of a federal health care program receives medical treatment."[16] Although it has been amended numerous times, it still serves its main purpose of prohibiting the payment or receipt of remuneration in exchange for referring individuals to providers of designated health care services.

The AKS makes it illegal to "knowingly or willfully offer, pay, solicit, or receive remuneration; directly or indirectly; in cash or in kind; in exchange for; referring an individual; or furnishing or arranging for a good or service; and for which payment may be made under

[14] FCA Primer, *Supra.*
[15] 42 U.S.C.A. § 1320a-7b.
[16] Andrew Dick, et.al. American Bar Association, Section of Real Property, Trust and Estate Law 20th Annual Spring Symposia Washington, D.C. May 1, 2009. *Available at*: http://www.americanbar.org/content/dam/aba/events/real_property_trust_estate/symposia/2009/andrew_dick_paper.authcheckdam.pdf

Medicare or Medicaid."[17] Certain types of financial relationships between referring providers can be defined as kickbacks, i.e., giving a reward in exchange for referrals. The AKS also covers many types of real estate arrangements. Whenever a physician rents office space from a hospital to which she refers patients, the lease will likely be covered by the AKS. The fact that the AKS applies to such arrangements has important implications. Charges of noncompliance put providers at risk for fines up to $25,000, imprisonment, and possible Medicaid and Medicare exclusion.

CMS procured regulations that describe "financial relationships that would clearly be safe from prosecution under the anti-kickback laws," known as "safe harbors."[18] They specify certain types of payment and business practices that are not considered to be "kickbacks, bribes, or rebates under the Medicare and Medicaid programs."[19] Examples of AKS safe harbors include investment interests, space rental, equipment rental, personal services and management contracts, sale of practice, referral services, discounts, employees, and group purchasing organizations, among others.[20]

a. Leasing arrangements with physicians should satisfy the "Space Rental" Safe Harbor.

Despite these considerations, leasing arrangements between physicians and hospitals are not prohibited. If the AKS applies to a leasing arrangement, it must conform to one of the statutes "safe harbors." A safe harbor that is commonly used to cover such arrangements is the

[17] 42 U.S.C. 1320a-7b
[18] American Speech Language Hearing Association. Summary of Self Referral and Anti-Kickback Regulations. *Available at:* http://www.asha.org/practice/reimbursement/medicare/regulations_sum/#footnotes. (Last viewed Jan 25, 2017).
[19] *Id.*
[20] *See* 42 U.S.C. §1320a-7b(b)(3) (2015).

space rental safe harbor. Pearson should utilize this safe harbor to avoid AKS liability. Requirements for the rental space safe harbor include:

> (1) written agreement signed by the parties; (2) lease describes premises covered; (3) term of at least one year; (4) the aggregate payment must be set in advance; (5) all payments and services must be reasonable and based upon fair market value; (6) all arrangements between lessor/lessee must be in one contract; (7) the arrangement must serve a commercially reasonable business purpose; and (8) the specific schedule of intervals must be set out in advance.[21]

In order to take advantage of the space rental safe harbor and gain immunity from AKS prosecution, all criteria must be met.[22] Due diligence findings indicated that at least one of Pearson's arrangements with a physician was not signed. One of the criteria of this safe harbor is that the agreement be set out in writing and signed by the parties. As counsel for Pearson, we strongly recommend that parties to the rental agreements outlined above make every effort to comply with the space rental safe harbor of the AKS.[23]

b. Payment arrangements with providers should satisfy all criteria of the "Personal Services and Management Contracts" Safe Harbor.

Pearson should also ensure that its contracts with individual physician groups satisfy the AKS safe harbor for personal services and management contracts. The agreement must meet the following standards:

> (1) written agreement signed by parties; (2) term of at least one year; (3) agreement must specify aggregate payment and such payment must be set in *advance* (4) compensation must be reasonable, fair market value and determined through arm's length negotiations (5) must set exact services required to be performed; (6) compensation must not be determined in manner that takes into account volume or value of referrals; (7) all arrangements must be in ONE contract. Cannot have multiple overlapping

[21] 42 C.F.R. § 1001.952(b) (2017).
[22] *Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer*, Office of the Inspector General, https://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm. (Last visited Feb. 17, 2017).
[23] *See* 42 CFR 1001.952(b), as amended by 64 Fed. Reg. 63518 (Nov. 19, 1999).

> contracts to circumvent the one-year rule; (8) the arrangement must serve a commercially reasonable business purpose.[24]

The due diligence findings indicated three instances in which payments under physicians' leases began and stopped. In one instance, the physician group made only three of the twelve scheduled payments and then stopped paying because it experienced financial difficulty. In the other two instances, the reason for non-payment is unclear. Due diligence uncovered a note from the former CEO indicating that two of the medical groups need not pay. Although the first instance of non-payment appears innocuous, Pearson should not continue to provide this group rental space if payments are not being collected pursuant to the written lease. In the second and third instances, Pearson should conduct a more thorough investigation into the circumstances of nonpayment. Given the statement from the former CEO that those groups need not pay, Pearson should conduct a thorough investigation, as this could be a possible AKS and/or Stark violation. Pearson should take this investigation very seriously and may need to consider self-disclosure in the event a violation is uncovered.

2. Stark Law Considerations

The Stark Law "prohibits Medicare and Medicaid payments when a physician refers any of the Designated Health Services ("DHS") to an entity where the physician has a financial relationship."[25] The Stark Law requires hospitals to follow certain standards to satisfy professional services contracts. Generally, the contracts (1) must be in writing, specify the services to be performed, and be signed by the parties; (2) must be for at least one year, and if terminated earlier, may not be renegotiated upon the same or substantially similar terms during the one-year period; (3) the services must not exceed those that are reasonably necessary for

[24] 42 CFR §1001.952.
[25] *Physician Self Referral*, CMS, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/PhysicianSelfReferral/. (Last visited Feb. 17, 2017).

legitimate business purposes; and (4) the compensation must be set in advance, represent fair market value, and not vary with the volume or value of referrals.[26]

According to the due diligence findings, PMC does not seem to have a well-maintained contract management system, especially with regard to its contracts with physicians. A review of eighty leases revealed that thirty-five were problematic. As counsel for Pearson, we recommend that all contracts and rental agreements be brought in compliance with AKS safe harbors and Stark exceptions, which will be outlined in the following paragraphs.

a. Holdover leases are permissible if they satisfy the requirements of the "Rental of Office Space Exception" to Stark Law.

The due diligence findings illuminated a situation in which a lease with a physician has expired and there is no evidence of renewal, even though lease payments pursuant to the now expired lease continue to be paid. Traditionally, CMS has considered the frequent renewal of leases and the renegotiation of those leases during the holdover period problematic because it may indicate a desire of the parties to negotiate terms based on the volume or value of referrals. However, following the publication of a CMS Final Rule, such holdover leases may be permissible provided that the compliant lease arrangement expires after a term of at least one year and that lease arrangements satisfy the requirements of the Rental of Office Space Stark Law Exception. [27]

On November 16, 2015, CMS announced the Final Rule regarding payment policies under the Physician Fee Schedule for CY 2016 ("Final Rule").[28] In the Final Rule, CMS explained its rationale for establishing a one-year term for various arrangements and noted that

[26] *See* 42 C.F.R. §§ 411.357(d), 1001.952(d).
[27] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,886 (Nov. 16, 2015) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, 425, 495). (*Hereinafter*, Federal Register, Holdover Arrangements).
[28] *Id*.

the requirements were intended to create stable arrangements between providers that cannot be renegotiated frequently to reflect the current volume or value of referrals.[29] CMS has traditionally taken the position that holdover arrangements could pose an increased risk of abuse among providers, which previously caused CMS to limit holdover leases to six months.[30] According to the Final Rule, CMS has now determined arrangements that continue beyond the six-month period do not pose a risk of abuse, as long as they continue to satisfy the specific requirements of the Rental of Office Space exception.

Through its administration of the Stark Physician SRDP, CMS reviewed numerous arrangements that "failed to satisfy the requirements of an applicable exception solely because the arrangement expired by its terms and the parties continued the arrangement on the same (compliant) terms and conditions after the 6-month holdover period ended."[31] CMS concluded the arrangement must "continue to satisfy the specific requirements of the applicable exception, including the requirements related to fair market value, compensation that does not take into account the volume or value of referrals or other business generated between the parties, and reasonableness of the arrangement."[32] CMS reconsidered its previous position and proposed to eliminate the time limitations on holdovers with safeguards to address two key areas of program abuse: "frequent renegotiation of short term arrangements that take into account a physician's referrals and compensation or rental charges that become inconsistent with fair market value over time."[33]

In the Final Rule, CMS adopted the proposed indefinite holdover provisions for the Rental of Office Space exception, with safeguards mentioned above. The Final Rule provides

[29] *Id*. at 71,318.
[30] *Id.*
[31] Federal Register, Holdover Arrangements, *Supra* at 71,318.
[32] *Id.*
[33] *Id.*

that if the lease arrangement expires after a term of at least one year, an indefinite holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of the Rental of Office Space exception if the following conditions are met:[34]

> (i) The original lease arrangement met the conditions of Rental of Office Space exception when the arrangement expired;
>
> (ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and
>
> (iii) The holdover lease arrangement continues to satisfy the conditions of the Rental of Office Space exception.

Following implementation of the Final Rule, an indefinite holdover lease is permissible if the arrangement proceeds under the same terms as the preceding arrangement. As discussed above, it is important that the holdover arrangement continue on the same terms and conditions because CMS has found that frequent renegotiation of short-term leases poses an increased risk of abuse. CMS is concerned that such arrangement may be influenced to include terms based on the volume or value of referrals.

The due diligence findings revealed that at least one of Pearson's leases with a physician had expired even though lease payments continued to be paid. Although it is important for Pearson to update its leases with physicians, CMS has adopted an indefinite holdover provisions for the Rental of Office Space exception. Thus, Pearson should conduct additional research into the lease provisions to determine the following: (1) whether the original lease contained a holdover provision, (2) whether the original lease met the conditions of the Office Space Stark

[34] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, Final Rule. 42 C.F.R. Parts 405, 410, 411, 414, 425, and 495, 1120. (Jan 17, 2017). *Available at,* http://federalregister.gov/a/2015-28005.

Law exception, (3) whether the holdover lease arrangement is on the same terms and conditions as the previous lease, and (4) whether the holdover lease continues to satisfy the exception. If Pearson determines that it is able to satisfy these criteria, this leasing arrangement will not expose the system to Stark Law liability.

b. No Signed Lease: The Stark Law Exception's "writing requirement" can be satisfied with a signature on a contemporaneous writing documenting the arrangement within ninety days.

The due diligence findings also indicated that at least one of the leases between Pearson and a physician was not signed by the parties. As counsel for Pearson, we strongly recommend that a copy of the lease be signed by all parties. In order to qualify for the Rental of Office Space Stark Law Exception, there must be a written copy of the lease signed by the parties. However, CMS clarified that, regarding lease arrangements, it is not required that the arrangement be in a single and formal contract.[35] A number of documents can satisfy the documentation requirement, depending on the facts and circumstances of the arrangement.[36] According to CMS, "the relevant inquiry is whether the contemporaneous documents permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made."[37]

A signature on a contemporaneous writing documenting the arrangement is still required; however, CMS provided the following list of examples of the types of documents that may constitute contemporaneous documents: board meeting minutes; documents authorizing payments for specified services; hard copy and electronic written communications between the parties; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be

[35] *Id*.
[36] *Id.*
[37] Final Rule. 42 C.F.R. Parts 405, 410, 411, et. al. *Supra,* at n.34.

provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services or rent.[38]

CMS proposed an amendment for arrangements involving temporary noncompliance with signature requirements allowing the parties up to ninety days to obtain all required signatures, regardless of whether the late signature is advertent or inadvertent.[39] Thus, although Pearson may not currently have a signed copy of the lease, it may take up to ninety days to obtain all necessary signatures and documents to satisfy the necessary aspects of the Stark Law exception.

B. Administrative Controls over clinical research are lacking

CMS issued the Medicare Clinical Trial Policy ("CTP") as a principal billing rule for services provided during clinical research. Medicare covers the routine costs of qualifying clinical trials and reasonable and necessary services used to diagnose and treat complications resulting from participation in the clinical trial.[40] Routine costs include all services that are typically available to Medicare beneficiaries, services required solely for the provision of the investigational item or service, and services needed for reasonable and necessary care arising from the diagnosis or treatment of complications.[41] The coverage excludes services already paid by the research sponsors. Clinical trial agreements specify what services are to be performed, who owns what, and how much money will be paid for services.

Clinical research billing compliance prevents entities from inappropriately billing Medicare for the following: (1) services being paid by a clinical research sponsor; (2) services

[38] *Id.*
[39] *Id.*
[40] CMS Publication. *Medicare Coverage; Clinical Trials. Available at:* https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/downloads/finalnationalcoverage.pdf (Accessed Jan 25, 2017).
[41] *Id.*

being paid by third-party payors; and (3) services that do not meet the requirements under the Clinical Trials National Coverage Determination ("NCD"). A bill that is incorrectly submitted to and paid by Medicare constitutes fraud under the FCA. As explained above, the FCA establishes liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[42] "Knowingly" does not require the claimant to have actual knowledge that the claim is false. Violations of FCA occur in research through improper billing and double billing, which will be addressed below.

The lack of meaningful administration or controls over the clinical research enterprise at PMC increases the risk for false claims and double billing because PMC does not have a standard process in place to coordinate relevant study information and identify which research trials are covered. The challenges associated with clinical research noncompliance include the inability to determine whether services are covered by research sponsors or by third-party payors, inability to track patients throughout the system, and inability for research teams to communicate with the billing services.

1. Compensation related to research involving non-employed physician investigators could implicate Stark Law.

In 2014, $18 million dollars in research funds were paid from Magis to Pearson for research-related clinical services at PMC. In 2015, Magis only transferred $500,000 in research funds to Pearson even though the volume of research at PMC remained the same. This is problematic because the amount of research funds from 2014 to 2015 varies tremendously despite the same volume of research at PMC, thus, indicating a potential Stark violation.

The Stark Law prohibits physicians from making referrals for designated health services payable by Medicare or Medicaid programs to any entity with which the physician has a

[42] *See* 31 U.S.C. § § 3729-3733

financial relationship.[43] Financial relationships include compensation arrangements, which are any arrangements involving direct or indirect remuneration between a physician and an entity.[44]

Pearson is a major academic medical center that has an academic affiliation with Magis Medical School, providing residencies in internal medicine, pediatrics, general surgery and orthopedics. The relationship between Magis and Pearson implicates the Stark Law because the research funds passed along to Pearson creates a compensation arrangement between the medical school and the academic medical center. Generally, medical schools refer their patients to their affiliated academic medical center and receive a portion of their compensation from them; therefore, Magis and Pearson have a financial relationship. This compensation arrangement implicates the Stark Law because the principal investigator's practice may refer enrolled patients to the medical school hospital to receive designated health services reimbursed under Medicare.

In order to avoid Stark liability, Pearson should ensure compliance with the Stark Law exception regarding personal service arrangements. This exception requires the arrangement to meet the following requirements: (1) must be set out in writing, be signed by the parties and specify the services covered; (2) must cover all services to be furnished by the physicians to the entity; (3) compensation paid over the term of each arrangement must be set in advance, must not exceed fair market value, and except in the case of a physician incentive plan, must not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.[45] In this case, all the requirements were not met because Magis did not cover all the services since it significantly cut the amount of research funds paid to Pearson even though the volume of research remained the same.

[43] 42 U.S.C. § 1395nn(a)(1) (2016).
[44] 42 U.S.C. § 1395nn(a)(2), (h)(1) (2016).
[45] 42 C.F.R. 411.357(d) (2016).

Since Magis transfers research funds to Pearson for research-related clinical services at PMC, an issue arises with non-employed physicians providing services during a research study. The PMC medical staff is a mixture of employed physicians and independent physicians; therefore, some of these physicians are considered non-employed physicians. The non-employed physician must be paid FMV for their services. Here, the significant cut in research funds does not reflect a fair market value for the research services.

In an arrangement such as this, Pearson must assess the FMV of the principal investigator's services provided in the study and ensure that the funds paid to him do not exceed FMV. Also, the arrangement between the hospital and physician should be documented in a research services agreement that specifies the services that will be provided by the principal investigator. This agreement should also address compliance concerns, indemnification, and other issues related to the hospital and physician's respective roles in the clinical trials. Although, from a fraud and abuse perspective, issues under the Stark Law are most notable here, this arrangement may also violate the AKS if it is not structured properly.

2. Third party payors may have been double-billed for services that should have been paid for by study funds.

Double billing also constitutes fraud and occurs when a bill is submitted to and paid by a third-party payor and the research sponsor reimburses for the same service. Double billing can occur in various ways, including: (1) billing more than once for the same goods or services; (2) billing for items promised for free in the informed consent document; and (3) being over-paid by the government for a service and then not reporting that overpayment. Informed consent documents ("ICD") disclose additional costs that may be incurred during clinical research. ICD may affect research billing because the financial language may promise that certain services will be provided by the research sponsor. Thus, anything provided by the sponsor in the ICD cannot

be billed to Medicare or else it will be deemed fraudulent. The University of Alabama at Birmingham paid $3.39 million to settle allegations that it unlawfully billed Medicare for clinical trials that were also billed to the sponsor of research grants, which resulted in the university being paid twice for the same services.[46] Consequently, Pearson may be liable for being paid twice for clinical research

The February 2015 internal audit reported PMA's poor mechanism of notifying PMC billing system that a patient was enrolled in a research study. The internal audit report tested ten random studies with a cumulative enrollment of thirty-two research patients and identified that the billing systems had been informed of only six of the patients being enrolled in a research study. The report speculated that the balance of the research patients that were not "flagged" in the billing system may have resulted in the patients' insurers being billed for research studies that should have been paid by study funds. Pearson's failure to determine which research costs were covered by the research sponsor and which costs may have been billed to Medicare could result in a violation of the FCA because PMA may have billed Medicare for a service that was already paid for by the research sponsor, resulting in double billing.

C. Patient steering to home health agency could implicate Stark liability

The due diligence findings revealed a complaint from the compliance hotline that PMC discharge planners are steering patients to a home health agency that a high referring physician of PMA owns. This physician is a full-time employee of PMA. The compliance office further discovered that the list of home health agencies that the discharge planners give to patients list the physician's home health agency first on the document. This agency is also the only agency

[46] *University of Alabama-Birmingham Will Pay U.S. $3.39 Million to Resolve False Billing Allegations*, Dep't of Justice, *Available at:* https://www.justice.gov/archive/opa/pr/2005/April/05_civ_194.htm. (Last visited Feb. 17, 2017).

listed that is based in Beazley; the other three listed are based in suburban or rural areas within the Beazley metropolitan area. Lastly, the compliance office revealed that PMA and PMC do not have a formal conflict of interest process in place.

Under Stark, a physician may not refer a patient to an entity for the furnishing of a designated health service if the physician has a financial relationship with the entity.[47] A physician's financial relationship includes an ownership or investment interest in the entity that is providing the designated health service.[48] Further, home health services are considered designated health services under Stark.[49] Stark also requires that a hospital have a procedure that requires a referring physician to disclose to the patient being referred any ownership or investment interest of the referring physician.[50] This disclosure must be made with sufficient time for a patient to make a meaningful decision regarding where to receive care.[51] As counsel, we recommend that Pearson conduct a more thorough review of this issue in order to more accurately determine the potential for risk exposure.

D. Anti-Kickback and Stark Law considerations related to physician compensation

1. Physician compensation is protected from Anti-Kickback Statute liability under the "Bona Fide Employee" safe harbor.

Lastly, the Due Diligence review of physician compensation packages at PMA revealed that a portion of the compensation package for the oncologists is tied to the profitability of the hospital service for both inpatient and outpatient services. The AKS prohibits anyone from knowingly and willfully soliciting or receiving remuneration in return for referring an individual for the furnishing of any item or service, or for purchasing, leasing, or arranging for an item for

[47] 42 U.S.C. § 1395nn(a)(1)
[48] § 1395nn(a)(2)
[49] § 1395nn(h)(6)
[50] § 1395nn(i)(1)(C)
[51] *Id*.

which payment may be made under a Federal health care program.[52] The statute further provides a safe harbor for amounts paid to an employee from an employer pursuant to a bona fide employment relationship for the furnishing of items or services.[53] Under the AKS, an employee is defined pursuant to federal statute, yet courts typically consider an individual as an employee if the employer has a right to control the manner and means with which the employee's work is done, the skill required, work location, method of payment, and the length of the relationship between the parties.[54]

As applied here, the compensation arrangement for oncologists at PMA would fall into the bona fide employment safe harbor of AKS. Of PMC's 650 physicians, 150 are employed with Pearson through PMA, making PMA physicians employees of PMC. Since it is fairly undisputed that PMA physicians are employees of Pearson, any compensation paid to PMA physicians would fall into the bona fide employee safe harbor of the AKS because the physicians are providing covered items and services pursuant to an employment relationship.

Compensation arrangements similar to the one PMA uses for oncologists have been upheld in federal courts. In 2002, a federal district court in the Northern District of Illinois upheld commission-based payments made to physicians who were employed at the hospital to which they made Medicaid referrals.[55] Of particular importance to these courts is whether the employee is providing a covered item or service. In *United States v. Starks*, the Eleventh Circuit affirmed convictions under AKS for employees of the Florida Department of Health and Rehabilitative Services who received per-patient payments for referring patients to a Medicaid

[52] 42 U.S.C. § 1320a-7b(b)(1)-(2)
[53] § 1320a-7b(b)(3)(B). *See also* 42 C.F.R. § 1001.952(i)
[54] *United States. v. Job*, 2010 WL 2773543, at *8 (8th Cir. July 16, 2010) (quoting *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 323-34 (1992)).
[55] *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045 (N.D. Ill. 2002).

funded drug program.[56] The court found that the state employees were not providing covered items or services, and the court noted that they did not receive a salary from the program but rather were paid merely for the referrals to the program.[57] Thus, the bona fide employment safe harbor will protect payments from an employer to an employee, even if the payments consider referrals, so long as the physician is an employee who provides covered items and services for the employer.

2. Physician compensation that is tied to profitability could result in liability under Stark Law.

Although the oncologists' compensation package falls into the bona fide employee safe harbor of the AKS, the arrangement does implicate Stark. Stark requires physician compensation arrangements to meet specific requirements.[58] Given that Stark is a strict liability statute, the compensation arrangement must meet the criteria outlined in the statute in order to avoid liability. The employment must be for identifiable services, and compensation must be consistent with fair market value.[59] The compensation cannot take into account the volume or value of referrals made by a referring physician.[60] Further, the remuneration must be provided under an agreement that would be commercially reasonable even if the physician did not make any referrals to the employer.[61] Lastly, the statute clarifies that these provisions do not prohibit an employer from distributing remuneration in the form of a productivity bonus based on services that the physician personally performs.[62]

[56] *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998).
[57] *Id*.
[58] 42 U.S.C. § 1395nn(e)(2).
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*

Halifax Hospital Medical Center demonstrated how a compensation arrangement such as the one currently utilized at PMA could result in significant financial loss for Pearson.[63] At issue in *Halifax* was the bona fide employment exception to Stark. Six oncologists working for Halifax had contracts with the hospital, which included participation in a bonus pool amounting to fifteen percent of the operating margin of the oncology program at the hospital.[64] The contracts included services, which were referred by the physicians, meaning that the volume or value of the referrals was tied to the physicians' compensation.[65] The court found that the incentive bonus failed to meet the bona fide employment exception because the formula utilized to calculate the percentage of the operating margin varied according to the volume or value of referrals from the oncologists, instead of services personally performed by the oncologists, as required by the statute. The hospital further conceded that the compensation included fees for other hospital services that were not personally performed by the oncologists. Eventually, Halifax settled with the government for 85 million dollars, and they further agreed, pursuant to a five-year Corporate Integrity Agreement, to put procedures in place to review and monitor compensation arrangements with physicians.

The *Halifax* case came on the heels of *United States v. Tuomey Healthcare System*, in which the government obtained a $237 million verdict against a hospital for paying productivity bonuses to physicians who ordered unnecessary nuclear imaging tests on patients.[66] Thus, it is very apparent that measures must be in place to monitor physician compensation arrangements so that they are consistent with the FMV, and that any bonus payments are actually compensation for services personally performed by physicians.

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[63] *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 09-cv-1002 (M.D. Fla. 2014).
[64] *Id.*
[65] *Id.*
[66] *Tuomey Healthcare Sys., Inc.*, 976 F. Supp. 2d 776 (D.S.C. 2013).

As previously mentioned, the current structure of the PMA oncologists' compensation package would implicate Stark because the compensation is tied to the profitability of the hospital service, both inpatient and outpatient, which encourages the oncologists to make referrals solely to increase their compensation. Stark requires physician compensation to be consistent with the FMV of a physician's service, thus the provision within the package that ties compensation to hospital profitability must be changed in one of two ways. PMC could remove the provision altogether and simplify the compensation calculations by ensuring that physicians are paid fair market value for their services. Alternatively, PMC could adjust the provision to award a productivity bonus to a physician based on services he or she personally performed.

IV. Implications and Plan of Action

A. Legal and business implications of due diligence findings and their impact on the transaction with Caring

The due diligence findings may have a significant impact on Pearson's transaction with Caring because they will shape the structure, price, and willingness to reach a final deal. Also, the due diligence findings may cause the transaction to be delayed or cancelled as Caring uncovers risks and violations associated with Pearson. Generally, the due diligence process exists in order for the seller to better understand a target's business before concluding the transaction. For example, if due diligence findings affect the value of the company, then the purchaser will adjust the purchase price. In addition, this process allows the seller to evaluate and identify risks while planning for the post-deal integration and operation of the organization to avoid liability for violations. Here, Caring has identified several due diligence findings that will impact the final deal.

Caring will most likely require Pearson to resolve any actual and potential Stark Law violations because liability may be transferred to the buyer, Caring. Pearson should submit the

SRDP under CMS, which can reduce the penalties associated with Medicare overpayments for Stark Law violations and potential lawsuits brought under the FCA for double billing.[67] Since CMS may expedite disclosures when the transaction's closing is dependent on Pearson's settlement with the government, Pearson has an incentive to make SRDP disclosures. While disclosure comes with its own set of risks, disclosing violations to CMS is preferable over the substantial penalties of a future FCA case. Stark is a strict liability statute that does not require intent and the government considers healthcare fraud an enforcement priority so penalties can rise to thousands and even millions of dollars. Caring may also require voluntary disclosures of FCA violations under the Fraud Enforcement and Recovery Act ("FERA") to disclose overpayments where there is an improper retention of overpayment of federal funds.

B. Types of modifications to the LOI expected from Caring

The effects of due diligence have the potential to ripple throughout an entire transaction. Recent mergers within the healthcare field have experienced this ripple effect and have seen them taint the business and cultural relationship between the recently married organizations. For example, in 2014, Tennessee-based Community Health Systems ("CHS") acquired Health Management Associates based in Naples, Florida for $3.9 billion in cash and took on $3.7 billion in debt. In addition to the debt load, CHS was faced with several government investigations into Health Management's practices, specifically how they admitted patients from the emergency department. As of mid-2016, CHS was still struggling to dissolve the high debt load and government inquiries that came with CHS' acquisition of the hospital system. Thus, as applied here, the results of Pearson's due diligence will most likely force Caring to negotiate for

[67] *Self-Referral Disclosure Protocol*, Centers for Medicare & Medicaid Services. *Available at:* http://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html. (Last visited Feb. 17, 2017).

provisions that will limit their liability in the event that Pearson cannot resolve the issues that arose during due diligence.

First, Caring will likely propose to extend the closing date of the transaction in order to ensure that Pearson has an opportunity to bring itself into compliance with the law. Caring will likely ask for a few more months, but an official date can be confirmed later. Second, Caring will desire to change the provisions related to representations and warranties, indemnification, and dispute resolution. Typically, after organizations exchange due diligence documents, buyers look to implement a "No Undisclosed Liabilities" representation and a "Compliance with the Law" representation because both are written to be favorable to the buyer. The latter representation usually applies to a specific period of time, but this is not a requirement.

With regard to indemnification, Caring might want to implement provisions such as sandbagging, indemnification caps, or survival periods. Pro-sandbagging terms require one party's representations and warranties to be accurate, despite whether the party looking for indemnification knows of the accuracy. These provisions typically protect buyers from being prevented to recover due to constructive knowledge of issues hidden within due diligence. The counter to such a provision is an anti-sandbagging provision, which provides that a party's knowledge of another party's breach or inaccuracy bars its indemnity claim. Lastly, parties may want to put caps on their indemnification combined with survival periods for representations, depending on the risk of the transaction. Sellers typically want indemnification caps or deductibles for future losses. Buyers will counter by limiting the caps and deductibles or applying them only to certain representations and warranties and limiting claims to certain time periods, known as survival periods. In addition, there is a trend toward using alternative dispute resolution, specifically binding arbitration, for parties seeking to resolve claims without significant expense.

Overall, Pearson should expect Caring to request terms that allow it to cap its liabilities while giving it a generous survival period during which it can make claims against Pearson for any potential liabilities resulting from the due diligence findings. Further, with the publishing of the Yates Memo in 2015, the Department of Justice has shifted its efforts towards holding individuals within corporations liable for corporate misdeeds. As such, Caring might demand that Pearson look for individuals within the hospital system, physicians, managers, and the like, to hold them accountable for the oversight or mismanagement of funds, contracts, and internal maintenance, if they resulted in violations of the law.

C. Recommended Plan of Action

As mentioned previously, potential Stark Law violations should be disclosed to CMS using the Voluntary SRDP; whereas, potential violations of the AKS or a combination of the AKS and the Stark Law should be disclosed to the OIG using the Provider SDP. Here, Pearson has an incentive to self-disclose the compensation tied to profitability as well as the double billing violations because both violations will likely result in significant penalties, but may be reduced if Pearson self-discloses.

Pearson should conduct a thorough investigation of the holdover leases to determine the following: (1) whether the original lease contained a holdover provision, (2) whether the original lease met the conditions of the office space stark law exception, (3) whether the holdover lease arrangement is on the same terms and conditions as the previous lease, and (4) whether the holdover lease continues to satisfy the exception. If Pearson determines that it is able to satisfy these criteria, this leasing arrangement will not expose the system to Stark Law liability.

With regard to the unsigned lease, Pearson should obtain all necessary signatures in order to avoid potential liability ensure that it satisfies the space rental Stark Law exception by providing contemporaneous documents supporting the arrangement within ninety days.

Pearson should stop providing rental space to the physician groups, especially to the one experiencing financial difficulty, if payments are not being collected pursuant to the written leases. In addition, Pearson should conduct a thorough investigation of the two medical groups the CEO indicated need not pay in order to determine whether any AKS or Stark violations exist in these agreements. Pearson may need to consider self-disclosure if any violations are uncovered. Pearson should also conduct a thorough investigation of the research fund and assess the FMV of the principal investigator's services provided in the study in order to ensure that the funds did not exceed FMV. Regarding research billing compliance, Pearson should implement a standard process to coordinate relevant study information and identify which research trials are covered by research funds in order to decrease the risk of false claims and double billing.

With regard to the patient steering to a home health agency, we recommend that Pearson conduct a more thorough review of the financial relationship between PMA and PMC in order to more accurately determine the potential for risk exposure. In the meantime, Pearson should establish a conflict of interest process in accordance with the requirements outlined in Stark.[68] These requirements mandate that the hospital have procedures to require a physician owner to disclose to the patient any ownership interest that the treating physician has, either in the hospital or another entity.[69] This disclosure must be made within enough time for the patient to make a "meaningful decision" about where to receive care.[70] Thus, Pearson must work to implement a policy that requires discharge planners to disclose to patients that a physician at the hospital owns that specific home health agency. Further, the Compliance Office should investigate into who reported this issue and assure him or her that it is being handled appropriately so as to limit the possibility that the individual reports the hospital to the government and brings Qui Tam suit

[68] 42 U.S.C. § 1395nn(i)(C).
[69] § 1395(i)(C)(iii)
[70] *Id*.

against the hospital. Lastly, the compensation arrangement for oncologists at PMA would fall into the bona fide employment safe harbor of AKS; however, because the physician compensation is tied to profitability and could result in Stark Liability we recommend self-disclosure.

Conclusion

In conclusion, Pearson should take appropriate action to address the issues uncovered by the due diligence findings. Pearson should take proactive steps to resolve instances of noncompliance including self-disclosure where appropriate to minimize risk of prosecution and severe penalties. Caring will likely require Pearson to take additional steps to resolve existing instances of noncompliance, demand that Pearson proactively address past and present instances of fraud and abuse, and insist upon the introduction of language in the LOI that limits Caring's assumption of liability. Pearson should have an open dialogue with Caring to ensure that the goals of both entities are properly aligned prior to the consummation of the transaction.