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Pearson: Stuck Between a Rock and a Stark Place

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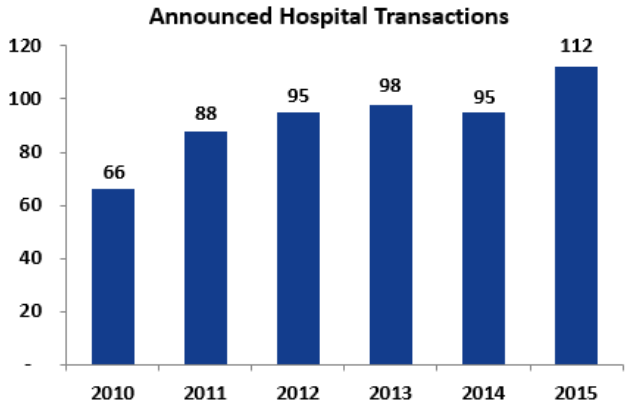
I. INTRODUCTION

Hospital consolidation has been on the rise since the 2010 implementation of the Affordable Care Act (ACA).[1] As patients transition to high deductible health plans, they now prioritize hospitals and health systems that provide ease of access, low cost, high quality care.[2] Coupled with the pressure on Medicare and Medicaid budgets, hospitals and health systems face increasing pressure to reduce costs, manage care more efficiently, and improve patient engagement and experience.

To achieve these goals, hospitals and health systems have pursued strategic partnerships to achieve clinical alignment, network breadth and depth, operational efficiency, and other critical capabilities. The rising number of transactions demonstrate mergers and acquisitions as an increasingly viable strategy as hospitals seek to provide coordinated, cost-effective care across the spectrum.[3] Furthermore, the regulatory climate demonstrates increased government enforcement and closer scrutiny of arrangements between physicians and hospitals.



Note: Includes reported combinations of acute-care hospitals in the U.S., including mergers, acquisitions, joint ventures, and member substitutions.

Source: Kaufman, Hall & Associates, LLC

Pearson, an urban non-profit, tax-exempt health system, is the sole member of a 500-bed tertiary level hospital (PMC) and a 150-bed rehabilitation and skilled nursing facility (PSNF).

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[1] Ellen Jean Hirst, *Hospital Mergers Continued to Create Larger Systems in 2014,* CHICAGO TRIBUNE, (February 10, 2015), http://www.chicagotribune.com/business/ct-hospital-mergers-0211-biz-20150210-story.html (The Affordable Care Act requires hospitals to transition from a traditional fee-for-service model to one that rewards hospitals for good outcomes).

[2] *Id.*

[3] *Hospital Merger and Acquisition Up Sharply in 2015, According to Kaufman Hall Analysis,* KAUFMAN HALL, https://www.kaufmanhall.com/software/news-detail/m_a-hospital-merger-and-acquisition-activity-up-sharply-in-2015-according-to-kaufman-hall-analysis (last accessed Feb. 17, 2017).

PMC is one of five hospitals serving Beazley and its surrounding area, where 150 physicians are employed by Pearson through Pearson Medical Associates (PMA), a wholly-owned, non-profit, tax-exempt subsidiary of Pearson. In addition, Pearson has an academic affiliation with Magis Medical School (Magis), where most PMA physicians have faculty appointments.

PMC's reputation is a distant second or third compared to other hospitals in the Beazley area. With its dated facilities, high debt load ($400 million), and failure to develop an integrated delivery model with its doctors, PMC's costs are much higher and its quality of care is lower compared to competing hospitals. With a shrinking market share, inability to tap into the younger, more affluent population, and high leadership turn-over, Pearson has found itself financially devastated. As a potential solution, Pearson has reached a Letter of Intent (LOI) with Caring Health System (CHS), the clear market leader. Prior to close, CHS has identified potential compliance issues from their Due Diligence Findings, which may undermine the transaction's success.

In this memo, we will first address the legal and business implications associated with CHS's Due Diligence findings. We will then discuss the impact the Due Diligence Findings may have on Pearson's transaction with Caring, and anticipate the types of modifications CHS will bring to the LOI while providing potential solutions for Pearson to best counter those demands.

II. LEGAL IMPLICATIONS OF THE DUE DILIGENCE FINDINGS

A. Legal Implications Defined

There are three primary regulatory schemes controlling suspect practices in health care. They are the Stark Law, the Anti-kickback statute, and the False Claims Act. These laws broadly limit the nature and structure of financial and referral relationships physicians and other health

care entities may have with each other. They each affect referrals and claims for medical services under the umbrella of a federal health care program, such as Medicare and Medicaid.

i. The Stark Law Defined

The Stark Laws are a set of United States federal laws prohibiting physicians from referring Medicare or Medicaid patients to an entity providing designated health services if the physician has a financial relationship with that entity.[4] If a relationship regulated by Stark does not qualify for an exception, then the relationship violates Stark and is *per se* illegal. However, such exceptions require compliance with certain terms that can be difficult to define.

Since Stark Law is a strict liability statute, a plaintiff does not need to show a hospital or physician intended to violate the law, or even had knowledge a violation was occurring. Even an inadvertent, technical violation is a violation of Stark Law. Consequences may include substantial civil monetary penalties, exclusion from participation in Medicare, and False Claims Act liability.

ii. Anti-Kickback Statute Defined.

The Anti-Kickback Statute (AKS) is broader than Stark and is a criminal statute applicable to referrals for items or services payable by any federal healthcare program. The federal AKS prohibits anyone from soliciting, receiving, offering or paying, directly or indirectly, any remuneration in return for a referral or an order of an item or service that may be paid for by any federal healthcare program (including Medicare and Medicaid). For purposes of the AKS, remuneration includes the transfer of anything of value, directly, overtly or covertly.

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[4] *Physician Self Referral*, (January 5, 2015), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/ (Section 1877 of the Social Security Act, codified as the Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn and implementing regulations 42 C.F.R. §§ 411.351 *et seq.*).

Importantly, for AKS, a "knowing and willful"[5] violation must be shown. For example, even if there are legitimate purposes for the payment, it is an AKS violation if one such purpose is to induce referrals. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to exclusion from Federal health care programs.

iii. False Claims Act Defined

Stark and AKS violations renders all related claims false or fraudulent overpayments, thus giving rise to False Claims Act (FCA) violations. The FCA permits a qui tam plaintiff with knowledge of fraud to file a lawsuit on behalf of the Government against the person or business that committed the fraud. Such plaintiffs have significant motivation for prosecution because they can receive up to one-fourth of the government's recovery as a reward for alerting the government to the false claims. Violations of Stark Law and the AKS may give rise to actions under the FCA, although it is not strictly a health care statute. Violations of the FCA are punishable by up to treble damages and an $11,000 per-claim penalty.[6]

B. Due Diligence Legal Analysis and Basic Remedial Measures:

i. Leases

Several problematic leases between PMC and its physician tenants have been identified. Since PMC is a landlord that furnishes designated health care services, these leases pose potential compliance issues in both the Stark Law and AKS. Before we begin a more granular analysis, it is important to note that lease agreements are viewed with suspicion under those laws

[5] Robert G. Homchick, *Federal Anti-Kickback Statute Primer,* https://www.healthlawyers.org/events/programs/materials/documents/fc12/101_homchick_williams.pdf, (In 1980, Congress amended the anti-kickback statute to add this requirement that defendant's requirement be "knowing and willful").
[6] 31 U.S.C. § 3729(a)(1).

unless they fit into a Stark Law exception or AKS safe harbor. Due to the significant amount of parallel terminology between the two laws, we will discuss both statutes together.

The Stark Law is built around the "financial relationship," which is defined as an arrangement between an entity furnishing designated health services and a referring physician or referring physician organization. Leases between physicians, physician organizations, hospitals, and other health care providers who furnish items or services payable by Medicaid or Medicare are financial relationships.[7] If such a financial relationship exists between a hospital and a physician who refers Medicare patients to the hospital, the arrangement must be structured in a specific way such that it meets a statutorily designated exception. The most relevant Stark Law exception specifically refers to the rental of office space and equipment, as promulgated under 42 USC section 1395nn(e). So long as all the relevant requirements under this exception are met, PMC will be compliant with the Stark Law.

The AKS framework similarly includes its own exceptions, or "safe harbors" that can protect office space rental agreements. Arrangements outside the AKS safe harbors are not per se violations – failure to satisfy the safe harbor will not in and of itself result in an AKS violation if the requisite intent to violate the statute is not present. However, lease arrangements that do not meet fair market value, commercial reasonableness, and/or the value of the volume standards are considered highly suspect by the government. It is in Pearson's best interest to provide evidence of the propriety of their agreements.

Table 1- Leases under Stark Law vs. AKS (Exceptions shortened for simplicity)

Stark—Lease for Space Exception	AKS—Office Space Safe Harbor
1. The lease is set out in a signed writing that specifies the covered premises.	1. The lease is set out in writing and signed by the parties.

[7] USLEGAL, *Financial Relationship under the Stark Act*, https://starklaws.uslegal.com/financial-relationship-under-the-stark-act/ (last visited Feb. 17, 2017).

2. The duration of the is at least one year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement during the first year of the original lease arrangement.	2. The lease covers all the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.
3. The leased space does not exceed that which is reasonable and necessary for the legitimate business purpose of the lease and is exclusively used by the lessee when being used by the lessee.	3. If the lease is intended to provide the lessee with access to the premises for periodic intervals of times, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and exact rent for such intervals.
4. The rental charges are set in advance and are consistent with FMV.	4. The term of the lease is not for less than one year.
5. The rental charges over the term of the lease arrangement are not determined: (i) in a manner that considers the volume or value of any referrals or other business generated between the parties, or (ii) based on a percentage of revenue generated in the space or on per-unit of service rental charges, to the extent such charges reflect services to patients referred by the lessor.	5. The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that considers the volume or value of any referrals or business otherwise generated between the parties for which payment made be made, in whole or in part, under Medicare, Medicaid, or other federal health care programs.
6. The lease agreement would be commercially reasonable even if no referrals were made between the parties.	6. The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.
7. A holdover rental is permissible indefinitely immediately following the expiration of a compliant agreement, if the lease arrangement previously met conditions (1) through (6) above, the holdover rental is on the same terms and conditions as the immediately preceding lease arrangement, and the holdover lease arrangement continues to meet conditions (1) through (6) above.	

Furthermore, the Stark exception and AKS safe harbors contain three interrelated concepts that are essential to determining whether an arrangement is compliant: whether it is

valued at fair market value (FMV), whether it is commercially reasonable in the absence of referrals, and whether the arrangement considers the volume or value of referrals.

a. Fair Market Value (FMV)

Within the Stark Law, FMV is defined as "the value of rental property for general commercial purposes (not considering its intended use).[8] This value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.[9]

For purposes of the AKS, the Office of the Inspector General's (OIG) FMV assessments do not contemplate traditional or common methods of economic valuation. Mere willingness of another buyer to pay a particular price is not sufficient to render the price paid to be FMV; rather, they utilize the Internal Revenue Service's FMV definition: "the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts."[10]

b. Commercial Reasonableness

Under the Stark Law, an arrangement is commercially reasonable if the arrangement is a sensible, prudent business arrangement from the perspective of both parties. This extends even in the absence of referrals. [11]

Under the AKS, however, CMS has stated that in analyzing rental agreements, it scrutinizes whether a rental agreement is appropriate at all and whether the time and space

[8] 42 C.F.R. § 411.351.
[9] *Id.*
[10] 26 C.F.R. § 20.2031-1(b).
[11] Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16093 (Mar. 26, 2004).

considerations are reasonable and necessary for the proposed use.[12] The OIG has stated that to avoid AKS liability, arrangements should be reasonable and necessary in the absence of other purchases or referrals. Recent advisory opinions have stated that in analyzing for violations, the OIG looks for "indicia that the rate is not commercially reasonable in the absence of other, non-discounted business."[13]

Unfortunately, there are several problematic leasing agreements uncovered by the Due Diligence findings that violate certain provisions of both Stark and the AKS.

1. Holdover Leases

The Stark Law's regulations regarding the rental exception provide that immediately upon the termination of an existing lease agreement of at least one year, a holdover is permitted indefinitely, so long as (1) the lease was previously valid under the Stark Law, (2) the holdover lease is on the same terms and conditions as the preceding lease, and (3) the holdover lease continues to otherwise be valid under the Stark Law.[14]

Unfortunately, we simply do not know whether the holdover leases were or continue to be valid under the Stark Law lease exception, or whether the original agreements lasted for a year or more. If any of the holdover leases do not meet all three conditions, then they would be in violation of the Stark Law.

2. No Signed Lease

The due diligence findings revealed an unsigned lease where the tenant has been making payments. Both the Stark Law and AKS require leases to be both in writing and signed by the

[12] OIG Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, 65 Fed. Reg. 9276 (Feb. 24, 2000).
[13] OIG Adv. Op. 12-09 (July 23, 2012), at 6, *available at* www.oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-09.pdf.
[14] 42 CFR 411.357(a)(7).

parties. The unsigned lease thus definitely violates the Stark Law. A conviction under the AKS still hinges on the intent requirement being met, so is uncertain.

3. Lease with Stopped Payments

Three leases have stopped payment. One tenant has stopped payments on the lease due to financial difficulty. Two leases have stopped payment with written permission by a former CEO.

There is no direct regulatory violation with the first lease involving financial difficulty on the part of the tenant. A potential violation could arise if PMC does not act and continues to allow the tenant to forego paying. PMC should take steps to secure payment to avoid being placed into a position where the tenants can claim reliance on PMC's decision not to collect.

The other two leases do pose compliance issues, however. It is highly unlikely that a lease agreement between PMC and a physician tenant requiring no payment would satisfy the FMV provision of the Anti-kickback statute. Such an arrangement would not satisfy the FMV requirement without extenuating circumstances that we are simply not privy to now.

Further, even if a lease agreement appears to comply with the applicable AKS safe harbor and Stark exception, clear improper intent may be sufficient for courts to impose liability. In *United States v. Goss*, a court found a physician liable for violating the AKS even though the physician complied with the safe harbor. There, the government was able to show the physician understood the rental payments were in exchange for patient referrals.[15] The note left by the former CEO excusing payment from two tenants establishes intent on the part of PMC, and thus likely establishes an AKS violation.

[15] United States v. Goss, 96 Fed. Appx. 365 (6th Cir. 2004).

ii. Preparing for the Worst: Fair Market Value

It is of upmost importance for Pearson to strictly comply with the technical terms of the safe harbor and exception. For the matters that are harder to determine, we strongly advise Pearson to carefully document all efforts to meet the statutory requirements. It is recommended that Pearson be proactive in evaluating any financial relationships with its physicians.

Health care valuations of FMV are unlike typical real estate valuations. Pearson should be aware it may ultimately bear the burden of proof to establish that they have complied with the Stark and AKS exceptions. Due to the unusually esoteric nature of FMV in the health care lease agreement context, we strongly advise independent evaluations of all suspect lease agreements. It is crucial to hire someone who will be sensitive to health regulatory issues.[16] Pearson will ultimately be responsible if a court determines the report to be flawed or inadequate. The table below offers several options to address PMC's inadequate contract-management system:

Table 2- Lease Practices

Suggested Compliance Practices for Office-Space Leases			
Subject	Best Action	Advantages	Challenges
Fair market value/commercial reasonableness	Hiring an outside valuation firm	• Independent firm reassures the Government[17] • More experience and expertise in making an objective valuation • May help to avoid unrealistic expectations • Spot issues to help parties arrive at workable terms	• Larger upfront costs that may outweigh benefits, especially for low-priced agreements • No guarantee that a 3rd party valuation will prevent liability • Results from a 3rd party can take longer than an internal process

[16] Courts are comfortable with rejecting expert fair market valuations on their own if they decide an important factor was left out of the expert appraiser's analysis. *See* United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr., 202 F. Supp. 2d 671, 674 (E.D. Mich. 2002) (ruling in favor of defendant physicians because government's claim that lease payments were above market value were substantiated by a FMV appraisal that did not take into account a more restrictive market area).

[17] Courts have found thorough valuations of both lease and compensation arrangements as persuasive evidence of FMV as against a less through valuation of a government expert witness. *See* US ex rel. Goodstein v. McLaren Med Center 202 F.Supp.2d 671 (2002); US ex rel. Villafane v. Solinger 543 F.Supp.2d 678 (2008).

Contract management	Using an updated software system to implement database	• Centralized contract approval process • Incorporate checklist to verify elements of compliant lease	• Costs of software licensing agreement • Can be seen as an overly formal and lengthy process for a great deal of contracts • Requires constant oversight and updates
Renew contracts	"Evergreen clauses"	• Allows an agreement to automatically renew for a predetermined length of time after the initial term is complete • Ensures provisions comply with Stark exception and that agreement will not inadvertently expire	• FMV/commercial reasonableness needs to be reevaluated periodically

iii. Tax-Exempt Status

PMC's status as a tax-exempt entity following the Due Diligence findings may be jeopardized due to the leasing agreements. Since Pearson, as a tax-exempt entity, is leasing space to physician tenants, it should ensure compliance with tax laws. Here, it is unclear as to whether the physicians are independent or employees. If any of the leases involve for-profit providers, Pearson should consider situations that may threaten their status: (1) whether the leasing arrangement would result in private inurement to the landlord or tenant; (2) whether the leasing arrangement would extend a private benefit to the landlord or tenant; (3) if the leased space is financed with tax-exempt bond proceeds; and (4) whether the leasing arrangement will affect a property tax exemption. Nonprofit, tax-exempt entities need to avoid private benefit; that is, the entity needs to operate exclusively for exempt purposes.[18]

[18] Centers for Medicare & Medicaid Services, Medicare Program; Reporting & Returning of Overpayments, 77 Fed. Reg. 9179 (Feb. 16, 2012) (proposed rule), available at www.gpo.gov/fdsys/pkg/FR-2012-02-16/pdf/2012-3642.pdf.

iv. Clinical Trials Contracts

a. Remittance discrepancy between CY2014 and CY2015

In 200 of the clinical trials taking place at Pearson, study funds are initially held by Magis and are later paid to Pearson for study-related clinical services. In Calendar Year (CY) 2014, approximately $18 million in such research funds were paid from Magis to Pearson for research-related clinical services. In CY2015, Magis transferred only $500,000. This represents more than a 97% decrease in remittance between CY2014 and CY2015.

At the outset, we strongly advise further investigation and due diligence into the clinical trial agreements between Pearson and Magis. It would be prudent to ensure there was no change in the express language of the agreements explaining the payment drop between CY2014 and CY2015. We should also rule out the possibility that the agreements between Pearson and Magis did not include a front-loaded payment arrangement that accounts for the year over year discrepancy. Further, it should be investigated whether there was an error on Pearson's end that resulted in fewer payments coming from Magis.

After that investigation, if it is found that the reduction in remittance in CY2015 is not supported by the terms of the research agreements between Magis and Pearson, then we advise treating the situation as a breach of contract and taking incremental steps towards resolving the underpayments in that context. The first step will be to openly approach Magis about the issue and work amicably with them to resolve the underpayments. A full financial audit and investigation should be conducted to ascertain the root cause of the missed payments. If it is at all possible, we should attempt to recover any owed payments in this fashion.

If Magis decides to not cooperate, then it would be advisable to set up formal negotiations between Magis and Pearson with legal counsel present and the threat of litigation in

the background. At this stage, the goal remains to recover missing funds cooperatively and amicably, but with a heightened sense of urgency with litigation being on the table. We should continue to attempt to avoid litigation at all reasonable cost to maintain a positive relationship with Magis.

Should negotiations fail, we recommend litigation as a last resort. Litigation could potentially push the issue to the public sphere and put pressure on Pearson's acquisition by CHS. There is also the possibility that recovery will be mitigated by affirmative defenses by Magis during litigation and legal fees. Litigation is a nuclear option that is only on the table because of the sheer volume of money at stake.

b. Clinical Research Billing

1. Regulatory Compliance Issues

A February 2015 internal audit report revealed that across ten studies with 32 enrolled patients, PMA failed to notify PMC's billing department that a given patient was enrolled in a research study 26 times. The report speculated that medical services rendered to those 26 patients may have been improperly billed to the patients' insurers when they should have been paid for with study funds. This issue poses a serious regulatory liability. The False Claims Act (FCA) states that any person who, among other things,

> "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim…[,]

…is liable to the United States Government."[19] The penalties associated with a FCA violation, as mentioned earlier in this memo, can be severe.

For Pearson to be liable under the FCA, a plaintiff must prove three elements: (1) a false or fraudulent claim; that was (2) presented, or caused to be presented by the defendant to the federal government for payment or approval; (3) with knowledge that the claim was false. It is self-evident that claims submitted to Medicare, Medicaid, or any other federal health care payer that should have been paid by another source is a false claim. Thus elements (1) and (2) are met.

Proving element (3), that the defendant had knowledge the claim was false, is slightly more tenuous. Ultimately, Pearson will likely fail to show this was not the case. Under the FCA, the terms "knowing" and "knowingly" mean that the person had actual knowledge of the information or acted in deliberate ignorance of the truth or falsity of the information; the act also makes illegal acting in reckless disregard of the truth or falsity of the information.[20] Further, the Act does not require proof of a specific intent to defraud.[21] The 2015 internal audit report explicitly criticized PMA for having a poor mechanism for identifying clinical study patients to PMC for billing purposes, and further identified that there was no process between PMC and Magis to reconcile their list of research patients. The existence of this report places Pearson on notice of the issue, and so an allegation that Pearson acted recklessly in submitting false claims would likely succeed at trial.

2. Recommended Remedial Measures

It is crucial to take steps to correct these billing issues, both from a regulatory compliance perspective, and from a fiscal perspective. There are two levels to the issues revealed in the 2015

[19] 31 U.S.C. § 3729(a)(1)(A)(B).
[20] 31 U.S.C. § 3729(b)(1)(A).
[21] 31 U.S.C. § 3729(b)(1)(B).

internal audit report. The first is the poor mechanism for notifying the PMC billing system that a patient is enrolled in a clinic. The second is the lack of a process for PMC and Magis to reconcile their lists of research patients. While we currently have limited information of the internal processes at Magis, PMA, and PMC, steps should be taken to limit further liability and to show that affirmative steps are being taken to resolve these issues.

Correcting PMA's research patient notification mechanism may be simple, depending on the current state of PMC's billing process. Given the information at hand, PMC's billing department is likely properly trained to process billing for research patients. Thus, the issue lies in their being unable to identify the correct payer. If the issue is truly contained to where PMA's research staff as opposed to PMC's billing staff, then several low-disruption steps can be taken to fix the issue. As examples, a new process that separately or conspicuously schedules patients for study visits combined with either a separate payer classification within the billing system for study payers, or a unique superbill for exclusive use with study patients would have relatively low implementation costs. More drastic steps, such as having a separate billing team exclusively handle study patients, can add an extra measure of accountability to the process. With a more practical look at PMC's current billing infrastructure, we can provide more meaningful suggestions and feedback.

We lack sufficient information to give detailed suggestions on the second issue regarding study patient lists across Magis and Pearson. Given the information we do have, a potential solution could be to simply integrate the list between PMC and Magis, so that the list is kept and maintained by one party and merely accessed by the other. This should even cut overall costs between the two parties. Given the close partnership Magis and Pearson already have, it should be possible to negotiate a cost-sharing and access agreement. It is likely more practical to assign

PMC the responsibility to maintain a research patient database, since it can possibly be piggybacked on top of its billing and medical records databases. The practice management solution in use by PMC likely already has utilizable infrastructure already in place to meet the needs of both Magis and Pearson.

v. Home Health Agency Conflict of Interest

A physician employed by Pearson via PMA owns a home health agency (HHA). On a list of HHAs distributed to discharged patients by the hospital, the only HHA listed within the Beazley metropolitan area is the one belonging to the PMA physician. This conflict of interest poses a likely regulatory violation under the Stark Law.

Stark Law prohibits physicians from referring Medicare and Medicaid patients to business entities for designated health services (DHS) in which the physicians or their immediate family members have a financial interest. DHS are defined by statute, and, among other items, specifically includes home health services.[22] A financial interest is defined within the Stark Law as an ownership or investment interest, through debt, equity, or other means.[23] The physician at issue owns a home health agency independently of Pearson. This is a clear financial interest for the purposes of Stark Law.

Referrals are defined within the statute as "the request or establishment of a plan of care by a physician which includes the provision of...designated health services."[24] Patients are unable to access home health services under Medicare without multiple certifications of necessity from a doctor.[25] Thus PMC's distribution of this selective list is effectively a referral for the purposes

[22] 42 U.S.C. § 1395nn(h)(6).
[23] 42 U.S.C. § 1395nn(a)(1).
[24] 42 U.S.C. § 1395nn(h)(5)(B).
[25] To be eligible for Medicare home health services, a beneficiary patient must be, inter alia, under the care of a physician, receive services under a plan of care established and reviewed by a physician, and have had a face-to-face

of the Stark Law.[26]

Assuming facts most favorable to Pearson (that the physician did not arrange the steering practice and that the list did not intentionally only include that physician's home health agency within Beazley), there is likely a Stark violation. This is because, the Stark Act is a strict liability statute. Even if an improper referral relationship forms purely by happenstance, a violation still exists. Thus, Pearson is directly implicated as violating the Stark Law's prohibition on improper referrals. The core violating act is in executing an employment contract with the physician at issue while the hospital steered patients to the physician's HHA. Even if we assume Pearson did not intentionally create this conflict of interest, the only material fact is that the improper referral arrangement exists, and Pearson allowed the employment of the physician and the referral steering to the physician's HHA to exist simultaneously.

a. Remedial Measures

It is crucial for Pearson to immediately stop handing out the current list to patients. If the hospital is going to recommend HHAs within the Beazley metropolitan area, the list cannot contain the PMA physician's HHA. It may be necessary for the physician to divest his ownership interest in the HHA to maintain a full-time employee relationship with PMA. The Stark statute and regulations are silent on whether the physician's HHA can be featured on the referral sheet if competitors are fairly featured on it as well.[27] If the physician's HHA is the only HHA in the

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encounter with a physician. *See* 42 U.S.C. § 1395f(a)(2)(C) & 42 U.S.C. § 1395n(a)(2)(A); Hillary Loeffler, Crystal Simpson, *Certifying Patients for the Medicare Home Health Benefit*, CENTER FOR MEDICARE, CHRONIC CARE POLICY GROUP 10 (2015), https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2014-12-16-HHBenefit-HL.pdf.

[26] We assume that patients are not given the list of home health agencies without having a need for home health services.

[27] There is an additional argument that CMS's position regarding referrals would consider a patient going to the physician's HHA even without steering a Stark violation. *Cf.* Jeffrey S. Baird, *What Does Referral Mean Under Stark?*, MEDTRADE (Dec. 5, 2016) (proposing that Stark Law's referral definition is vague enough that a violation can occur even if a physician did not direct their patient to an entity in which they have a financial interest, and

Beazley metropolitan area, a geographic necessity argument could be made during litigation. However, no such exception is explicitly laid out for urban areas, so there would be significant risk involved in doing so.

b. Compensation Arrangements Scaling with Profitability of Services

A component of the Physician compensation for oncologists employed by PMA relates to the profitability of the hospital service. This constitutes a financial relationship between the PMA and the oncologists for purposes of the Stark Law, which substantially impacts the form and structure physician compensation arrangements may take.

1. Stark Law

As previously mentioned, the Stark Law prohibits physicians from referring Medicare and Medicaid patients to business entities in which the physicians or their immediate family members have a financial interest. The statute contains a list of DHS which includes, inter alia, inpatient and outpatient hospital services.[28] It is a fair assumption that most, if not all, services performed by the PMA oncologists fall under that category.

In addition to what was mentioned in the preceding section, a financial interest under the Stark Law can also be a compensation arrangement, which is broadly defined as "any arrangement involving any remuneration between a physician...and an entity."[29] Remuneration includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind."[30]

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patient goes there on their own volition), http://www.medtrade.com/news/general-healthcare/What-Does-Referral-Mean-Under-Stark-3219.shtml.
[28] 42 U.S.C. § 1395nn(a)(1)(K).
[29] 42 U.S.C. § 1395nn(h)(1)(A).
[30] 42 U.S.C. § 1395nn(h)(1)(B).

The key issue is that the compensation agreement between the hospital and the oncologists scales with the financial performance of some aspect of the hospital's DHS.[31] While the Stark Law does allow for arrangements such as this in group physician practices, it specifically excludes hospitals in that carve-out.[32] If the arrangement does qualify as a financial interest in the hospital, then there is likely a Stark violation.

Stark Law does set forth several exceptions to its prohibitions on referrals. The most relevant exception requires that physicians and hospitals be in a "bona fide employment exception." This exception provides that amounts paid by an employer to a physician will not be considered a compensation arrangement for purposes of the Stark Law if:

> (A) the employment is for identifiable services;
>
> (B) the amount of remuneration under the employment
>
> > (i) is consistent with the fair market value for services performed;
> >
> > (ii) is not determined in a manner that considers the volume or value of referrals by the referring physician to the hospital; [and]
>
> (C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer.[33]

Barring something out of the ordinary that was not disclosed in the due diligence thus far, there should not be Stark Law issues with requirements (A) or (C). Assuming the oncologists' responsibilities are straightforward and typical for their positions, and their billing relatively

[31] The facts stated are ambiguous, but for purposes of this memo we assume it involves the profitability of oncology services.
[32] 42 C.F.R § 411.352(a).
[33] 42 U.S.C. § 1395nn(e)(2) (subsection (D) omitted).

clean, there should not be an issue with their compensation being for "identifiable services. Requirement (C) is self-explanatory, and like the FMV requirement, will require expert testimony and documentation to be defended in court.

The FMV requirement merits a closer look. FMV under the Stark Law means the value of the services in arm's length transactions, based on comparable service agreements, where compensation has not taken into account the volume or value of any future referrals or any actual referrals. Compensation can only be based on the value of the physicians' services. All sources of compensation are relevant (e.g., number of hours worked, research, nature and complexity of the services provided, the prevailing rate for comparable types of professionals performing comparable services, how often the physicians are on-call, etc.). For the purposes of defending against a potential regulatory violation, the burden of showing FMV initially sits with the plaintiff, who must make an evidentiary showing of a violation. After that, the burden shifts to the defendant to counter the allegation. It will be important to have expert testimony and documentation available to affirmatively show that the compensation was at fair market value. While it is unclear exactly how the oncologists' scaling compensation package was arranged, if it is based on referrals at all, there may be a violation. More information is necessary before further legal advice can be given on this matter.

The third requirement, that the compensation cannot take into account the volume or value of referrals by the referring physician to the hospital, is likely problematic here. Referrals under the Stark Law are defined as, among other things, "a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated

health service, or the certifying or recertifying of the need for such a designated health service."[34]

In 2013, a federal district court in Florida heard a case with substantially similar facts to the current situation revealed in the due diligence findings.[35] As an important caveat, this case was eventually settled out of court and did not have a final decision on the merits. However, summary judgment rulings made throughout the trial phase are available to the public and give valuable insight to how a federal court in the future may interpret the Stark Law. In *Halifax*, a hospital employed physicians through a staffing entity while those physicians also made referrals of DHS to the hospital.[36] Those physicians were paid a salary, but a component of their compensation arrangement also scaled with the hospital's financial performance. The physicians would receive incentive payments equal to 100 percent of the hospital's gross collections less the amount of their salary and the hospitals' costs for billing and collection.[37]

Despite a spirited defense made by the defendants, the district court ultimately ruled that "for purposes of assessing the applicability of the [bona fide employment] exception, the question is...whether the physicians' compensation varied with the volume or value of referrals."[38] The district court entered summary judgment against the physicians.

Pearson's oncologists have a compensation arrangement similar in all important respects to those of the physicians in the *Halifax* case. While the case did not reach the appellate level and does not possess precedential force, it is still important with regards to how other federal courts may interpret the Stark Law. Thus, we strongly recommend adjusting the oncologists'

[34] 42 C.F.R. 411.351.
[35] U.S. v. Halifax Hosp. Medical Center, WL 68603 1 (M.D. Fla. 2014).
[36] *Id*.
[37] *Id*.
[38] *Id*.

compensation arrangement to avoid any possible regulatory violation with the Stark Law.

2. Anti-Kickback Statute

The AKS, like the Stark Law, seeks to prohibit improper referrals in health care for services paid by federal programs. Unlike the Stark Law, it is a criminal statute that requires improper inducements to be willful and knowingly made. It criminalizes knowingly and willfully offering or paying any remuneration to any person to induce them to refer an individual for the furnishing of any item or service payable in whole in part under a federal health care program.[39]

The AKS is triggered here because Pearson knowingly executed the compensation arrangements with the oncologists containing the scaling provision. However, the AKS contains a bona fide employment exception with different requirements from the Stark Law. Under the AKS, a "'remuneration' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under…federal health care programs."[40] In defining what constitutes a bona fide employer-employee relationship, the AKS relies on a portion of the IRS tax code.[41] The cited portion of the IRS code defines an "employee" as "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee."[42] Under the corresponding federal regulation, an employer-employee relationship exists when the employer "has the right to control and direct the individual who performs the services, …not only as to what shall be done

[39] 42 U.S.C § 1320a-7b(b)(2).
[40] 42 C.F.R. § 1001.952.
[41] *Id.* (referring to 26 U.S.C. 3121(d)(2) of the IRS tax code).
[42] 26 U.S.C. § 3121(d)(2).

but how it shall be done."[43] This bona fide employment definition is significantly less onerous than under the Stark Law.

The PMA oncologists likely fall safely within the bona fide employment exception. Their status as PMA employees likely does not matter, as PMA is a wholly-owned subsidiary of Pearson generally. If argued properly in court, PMA will likely be considered merely an instrumentality of Pearson at large. Further, the oncologists are safely full employees of Pearson who are under its authority and control. Thus, there is likely no AKS violation.

III. IMPACT OF THE DUE DILIGENCE FINDINGS ON THE TRANSACTION

The Due Diligence Findings will be an important tool for both business and legal aspects of negotiating the final deal terms and subsequent definitive agreement. In consideration of these findings, Caring Health System may categorize its potential transaction with Pearson as one of three differing options of valuation: optimistic, pessimistic, and cautious. See table below for general guidance:

Table 3- Options of Valuation

Valuation Options	Definition	Result
Optimistic	Initial assumptions of the buyer have been substantiated. There are no known material issues.	Prospective buyer makes the deal.
Pessimistic	Material issues are identified (i.e., significant legal risks).	Transaction between the two parties is questioned.
Cautious	Small issues are identified (i.e., limited legal risks).	Transaction price may be changed, the cost of the buyer to remove these risks may be compensated for by the seller, or the risks may be removed by the seller.

[43] 26 C.F.F. § 31.3121(d)-1(c)(2).

Here, the transaction between Pearson and CHS is most likely to be viewed as a cautious valuation option. The Due Diligence Findings have identified several clear violations federal law, which expose Pearson to liability and potential sanctions.

A. Path to Closure via Self-Disclosure

Because Stark liability can be transferred to buyers in hospital transactions, sellers are facing growing pressure to resolve actual and potential violations as a condition to closing.[44] With the Fraud Enforcement and Recovery Act (FERA), providers are liable not only for affirmative acts that conceal overpayments, but also for failure to repay an identified overpayment; essentially no attempt to conceal is required.[45] The ACA has further changed the FCA by establishing a sixty-day window within which an identified overpayment must be reported and returned to the government. However, self-disclosure could stop the "ticking of the clock" on the provider's obligation to repay the overpayment.[46]

The biggest incentive to disclose is that it is demanded by the ACA and other statutes.[47] The Medicare Self-Referral Disclosure Protocol (SRDP) was established in 2010 by the ACA to facilitate the resolution of matters that are actual or potential Stark violations.[48] The ACA gave the U.S. Department of Health and Human Services authority to reduce amounts due for actual

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[44] *9 Considerations for Hospitals Evaluating Self-Disclosure of Stark Law Violations*, MCGUIREWOODS LLP (Oct. 14, 2014), https://www.mcguirewoods.com/Client-Resources/Alerts/2014/10/9-Considerations-for-Hospitals-Stark-Law-Violations.aspx.

[45] Jean Wright Veilleux, *Catching Flies with Vinegar: A Critique of the Centers for Medicare and Medicaid Self-Disclosure Program*, 22 HEALTH MATRIX: J. L.-MED. 169, 172 (2012).

[46] *Id.* at 199.

[47] 42 U.S.C. § 1330a-7k(d)(1); see also 42 U.S.C. § 1395nn(g)(2) ("If a person collects any amounts . . . billed in violation of [Stark] . . . , the person shall be liable to the individual for, and shall refund on a timely basis . . . amounts [] collected."); 42 C.F.R. § 411.353(d) (2010) (collecting payments for services provided pursuant to a Stark violation "must refund [payments] on a timely basis"); 31 U.S.C. § 3729(a)(1)(G) (Supp. III 2010) (stating that an entity that "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" is subject to False Claim liability).

[48] CMS Voluntary Self-Referral Disclosure Protocol, OMB Control No. 0938:1106, available at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

or potential Stark violations disclosed via SRDP. Even an organization with a robust compliance program may find that self-disclosure is the best way to return overpayments.[49] Yet, this protocol is new; the SRDP is so punitive and difficult to navigate that very few healthcare providers have made disclosures.[50] Thus, Pearson should be wary – voluntary disclosures may shield them from exclusion from Medicare, Medicaid, and other federal health care programs, but at a high cost.

In assessing whether Pearson may find benefits to self-disclosure, the following case provides valuable insight. In April 2013, the Department of Justice announced a settlement with Intermountain Healthcare after Intermountain submitted a voluntary disclosure of potential violations under Stark that were largely technical in nature. These included similar conduct as in the present case: failure to renew several leases, leasing arrangements with physicians without written or executed lease arrangements, and compensation arrangements with employed physicians that contained bonus structures that may have considered the volume or value of referrals to Intermountain.[51] Notably, the settlement did not include any admission of wrongdoing on Intermountain's part and the Department of Justice did not seek exclusion.[52]

Intermountain's case demonstrates that self-disclosure can result in lowered penalties. Considering Pearson's high debt load, self-disclosure is an attractive option. One hospital which settled for an amount lower than the hospital's counsels' lowest estimates of potential obligations said they were pleased with the amount in light of potential penalties.[53] Other benefits of self-

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[49] Linda A. Baumann and Hillary Stemple, *Staying Compliant: A Roadmap to Self-Disclosure*, AHLA WEEKLY (Dec. 18, 2015), available at https://www.arentfox.com/sites/default/files/20151218AHLAWeekly.pdf
[50] Veilleux, *supra,* note 7 at 183.
[51] *Intermountain Healthcare Settlement of $25.5 Million Stems from Stark Law Violations*, ARENT FOX (Apr. 8, 2013), https://www.arentfox.com/newsroom/alerts/intermountain-healthcare-settlement-255-million-stems-stark-law-violations.
[52] *Id.*
[53] Julie E. Kass et al., *Seven Months Later: An Interactive Dialogue Regarding Initial Experiences and Practical Advice in Dealing with CMS' Self-Referral Disclosure Protocol*, AM. HEALTH LAWYERS ASS'N (Apr. 11,

disclosure include the ability to more fully frame the issues, complete a thorough internal investigation, develop an improved and less-adversarial relationship with law enforcement officials, and demonstrate that the organization is ready and willing to act responsibly.[54]

The possibility of lowered penalty obligations is not dispositive as to Pearson's situation. We caution that self-disclosure can be used against Pearson by qui tam plaintiffs. If Pearson chooses to self-disclose, it will reveal its own information, thus inadvertently providing the means to file suit. This is despite the FCA generally baring private parties from bringing qui tam suits based on public disclosures.[55] However, some courts have found that self-disclosed information by providers does not constitute a public disclosure.[56] Other courts have held that voluntary disclosure precludes an FCA qui tam action.[57]

Furthermore, self-disclosure also involves the risk that the government may inquire deeper into the violations. If the government investigation indicates that the provider limited the scope of the self-disclosure when the provider knew, or should have known, that there were other related issues, the potential liability could increase dramatically.[58] Thus, we recommend that Pearson weigh the risks before deciding to self-disclose.

B. Roadblock: Pearson's Current Financial Situation

CHS will be undoubtedly be concerned with Pearson's financial statements and related financial metrics, and the reasonableness of Pearson's projections of its future performance. CHS may inquire about a more in-depth analysis on Pearson's overall financial statements to obtain a

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2011), https://www.healthlawyers.org/Events/Webinars/RoundtableDiscussions/2011/Pages/SevenMonthsLater.aspx.

[54] AM. HEALTH LAWYERS ASS'N, HEALTHCARE COMPLIANCE LEGAL ISSUES MANUAL 106 (Harry R. Silver & Cynthia F. Wisner eds., 3d ed. 2011).

[55] 31 U.S.C. § 3730(e)(4)(A).

[56] United States *ex rel*. Liotine v. CDW Gov't Inc., No. 05-33-DRH, 2009 WL 3156704, at *7 (S.D.Ill. Sept. 29, 2009) (quoting United States *ex rel*. Mathews v. Bank of Farmington, 166 F.3d 853, 862 (7th Cir. 1999).

[57] United States ex rel. Cosens v. Yale-New Haven Hosp., 233 F. Supp. 2d 319, 327 (D. Conn. 2002).

[58] Baumann & Stemple, *supra*, note 49 at 2.

more accurate examination of its financial performance and condition. Further, as to the high debt load, there may be a question of the current integrity and effectiveness of the Board. CHS may be wary of the extent and quality of Pearson's management skills. CHS may elect to hire an independent forensic accountant or financial auditor to review them.

CHS would also be inclined to initiate a review of Pearson's employee benefit plans to ensure their current and past personnel policies follow federal and state labor laws. Employee turnover may also be reviewed because Pearson, being a large entity, can lead to further liability to CHS if there are a lot of former employees suing for labor law violations. CHS would undoubtedly want to protect themselves from assuming such a liability.

IV. ANTICIPATED MODIFICATIONS TO THE LOI BY CARING HEALTH SYSTEM

A. Terms to be Amended

Pearson and CHS agreed to a non-binding[59] LOI. CHS will likely seek to make modifications to the LOI or seek changes in the definitive agreement. With Pearson's high debt load coupled with its potential federal regulatory violations, CHS likely appreciates that Pearson has significant liabilities. Consequently, we foresee CHS acting in a manner that will protect their own interests and shield themselves from potential future liability arising from their transaction with Pearson. We anticipate the following LOI terms will be subject to modifications:

(1) The Articles of Incorporation and Bylaws of PMC and PSNF will be amended so that all strategic, operational policy and financial decision-making will be reserved to Pearson.

[59] With exceptions to the provisions regarding confidentiality of information, payment of attorneys' fees, no third-party beneficiaries, and choice of law being in the State of Loyola.

(2) Upon closing of the transaction Pearson will get 5 out of 15 seats on CHS' Board of Directors; each appointee will serve a 3-year term.

(3) CHS will make $125M in capital commitments to PMC, and $10M in commitments to PSNF, within three years of the transaction closing. In addition, CHS will contribute $25M to a newly formed foundation to be created by Pearson. The foundation will be wholly independent of CHS and Pearson.

With respect to (1), CHS will attempt to regain control of strategic, operational policy and financial decision-making. CHS will likely extend its "reserved powers"[60] to encompass PMC and PSNF. Since meaningful administration or controls over the clinical research enterprise at PMC are lacking, and PMC's lack of a well-maintained contract management system, CHS will be wary in allowing Pearson to retain control over managerial duties.

With respect to (2) CHS may try to decrease the number of board seats transferred to Pearson. CHS can easily assert Pearson's management to be inadequate due to factors such as PMC's high debt load and overall failure to adapt to challenging market conditions.

Lastly, (3) may be modified. CHS will possibly attempt to decrease its capital commitments to PMC and PSND while citing concerns arising from Pearson's history of funding mismanagement. It may also seek to decrease capital to keep cash on hand if any Stark or AKS obligations are imposed upon them following closing.

B. Countering CHS' Demands

To mitigate CHS' demands, Pearson must assess its priorities. Looking at the LOI, Pearson must triage and prioritize what items are critical and what it is willing to concede. It is paramount for Pearson to protect its interests in completing the transaction.

[60] "Reserved Powers", as stated by the LOI with CHS, provides that all strategic, operational policy and financial decision-making of Pearson will be reserved to CHS.

Although CHS may seek to retain sole power of strategic, operational policy and financial decision-making by amending the LOI provisions and reducing Pearson's seats on CHS' Board of Directors, Pearson may argue the loss of these seats will be counterintuitive for the smooth transition between Pearson and CHS.

The major argument Pearson has at its disposal is that it employs a majority of its own doctors for the sake of cohesion and learning Pearson's unique administrative practices. PMC's medical staff employs approximately 650 physicians and is a 500-bed tertiary level hospital. Pearson can safely assert its long-running experience in running a hospital of PMC's size and nature as a tertiary level hospital. First, tertiary level hospitals are frequently the first point of contact for health services for many patients.[61] This makes Pearsons' staff experienced about such patients' needs. Second, such hospitals are highly specialized in staff and technical equipment, separated by differentiated clinical services.[62] Indeed, the size of CHS' two hospitals combined constitute PMC's size. Although CHS is regarded for sophisticated leadership, Pearson's appointees will bring previous knowledge that CHS does not have the time or resources to learn in a short time. Consequently, Pearson should be able to retain at least a few seats on the Board of Directors due to these circumstances.

Further, while CHS may be wary of providing additional capital investments to Pearson post-transaction, Pearson can argue that the resulting improvements from a cash infusion will benefit both parties. A weakness of PMC is its inability to invest in new equipment to keep up with local competitors. Holding back cash to jumpstart PMC's access to new medical technology will only further exacerbate this problem, and directly works against CHS's interest in gaining an

[61] Hensher et al., *Referral Hospitals*, *in* DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 1229, 1230 (2d ed. 2006).
[62] *Id.*

asset through this acquisition. We advise that the capital investment is the safest term of the LOI and that Pearson should expect to compromise on the transition of management power.

V. CONCLUSION

Due to its inability to cut debt and invest in plant and equipment, the most viable solution is to complete the transaction with CHS to alleviate its financial burdens. However, with the implications of the Due Diligence Findings, Pearson inevitably must make compromises. Further detailed investigations will be necessary to determine the extent of the regulatory compliance violations. It is imperative to stabilize Pearson's financial health to secure its future. To do so, Pearson must remain open to relinquishing management and administrative power to secure capital commitments and ensure a smooth transaction with CHS.

By bringing awareness to these issues, Pearson should gain the confidence to make the appropriate decisions and take action. With this information in mind, please consider these recommendations.