

CHAPTER 3

HEALTH CARE COMPLIANCE ISSUES IN HEALTHCARE MERGERS AND ACQUISITIONS

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§ 3.01 INTRODUCTION TO HEALTH CARE MERGERS AND ACQUISITIONS

Fueled by the healthcare reimbursement shift toward value-based care, the growing administrative and regulatory complexity of our healthcare system and increased private equity interest in health care investing, recent merger and acquisition activity has been, and is likely to continue to be, strong in healthcare. While the beginning of 2017 presented uncertainty related to a new presidential administration, the potential repeal and replacement of significant portions of the Affordable Care Act (ACA) and tax reform, 2017 was an active year for health care transactions. Despite continued regulatory uncertainty, deal activity for 2018 remains steady, but deal volume has declined as of Q2. At the same time criminal, civil, and administrative enforcement of noncompliance with health care laws remains very strong and of high consequence. The year 2017 was the eighth consecutive year that civil health care fraud settlements and judgments exceeded \$2 billion.¹ As a result, buyers must carefully evaluate and mitigate risk; particularly, when consolidating resource-strapped businesses that may not have been able to make compliance with the multitude of applicable health care laws and regulations a priority.

In this chapter, we will review recent trends, discuss considerations in structuring health care transactions, explain why due diligence is so important, highlight significant areas to review in performing diligence, and, finally, discuss the avenues for handling identified diligence risks.

§ 3.02 RECENT TRENDS IN HEALTH CARE TRANSACTIONS

[A] Recent Transaction Activity

Health care transaction activity has reached 200+ transactions a quarter for each of the last 15 consecutive quarters.² While overall health care deal volume decreased slightly in 2017, the total deal value increased significantly, largely due

¹ Press Release, Dept. of Justice, Justice Department Recovers Over \$3.7 Billion from False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), *available at* <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017> (hereinafter “DOJ Press Release FY 2017”).

² PwC Deals, US Health Services Deals Insights Q2 2018, (2018), PwC Deals, US Health Services Deals Insights Year-end 2017, (2018), <https://www.pwc.com/us/en/health-industries/publications/pdf/pwc-health-services-deals-insights-year-end-2017.pdf> (hereinafter “PwC Deals Insights”). (hereinafter “PwC Deals Insights Q2 2018”). PwC Deals, US Health Services Deals Insights Year-end 2017, (2018), <https://www.pwc.com/us/en/health-industries/publications/pdf/pwc-health-services-deals-insights-year-end-2017.pdf> (hereinafter “PwC Deals Insights”).

to several high dollar transactions.³ There were five health care transactions that exceeded \$5 billion in 2017.⁴

The managed care and long-term care health care industry sectors saw the most transaction activity in 2017.⁵ Deal value, value growth, and volume growth were highest in managed care transactions, and long-term care transactions led in deal volume.⁶ Notably, there were significant declines in behavioral health deal value (81%).⁷ There were also declines in home health care deal volume (32%).⁸ According to PwC, industry wide EBITDA (*i.e.*, earnings before interest, taxes, depreciation and amortization) multiples increased generally by 1.7x to 13.4x, with the highest multiples and largest increases being in the laboratory and imaging sectors.⁹

As for 2018 deal activity, while complete statistics have not yet been released, as of Q2 2018, deal volume decreased by 7.3% over prior quarter but increased by 9.4% over prior year.¹⁰ Further, total deal value declined by double-digits versus Q1 2018 and Q2 2017; however, both of those quarters experienced exceptional mega deal activity that drove the deal value up.¹¹ Notwithstanding Q2 2018 had one notable mega deal with KKR & Co.'s announced acquisition of Envision Healthcare Corporation, which is the third largest transaction since 2016.¹²

Similar to 2017, as of Q2 2018, the long term care sector experienced the largest deal volume.¹³ The physician medical groups sector accounted for the largest subsector of deal value (49.4%).¹⁴ This sector also experienced the most rapid growth in terms of deal volume and the managed care space saw the most growth in deal value over the prior year.¹⁵

[B] Current Drivers of Health Care Transactions

There are several current drivers of health care transactional activity. Perhaps most notable is the ACA, which continues to place downward pressure on reimbursement and encourage the use of alternative payment models.¹⁶

³ PwC Deals Insights.

⁴ PwC Deals Insights.

⁵ PwC Deals Insights.

⁶ PwC Deals Insights.

⁷ PwC Deals Insights.

⁸ PwC Deals Insights.

⁹ PwC Deals Insights.

¹⁰ PwC Deals Insights Q2 2018.

¹¹ PwC Deals Insights Q2 2018.

¹² PwC Deals Insights Q2 2018.

¹³ PwC Deals Insights Q2 2018.

¹⁴ PwC Deals Insights Q2 2018.

¹⁵ PwC Deals Insights Q2 2018.

¹⁶ Gary W. Herschman, *et al.*, *Health-Care Transactions Update: Will 2018 Surpass 2017?*, Bloomberg BNA (Jan. 25, 2018), available at <https://www.ebglaw.com/content/uploads/2018/01/Herschman-Ryan-January-2018-BNA-Transactions-Update.pdf> (hereinafter "Herschman Article").

Initially many facilities received additional government funds from the enactment of the ACA; however, these benefits were temporary.¹⁷ Further, as hospitals focus on cutting costs, many facilities have started selling certain outpatient services to third parties.¹⁸

In addition, there is high significant interest in companies that provide innovative technology.¹⁹ Providers and health care companies are consistently looking to improve efficiency and quality; therefore, they continue to purchase and contract for technology services and systems.²⁰

Another current driver of both increased volume and higher transaction prices are new classes of investors. For example, in the physician practice space, there has been a significant increase in private equity investments. Within the last two years, practices specializing in orthopedics, gastroenterology, urology and OB/GYN have, for the first time, been involved in private equity transactions.²¹ Private equity investors provide an alternative to the traditional hospital-physician organizations and increase competition in the market. This added competition is driving up purchase prices.

[C] Health Care Transaction Outlook

Barring a significant change in the market, the rest of 2018 should be a steady year for health care deal activity. Already in first part of 2018, we have seen companies focused on autism and opioid treatment programs are receiving 17–19 times trailing EBITDA²² and industry-wide mean EBITDA multiples has risen by 1.5x to 14.9x.²³ For the remainder of 2018, it is likely that healthcare care companies will continue to look to drive efficiency and quality through innovation and economies of scale to adapt to a regulatory landscape that encourages cost reduction, including achieving quality measures and participation in new delivery models.²⁴ In addition, the market still remains full of available capital as a result of relatively low (but rising) interest rates, the tax reform bill and record setting private equity investments.²⁵ Finally, big innovators such as Amazon, Walmart, and Apple have entered the health care space, which should result in large-scale investments in the industry. Amazon has collaborated with Berkshire

¹⁷ Herschman Article.

¹⁸ Herschman Article.

¹⁹ Herschman Article.

²⁰ Herschman Article.

²¹ Herschman Article.

²² Lisa Phillips, *A Bubble in Healthcare Services? What Bubble?*, available at <https://healthcare.levinassociates.com/2018/05/20/a-bubble-in-healthcare-services-what-bubble/> (May 20, 2018).

²³ PwC Deal Insights Q2 2018.

²⁴ Herschman Article.

²⁵ M&A Trends.

Hathaway and JP Morgan Chase & Co. to develop a new company intended to improve the provision of health care to its employees.²⁶ Walmart has contemplated several health care transactions, most recently engaging in discussions with Humana.²⁷ Apple has joined Walmart and Amazon in the health care space and is preparing to launch healthcare clinic for its employees.²⁸

Although transactions in the health care space will likely still remain active in 2019, it is possible that rising interest rates, slowing global trade and investment growth, and leveling of equity prices will drive down health care transactions versus 2017/2018 activity.²⁹

§ 3.03 CONSIDERATIONS IN STRUCTURING THE DEAL

The recent trends surrounding initial deal structuring (typically a pre-diligence process) are seemingly focused on avoiding pitfalls demonstrated by transactions that failed to comply with applicable fraud and abuse laws, and reducing—to the extent possible—taking on risk associated with pre-transaction activities. Below we highlight some of the more significant issues that impact structuring the deal, setting the purchase price, and mitigating risk.

[A] Structuring to Comply with Fraud and Abuse Laws, Generally

Much of the regulation in health care is aimed at protecting patients against inappropriate influences affecting the independent medical judgment of health care practitioners, particularly physicians. Toward that end, when considering a health care transaction, first and foremost the parties need to consider who has the ability to influence patient referrals, and ensure that the structure of the transaction itself and the post-closing structure comport with any applicable health care fraud and abuse laws.

Two of the most important laws that must be considered in any health care transaction are the federal Anti-Kickback Statute³⁰ and the federal Stark Law.³¹

²⁶ Ayla Ellison, *Amazon vs. Walmart: Who Has More Power to Change Healthcare's Landscape?*, Becker's Hospital Review (Apr. 5, 2018), available at <https://www.beckershospitalreview.com/hospital-management-administration/amazon-vs-walmart-who-has-more-power-to-change-healthcare-s-landscape.html> (hereinafter "Ellison Article").

²⁷ Ellison Article.

²⁸ Natasha Bach, *Apple Is Joining Amazon and Warren Buffett in the Health Care Business*, Fortune (Feb. 27, 2018), available at <http://fortune.com/2018/02/27/apple-health-clinics-ac-wellness-employees-amazon-warren-buffett/>.

²⁹ Baker McKenzie, *Global Transactions Forecast-Healthcare* (Jan. 5, 2018) https://www.bakermckenzie.com/-/media/files/insight/publications/gtf/healthcare_sector_report.pdf?la=en.

³⁰ 42 U.S.C.A. § 1320a-7b (West 2018); 42 C.F.R. § 1001.951-52 (2017).

³¹ 42 U.S.C.A. § 1395nn (West 2018); 42 C.F.R. §§ 411.351, *et seq.* (2017).

Unsurprisingly, in this highly regulated industry, each state often has its own versions of these laws—some more stringent and some less stringent than their federal counterparts. These state laws are important to consider in the course of structuring any transaction. In addition, several states have laws limiting ownership of entities providing professional services, such as physician practices, to licensed professionals. These “corporate practice of medicine” laws are aimed to prevent unlicensed owners from having influence over the professional judgment of physicians and sometimes other categories of practitioners.

[1] Anti-Kickback Statute

The Anti-Kickback Statute makes it a criminal offense to offer or pay any remuneration (including any kickback, bribe, or rebate) to any person to induce that person to recommend or purchase any service or item covered in whole or in part under a federal health care program (*e.g.*, Medicare, Medicaid).³² The Anti-Kickback Statute is an intent-based statute; however, only “one purpose” needs to be to induce referrals, not even necessarily the main purpose.³³ The Office of Inspector General (OIG) has established “safe harbors” that will protect an arrangement from enforcement if all of the requirements of the safe harbor are met.³⁴ Failure to comply with a safe harbor is not a *per se* violation of the Anti-Kickback Statute, but it does increase the risk that the arrangement may be scrutinized by the OIG. Often, health care transactions will fall outside of a safe harbor and be analyzed on a facts-and-circumstances basis, which includes analysis of whether the transaction is fair market value (FMV) and commercially reasonable without considering referrals or other business generated between the parties. Each violation of the Anti-Kickback Statute constitutes a felony, punishable by a maximum fine of up to \$100,000,³⁵ felony imprisonment or both. Conviction may also lead to exclusion from the federal health care programs. Violations of the Anti-Kickback Statute may also trigger penalties under the False Claims Act and the Civil Money Penalty Statute³⁶ (CMP Statute). Civil sanctions under the CMP Statute may include \$74,792³⁷ for each prohibited act plus damages up to three times the total amount of remuneration offered, paid, solicited, or

³² 42 U.S.C.A. § 1320a-7b(b)(2).

³³ *See, e.g.*, *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985).

³⁴ *See* 42 C.F.R. § 1001.952 (2017).

³⁵ Bipartisan Budget Act of 2018, Pub. L. No. 115-123 (Feb. 9, 2018) increased AKS criminal fine from \$25,000 to \$100,000.

³⁶ 42 U.S.C.A. § 1320a-7a. (West 2018)

³⁷ 45 C.F.R. § 102.3 (2017). Note: Civil monetary penalties are subject to annual adjustment based on updates to the consumer price index and the numbers for 2018 had not been published at this time this chapter was written.

received. Violations of the federal False Claims Act are punishable by treble damages (*i.e.*, three times the claim amounts submitted) and up to \$22,363 per false claim.³⁸

[2] Stark Law

The federal Stark Law prohibits a physician from referring patients to an entity for the furnishing of designated health services (DHS)³⁹ that are otherwise reimbursable by Medicare and/or Medicaid if the physician⁴⁰ (or an immediate family member⁴¹) has a financial relationship with that entity, unless a specific exception is met.⁴² Many of these exceptions specifically require, among other things, that compensation be FMV and commercially reasonable absent consideration of the referrals or business generated between the parties. The Stark Law is a strict liability statute, meaning intent does not matter—the failure to meet an exception equates to a violation of the law. Violations of the Stark Law can result in one or more of the following sanctions: (1) denial of payment to an entity furnishing services under a prohibited referral; (2) refunds of billed or collected amounts; (3) assessment of CMP Statute of up to \$24,253 per prohibited referral (and up to \$161,692 for a circumvention scheme); and (4) exclusion from participation in the Medicare program. The Stark Law’s prohibition applies both to the physician making the prohibited referral and the entity billing for DHS.⁴³ Like the Anti-Kickback

³⁸ Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944 (Jan. 29, 2018).

³⁹ *Designated health services* means any of the following services (other than those provided as emergency physician services furnished outside of the United States.): (1) Clinical laboratory services, (2) Physical therapy, occupational therapy, and speech-language pathology services, (3) Radiology and certain other imaging services, (4) Radiation therapy services and supplies, (5) Durable medical equipment and supplies, (6) Parenteral and enteral nutrients, equipment, and supplies, (7) Prosthetics, orthotics, and prosthetic devices and supplies, (8) Home health services, (9) Outpatient prescription drugs, and (10) Inpatient and outpatient hospital services. Except as otherwise noted in this subpart, the term DHS means only DHS payable, in whole or in part, by Medicare. DHS does not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). 42 C.F.R. § 411.351; 42 U.S.C.A. § 1395nn(g).

⁴⁰ For purposes of the Stark Law, the term *physician* includes medical doctors, osteopathic doctors, dentists, podiatrists, optometrists, and chiropractors. 42 C.F.R. § 411.351.

⁴¹ The Stark Law defines *immediate family member* to mean husband or wife; birth or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

⁴² 42 U.S.C.A. § 1395nn.

⁴³ 42 U.S.C.A. § 1395nn.

Statute, violations of the Stark Law are often enforced through the False Claims Act, which carries penalties up to \$22,363 per false claim and treble damages.⁴⁴

[3] Corporate Practice of Medicine

Many states have corporate practice of medicine laws, which prohibit the employment of physicians by non-licensed entities. The corporate practice of medicine doctrine is grounded in the concern that a for-profit employer or manager could interfere with a physician's professional judgment in treating patients and could disrupt a physician's duty of loyalty to his or her patients.

However, in most states, physicians can incorporate, own, and be employed by professional corporations (PCs). A common method for addressing compliance with the corporate practice of medicine doctrine is structuring a transaction to use a friendly PC model. In the friendly PC model, a physician-owned PC is established that employs the physicians and receives all of the revenues from professional services rendered. The PC contracts with a management company to which it pays a management fee for furnishing non-medical items to the PC (which may include items and services such as office space, equipment, supplies, billing services, financial accounting, receptionist services and compliance advice).

Parties to a transaction need to be aware of any applicable corporate practice of medicine prohibitions and how states enforce the prohibitions. For example, some states may have historically recognized a corporate practice of medicine prohibition but do not regularly enforce it.⁴⁵ On the other hand, states like New York, New Jersey, and California have strong prohibitions that are actively enforced. Prior to determining the structure of a deal, it is important to understand the existence of corporate practice of medicine prohibitions and the enforcement landscape.

[B] Assessing Fair Market Value and Commercial Reasonableness

In evaluating compliance with the Anti-Kickback Statute and the Stark Law, as well as similar state fraud and abuse laws, a significant focus is whether transactions are FMV and commercially reasonable absent consideration of referrals

⁴⁴ Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944 (Jan. 29, 2018).

⁴⁵ For example, Kentucky's CPOM prohibition was established by case law, but it appears the Kentucky Board of Medical Licensure indicated that it will not enforce the prohibition against the corporate practice of medicine if: (a) the physician remains in compliance with standards of practice and professional responsibility; (b) the employer does not interfere with the exercise of the physician's independent medical judgment or the patient-physician relationship; and (c) the salary and bonus of physicians employed by the entity are not based in any way on the volume or value of medical services the physician may make to the entity's medical practice. *See* KY Bd. of Med. Licensure, opinion letter dated 02/10/95.

between the parties. While these terms are distinctly different, the OIG and Centers for Medicare and Medicaid Services (CMS) have emphasized through advisory opinions and enforcement actions that the two terms are entangled, must co-exist, and compliance with one does not ensure compliance with the other.⁴⁶

[1] Fair Market Value

The term *fair market value* (FMV) has a very distinct meaning with respect to transactions in the health care space. Under the Stark Law, FMV means “the value in arm’s-length transactions, consistent with the general market value.”⁴⁷ *General market value* means the price that an asset would bring as the result of bona fide bargaining between well informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well informed parties to the agreement who are not otherwise in a position to generate business for the other party on the date of acquisition of the asset or at the time of the agreement.⁴⁸

While there is no specific definition of FMV under the Anti-Kickback Statute, the definition above is consistent with OIG guidance on FMV relating to the Anti-Kickback Statute.⁴⁹ In the business valuation context, FMV is also defined as “the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts.”⁵⁰

Whenever a transaction involves referral sources that will continue to refer post-closing, ideally the parties would obtain a third-party valuation from an outside valuation firm. Valuators often use three methods when analyzing FMV: the income approach, the asset approach, and the market approach.⁵¹ The income

⁴⁶ Nicole Gossett & H. Kennedy Conner, *Analysis of the Interconnectivity Between Fair Market Value and Commercial Reasonableness*, available at <http://www.elliotttdavis.com/assets/Analysis-of-the-Interconnectivity-between-Fair-Market-Value-and-Commercial-Reasonableness.pdf>; Gregory D. Anderson, *Fair Market Value: What’s Fair and Is It Commercially Reasonable?* (June 2011), available at <https://www.healthlawyers.org/Publications/Documents/K.%20anderson.pdf> (hereinafter “Anderson Paper”).

⁴⁷ 42 C.F.R. § 411.351.

⁴⁸ 42 C.F.R. § 411.351.

⁴⁹ 42 C.F.R. §§ 1001.952(b)(6), 1001.952(c)(6); see also Mike Glomb, *The Importance of Fair Market Value in Health Care Transactions*, HealthCenterCompliance.com (May 7, 2013), available at <https://www.healthcentercompliance.com/subscriber/compliance-connection/1009>; Timothy Smith & Mark O. Dietrich, *BVR/AHLA Guide to Healthcare Industry Compensation and Valuation* (2012), available at https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2013/POST/POSTAM2handout1.pdf; Anderson Paper at 1–3.

⁵⁰ Rev. Rul. 59-60, 195901 C.B. 237; see also Anderson Paper, at 1.

⁵¹ Anderson Paper, at 7–11.

approach involves “determining a value indication of a business, business ownership interest, security, or intangible asset using one or more methods that convert anticipated economic benefits into a present single amount.”⁵² Under the asset approach, the valuator evaluates “a business, business ownership interest, or security using one or more methods based on the value of the assets’ net of liabilities.”⁵³ The market approach is defined as “a general way of determining a value indication of a business, business ownership interest, security, or intangible asset by using one or more methods that compare the subject to similar businesses, business ownership interests, securities, or intangible assets that have been sold.”⁵⁴

Generally, a valuation should utilize more than one of the methods listed above. The buyer should avoid relying solely on the income approach when the sellers will be in a position to refer post-closing.⁵⁵ The income method typically takes into account future business which may be derived from referral sources who will receive funds from the transaction, calling into question the credibility of the income approach.⁵⁶ As a result, the income approach should at a minimum be supported by another common valuation method whenever the sellers will be in a position to make referrals to the buyer post-closing.

Having contemporaneous documentation of the FMV analysis is very important to support compliance should the transaction be questioned in the future. If obtaining a third-party valuation is cost prohibitive, an internal valuation should be prepared, including reference to any comparison points and the rationale for any assumptions that are made in determining what is considered FMV.

[2] Impact of Private Equity on Valuations

In recent years, private equity investment in health care companies has increased significantly. In fact, “healthcare was the only sector in the U.S. to receive more private equity dollars in 2017 than 2016, despite the U.S. [private equity] industry’s record-breaking year for fundraising.”⁵⁷ Despite market uncertainty and reimbursement pressures, private equity investment in healthcare is

⁵² *Internal Revenue Service Business Valuation Guidelines*, Banister Financial, available at <https://www.businessvalue.com/resources/Valuation-Cases/IRS-Valuation-Report-Guidelines-Final.pdf> (hereinafter “Business Valuation Guidelines”).

⁵³ Business Valuation Guidelines.

⁵⁴ Business Valuation Guidelines.

⁵⁵ Joseph Wolfe, Esq., *Fundamentals of Healthcare Valuation for Health Lawyers and Compliance Officers*, AHLA Fraud and Compliance Forum Presentation (Oct. 7, 2014) (hereinafter “Wolfe Presentation”).

⁵⁶ Wolfe Presentation.

⁵⁷ Keith Button Archive, *Healthcare Private Equity Investments Were Up in 2017, Despite Obamacare Uncertainty*, Mergers & Acquisitions (Feb. 27, 2018), available at <https://www.themiddlemarket.com/news/private-equity-investing-in-healthcare-rises>.

driven by undeniable long term trends such as an aging population, increase in chronic diseases, and expanding demand for efficient services.⁵⁸ Spurred by innovation and encouraged by low interest rates and available capital, private equity's focus on healthcare is creating significant competition for more traditional health care companies bidding on deals.⁵⁹ Private equity companies looking to invest in healthcare are less likely to own facilities to which practitioners refer, so particularly in the context of physician practices (*e.g.*, anesthesia, pain management, OBGYN, radiology), they are less constrained by the need to support the FMV of the purchase price using traditional measures. As a result, private equity investment is increasing multiples and driving valuations higher in the bidding process as both traditional and non-traditional investors compete for health care deals.

[3] Commercial Reasonableness

Commercial reasonableness is a completely separate, but related, concept from FMV. Commercial reasonableness is focused more on the underlying legitimate business rationale of the transaction rather than the actual value. The rationale underpinning the transaction should in no way relate to obtaining or incentivizing referrals from existing or potential referral sources.

In the commentary to Phase II of the Stark Law, CMS noted that an arrangement “will be considered ‘commercially reasonable’ in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.”⁶⁰ The OIG has stated that “[b]y ‘commercially reasonable business purpose,’ we mean that the purpose must be reasonably calculated to further the business of the lessee or purchaser.”⁶¹

When analyzing whether a transaction is commercially reasonable, the parties need to consider whether the transaction is sensible even absent referrals, *i.e.*, what is the business motivation for engaging in the transaction? This analysis involves knowing and understanding the buyer's business, the seller's business and how the transaction furthers the buyer's business goals, as well as the alternatives to achieve those goals.

⁵⁸ Kara Murphy & Nirad Jain, *How Private Equity Picks Healthcare Winners*, Forbes (June 20, 2017), available at <https://www.forbes.com/sites/baininsights/2017/06/20/how-private-equity-picks-healthcare-winners/#45ec0e751249> (hereinafter Murphy & Jain Article).

⁵⁹ Murphy & Jain Article.

⁶⁰ Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054, 16,093 (Mar. 26, 2004) (to be codified at 42 C.F.R. Parts 411 & 424).

⁶¹ Medicare and State Health Care Programs: Fraud and Abuse, 64 Fed. Reg. 63,518, 63,525 (Nov. 19, 1999) (to be codified at 42 C.F.R. Part 1001).

In recent years, third-party valuation firms—who have historically performed fair market valuations—have begun offering commercial reasonableness opinions. While there may be some value in a third party evaluating your business logic, seemingly a well-reasoned internal analysis may also be sufficient. Either way, having contemporaneous documentation of the business rationale for doing the transaction is important in the event the commercial reasonableness is later questioned. It is hard to refute an allegation of an inappropriate purpose several years later absent documentation reflecting the business rationale that was created at the time of a transaction.

[4] Transactions Involving an Entity Operating at a Loss

In recent years, several enforcement actions have brought to the forefront whether it is ever commercially reasonable to purchase a business when economic losses are anticipated going forward. After prolonged litigation involving Tuomey Health Care System (“Tuomey”), a South Carolina hospital, a \$72.4 million settlement was announced in 2015 before the purchase of Tuomey by Palmetto Health.⁶² In the underlying claims against Tuomey, the government asserted that Tuomey lost money after paying the physicians more than their actual professional collections.⁶³ The success of the *Toumey* case spurred a wave of similar cases.

On December 23, 2015, Memorial Health, Inc. (“Memorial”) paid a \$9.8 million settlement to resolve alleged violations of the Stark Law and Anti-Kickback Statute which involved net operating losses stemming from, in part, over compensating physicians.⁶⁴ Similarly, on September 15, 2015, North Broward Hospital District (“Broward”) paid \$69.5 million to settle allegations that it had over compensated physicians, resulting in a loss of over \$17 million from the physicians practice.⁶⁵ The relator claimed that Broward was able to offset losses

⁶² United States *ex rel.* Drakeford, v. Tuomey, d/b/a/ Tuomey Healthcare Sys., 792 F.3d 364 (4th Cir. 2015).

⁶³ *Drakeford*, 792 F.3d 364.

⁶⁴ United States *ex rel.* Schaengold v. Mem’l Health, Inc., Case No. 4:11-CV-00058 (S.D. Ga.), Press Release, Dept. of Justice, Government Settles Alleged False Claims Act Violations with Memorial Health, Inc. (Dec. 23, 2015), available at <http://www.justice.gov/usao-sdga/pr-government-settles-alleged-false-claims-act-violations-memorial-health-inc>. See also Danielle Sloane, Lauren Gaffney & Richard Eiler, *A Guide to Setting 2016 Fraud and Abuse Resolutions (Based on Developments and Lessons Learned in 2015)*, AHLA Connections (Feb. 2016) (hereinafter “2016 Fraud & Abuse Guide”).

⁶⁵ United States *ex rel.* Reilly v. North Broward Hosp. Dist., Case No. 10-60590 (S.D. Fla.); Press Release, Dept. of Justice, Florida Hospital District Agrees to Pay United States \$69.5 Million to Settle False Claims Act Allegations (Sept. 15, 2015), available at <http://www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act>; see also 2016 Fraud & Abuse Guide.

through approximately \$28 million in profits generated by those physicians' referrals to the health system.⁶⁶

Further, Citizens Medical Center ("Citizens") settled similar allegations for \$21.8 million.⁶⁷ In the early stages of the case, the District Court for the Southern District of Texas denied Citizens' motion to dismiss the relator's Stark Law claims relating to certain compensation agreements with cardiologists in part based on the relator's allegation that "the cardiologists' office practices have systematically lost money even while [Citizens] has prospered."⁶⁸

As a result of these settlements and the current regulatory landscape, health care companies should be cautious when entering into transactions or other arrangements that are expected to result in operating losses.⁶⁹ Health care companies planning to enter into an arrangement with likely future losses should evaluate the anticipated timeline for the losses. If the losses are expected to continue for more than a reasonable start-up period, the parties should carefully evaluate the legitimate business reasons for entering into the transaction or arrangement—*e.g.*, significant community need, service required by the hospital to maintain accreditation, etc.⁷⁰ Further, post-closing, healthcare companies should continuously monitor existing physician arrangements to ensure that each arrangement remains commercially reasonable and does not exceed FMV.⁷¹

[C] Representations and Warranties Insurance

The significant potential liability associated with running afoul of health care laws, coupled with increasing competition to win auctions for healthcare deals, is causing buyers to increasingly look to a new source of risk protection: representations and warranties insurance. A resource often used in other industries, representations and warranties insurance protects against losses caused by breaches of the seller's representations and warranties in the purchase agreement. In years past, representations and warranties insurance was not available in the

⁶⁶ *Reilly*, Case No. 10-60590, Relator's 3rd Am. Compl. dated September 11, 2012; *see also* 2016 Fraud & Abuse Guide.

⁶⁷ United States *ex rel.* Parikh. v. Citizens Med. Ctr., Case No. 6:10-CV-64 (S.D. Tex. Sept. 29, 2013); Press Release, Dept. of Justice, Texas-Based Citizens Medical Center Agrees to Pay United States \$21.75 Million to Settle Alleged False Claims Act Violations (Apr. 21, 2015), *available at* <http://www.justice.gov/opa/pr/texas-based-citizens-medical-center-agrees-pay-united-states-2175-million-settle-alleged>; *see also* 2016 Fraud & Abuse Guide.

⁶⁸ *Parikh*, 977 F. Supp. 2d at 670; *see also* 2016 Fraud & Abuse Guide.

⁶⁹ 2016 Fraud & Abuse Guide.

⁷⁰ 2016 Fraud & Abuse Guide.

⁷¹ 2016 Fraud & Abuse Guide.

health care context, but it has become increasingly sought after as a tool for managing risk in transactions.⁷² The challenges, some of which still exist, historically include insurers not being interested in underwriting the risk, policies being cost prohibitive or inclusion of so many coverage exclusions as to make the policy unattractive to buyers.⁷³

Recently, insurance underwriters have been more willing to consider policies in healthcare transactions, particularly in transactions involving businesses that are reimbursed under simpler billing methods (*i.e.*, capitation) and transactions involving single provider lines.⁷⁴ Buyers in a health care transaction are interested in obtaining representations and warranties insurance because it provides protection post-closing for unknown pre-closing liabilities and eliminates the risk of not recovering from a target company's prior owners post-closing. Bidders in an auction process are increasingly offering to obtain representations and warranties insurance as a means to make their bid more attractive by avoiding or minimizing the use of escrows, holdbacks and post-closing indemnification by sellers. Generally, a buyer side policy is preferable, regardless of whether the parties negotiate an arrangement where the seller pays the premiums.

In the authors' experience, while parties often start out aiming to obtain representations and warranties insurance, few are successful in health care transactions involving federal health care program reimbursement. Obtaining the insurance is often undermined by the cost, policy limitations and length and scope of diligence. Prior to issuing a representations and warranties insurance policy, the insurer will expect thorough diligence on the target, in some cases involving a broader scope of diligence than the buyer or buyer's counsel would undertake. Typically, insurer diligence involves reviewing materials prepared by law firms, third-party valuers, and billing and coding auditors, but insurers may also perform their own review of key documents or require expansion of the diligence performed by the buyer. For example, an insurer may require a billing and coding audit to take a broader sample of records going as far back as six years. This diligence process can be costly and time consuming. Ultimately, any risks identified in diligence either by legal counsel or by the insurer are carved out of the policy. Further, while non-disclosure and common interest agreements may be utilized, providing privileged legal material and analysis to an insurer may nonetheless destroy privilege on the legal advice and conclusions contained therein; this is especially concerning with respect to any identified historic regulatory risk.

⁷² See Christopher J. Donovan, *Health Care Rep and Warranty Insurance: New Solutions for Private Equity Buyers and Sellers*, Foley & Lardner LLP (July 15, 2015), available at <https://www.healthcarelawtoday.com/2015/07/15/health-care-rep-and-warranty-insurance-new-solutions-for-private-equity-buyers-and-sellers/> (hereinafter "Donovan Article").

⁷³ Donovan Article.

⁷⁴ Donovan Article.

[D] Earnouts and Contingent Pricing Mechanisms

Earnouts and contingent price mechanisms (collectively, “earnouts”) are common in transactions outside the health care industry. In health care, however, they must be carefully vetted. In a typical earnout provision, a portion of the purchase price is contingent on the target reaching certain earnings or revenue benchmarks during a specified period post-closing. Incentives to increase revenues or earnings can present risk under the healthcare fraud and abuse laws when the sellers are in a position to refer or generate business for the buyer. Regardless, in the competitive deal climate, potential investors are increasingly proposing such mechanisms in effort to both remain competitive in their offers and protect their significant investments.

[1] Earnouts and the Anti-Kickback Statute

Where the seller is in a position to refer during the earnout period, earnouts can cause earnouts particular concern under the Anti-Kickback Statute because it creates an incentive for the seller to increase referrals to maximize their earnout proceeds. The Anti-Kickback Statute is an intent-based statute; however, only “one purpose” needs to be induce referrals, not even necessarily the main purpose.⁷⁵ Further, intent is often inferred from the surrounding facts and circumstances, *e.g.*, emails. Thus, if payments are to *any* extent motivated by intent to induce referrals, there is risk of running afoul of the Anti-Kickback Statute. Referrals are a concept that may be hard to differentiate entirely in the context of earnouts, which typically are designed to invest sellers in the continued growth and operation of the business.

Besides the sale-of-practice safe harbor,⁷⁶ the OIG has not formally addressed earnouts. Even the informal guidance from the OIG is dated at this point; and, as a result, often overlooked. However, given earnouts are increasingly being considered in healthcare transactions, it is worthwhile to revisit the OIG’s statements on this point. Through a series of letters, the OIG has indicated that a transaction in which the seller is at risk of not receiving the purchase price unless referrals continue may result in an Anti-Kickback Statute violation.⁷⁷ Further, the OIG has expressed suspicion of installment payments conditioned on

⁷⁵ See, *e.g.*, *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985).

⁷⁶ 42 C.F.R. § 1001.952(e).

⁷⁷ Letter from Harvey A. Yampolsky, Chief Counsel to the Inspector General, to Hope S. Foster, American Clinical Lab. Ass’n (Jan. 23, 1990); and Letter from D. McCarty Thornton, Associate General Counsel, Inspector General Division, Office of the General Counsel, U.S. Dep’t of Health & Human Servs., to John E. Steiner, Assistant General Counsel, American Hosp. Ass’n (Nov. 2, 1993).

continuing referrals by the sellers subsequent to the sale, non-recourse promissory notes and thinly capitalized purchasers.⁷⁸

Notably, the Anti-Kickback Statute goes beyond prohibiting referrals to also prohibiting Kickbacks to induce “recommending or arranging for” the purchase of services that are covered by a federal or state healthcare program; and it applies to anyone—not just physicians. The terms “recommending” and “arranging” are not defined, but the OIG has made clear that they are broadly construed such that “many marketing and advertising activities may involve at least technical violations of the statute.”⁷⁹ While technically any seller receiving an earnout—not just physicians—could be perceived as recommending the business going forward, the OIG’s concern is heightened where physicians are involved in the promotion of a business, commonly referred to as “white coat marketing.” The OIG views physicians as holding a position of public trust and having the ability to “exert undue influence when recommending healthcare-related items or services, especially when marketing to their patients.”⁸⁰ Nonetheless, the OIG has suggested it will exercise enforcement discretion with typical marketing arrangements where the Medicare program’s costs are not increased by the purchases, and the marketing efforts are made to the health facility’s sophisticated purchasing departments, not to physicians or others in a position to directly make the referrals to the seller.⁸¹ Thus, the risk of an earnout, even if it does incentivize a non-physician seller to continue to promote the business is not as high as when the seller is a physician, particularly a physician in the position to increase revenue by directly ordering federal healthcare services.

[2] Earnouts and Stark Law

Where the sellers include referring physicians, the Stark Law may also be implicated by an earnout if the physician’s post-closing referrals may include DHS. As a reminder, to comply with Stark Law each financial relationship with a referring physician must qualify for an exception. The Stark Law exception most applicable to practice acquisitions is the isolated transaction exception. To qualify for the exception, an “isolated financial transaction” must involve either “a single payment” or installment payments that are (1) fixed in advance and do not take into account the volume or value of referrals or other business generated between the parties, and (2) immediately negotiable, guaranteed by a third party,

⁷⁸ Letter from D. McCarty Thornton, Associate General Counsel, Inspector General Division, Office of the General Counsel, U.S. Dep’t of Health & Human Servs., to Kandy F. Waldie, Hooper, Lundy & Bookman (July 15, 1990).

⁷⁹ 56 Fed. Reg. at 35,974.

⁸⁰ See Off. of Inspector Gen., Advisory Opinion 99-12 (Dec. 6, 1999); Off. of Inspector Gen., Advisory Opinion 02-12 (Aug. 30, 2002).

⁸¹ See Off. of Inspector Gen., Advisory Opinion 98-10 (Sept. 8, 1998); Off. of Inspector Gen., Advisory Opinion 99-3 (Mar. 23, 1999).

secured by a promissory note, or some other similar mechanism to ensure payment in the event of default.⁸² Given that earnouts are not set in advance, and not generally secured or negotiable, they typically cannot qualify for this exception. There are other exceptions that can be considered, such as the fair market value exception, but most exceptions include requirements that make them challenging to apply to an earnout payment, such as a limitation on any payments that take into account the volume or value of referrals or other business generated between the parties. If earnout payments cannot qualify for an exception, then the parties will need to consider alternatives to the earnout.

[3] Evaluating an Earnout; Alternatives

While generally earnouts present risk under the Anti-Kickback Statute and Stark Law when the seller is a referring physician and the buyer is, or will be, the owner of a health care provider or supplier to which the physician will refer post-closing, there are certain instances where the risk may be sufficiently low. For example, earnouts in managed care and health care IT transactions that do not involve physician owners present a lower risk. There are also some categories of physicians that tend to be referral recipients rather than referral sources. The classic example is diagnostic radiologists, who are often interpreting imaging studies initiated by another physician. In addition, other hospital-based physician practices (emergency, anesthesia, and hospitalist) do not send patients to the hospital; rather, they are present in the hospital to handle patients that come to them. Hospital-based physicians, however, still may order ancillary services (*e.g.*, imaging, labs, pharmaceuticals, and devices) and may influence admission, length of stay, and treatment decisions. These situations demonstrate that whether an earnout might be of sufficiently low risk for the sellers is highly dependent upon the specific details of the transactions and post-closing relationships.

Often, the goal of a proposed earnout does not involve a nefarious intent; rather, the buyer wants to ensure that the sellers will remain active and engaged in the business to help them continue to grow and expand the services; but, not in an inappropriate way. As a result, increasingly practitioners are asked to help evaluate or come up with alternative contingent payments that can accomplish a similar goal and carry less risk. For example, depending on the situation a contingent payment for maintaining a large customer contract or for winning new customer contracts may be of lower risk. Alternatively, the parties can consider basing contingent payments on cost reduction, or other efficiency or quality measures rather than on revenues. We have also seen earnouts based on completing pipeline acquisitions, expanding to new states or recruiting additional providers.

⁸² 42 C.F.R. § 411.351.

[E] Licensure and Government Program Filings

Many health care transactions involve some sort of licensed entity, meaning the target company is required under state or federal law to maintain state licenses, certificates of need, accreditations, or government enrollments in order to operate and bill for its services. While state licensures and enrollments tend not to be at the forefront of deal negotiations, these matters are a critical aspect of a transaction because they can affect deal timing and cash flow post-closing. The timing and the process of updating ownership information and/or transferring licenses and enrollments is often a source of frustration with investors, particularly when it stalls their ability to quickly close a transaction or impacts the cash flow post-closing.

If the transaction qualifies as a “change of ownership” or “change of information” for a particular government license or health care program enrollment, a state or federal regulatory body may expect some sort of filing. Often these are post-closing filings, particularly if the target entity is remaining in existence and/or there is only a minority ownership change. There are, however, a number of states that require pre-closing notification or approval (often up to 90 days pre-closing) to evaluate the new owner’s application. For example, in Florida, upon the change of ownership of an ambulatory surgery center, a new permit application must be filed with the Florida Agency for Health Care Administration at least 60 days prior to the effective date of the change. The application must be processed and approved prior to the effective date of the change.⁸³ Comparatively, for most types of Medicare providers and suppliers, Medicare requires notice within 30 days after a “change of ownership or control, including changes in authorized official(s) or delegated official(s)” and all other changes must be reported within 90 days.⁸⁴ A few types of Medicare enrollments have more stringent requirements (*e.g.*, DME suppliers must notify Medicare of any change in information supplied on the 855 application within 30 days of the change.)⁸⁵

Determining the required licensure procedures for a particular state license or federal enrollment early in the transaction process is ideal for setting the transaction timeline. Clients are often surprised by the amount of work necessary to analyze the filing requirements necessary for each type of licensure and enrollment held by a company. This is particularly true for transactions that have operations in several states. In addition, it may take more time than anticipated to complete the various filings and applications, which often requires coordination between the buyer and the seller.

If the transaction qualifies as a change of ownership and the parties wish to close the transaction prior to the buyer’s obtaining necessary regulatory approval of the change of ownership, to avoid a lag in revenue, the parties can consider

⁸³ Fla. Stat. Ann. §§ 408.806–408.807 (West 2018).

⁸⁴ 42 C.F.R. § 424.516(e) (2017).

⁸⁵ 42 C.F.R. § 424.57(c)(2) (2017).

utilizing what is commonly referred to as an interim management agreement. In an interim management agreement, the buyer purchases and then leases back all the operating assets and business administration necessary to the seller, who continues to operate the business under its existing licenses until the licensure approvals are received. Typically, as compensation for providing all the assets and business administration, the seller pays 100% of the revenues to the buyer less its costs. It is debatable, however, whether regulators will recognize the interim management agreement as having prevented the change of ownership until the new licenses have been issued.

§ 3.04 DUE DILIGENCE: WHY IS IT SO IMPORTANT IN HEALTH CARE TRANSACTIONS?

[A] Successor Liability

In recent years, the U.S. Department of Justice (DOJ) has recovered billions in False Claims Act cases involving claims submitted to the government for health care services by health care companies. Of \$3.7 billion in settlements and judgments from civil cases involving fraud and false claims in fiscal year 2017, \$2.4 billion involved the health care industry.⁸⁶

Recent settlements demonstrate that buyers are continually resolving liabilities that originated prior to their ownership; though whether the buyers were aware of the conduct prior to closing is not always clear. For example, in 2017, Quest Diagnostics, Inc. (“Quest”) settled with the DOJ for \$6 million to resolve a lawsuit alleging improper kickbacks provided by Berkeley HeartLab, an entity acquired by Quest in 2011.⁸⁷ Similarly, in 2017 Genesis Healthcare, Inc. (“Genesis”) agreed to pay \$53.6 million to resolve False Claims Act allegations regarding medically unnecessary therapy and hospice services, and sub-standard nursing home care provided by entities acquired by Genesis. The allegations all related to pre-acquisition activities.⁸⁸ Given the breadth of enforcement in the health care space and the astronomical settlement amounts, buyers need to understand that they may be held responsible for past noncompliance, including liability for past fraud and abuse violations and billing improprieties. Liability, if egregious

⁸⁶ DOJ Press Release FY 2017.

⁸⁷ Press Release, Dept. of Justice, Blood Testing Laboratory to Pay \$6 Million to Settle Allegations of Kickbacks and Unnecessary Testing (May 2, 2017), <https://www.justice.gov/usao-sc/pr/blood-testing-laboratory-pay-6-million-settle-allegations-kickbacks-and-unnecessary>.

⁸⁸ Press Release, Dept. of Justice, Genesis Healthcare Inc. Agrees to Pay Federal Government \$53.6 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy and Hospice Services, (June 16, 2017), *available at* <https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act>.

enough, could involve potential termination or exclusion from federal healthcare programs.⁸⁹

In the context of Medicare, successor liability is tied to the nature of the transaction and whether the buyer accepts (intentionally or not) the target's medicare participation agreement. In most equity or stock transactions, the entity holding the Medicare enrollment does not change; thus, the target company's liability remains with the post-closing entity. Even in asset transactions involving Medicare "providers"⁹⁰ and "certified suppliers" (*i.e.*, suppliers requiring some sort of survey, *e.g.*, ambulatory surgical centers) successor liability is likely to flow through to the post-closing entity unless the buyer and seller take active pre-closing steps to reject assignment of the provider/supplier agreements.⁹¹ If the buyer does not take any action, CMS views the existing provider/supplier agreement as having been automatically assigned to the new owner, along with all successor liability related to all pre-closing claims.⁹²

For Medicare Part A providers (*e.g.*, hospitals, home health agencies, hospices), Medicare rules are quite clear that the refusal to accept assignment must be put in writing by the new owner and forwarded to the CMS regional office at least 45 days prior to the change of ownership date to allow for the orderly transfer of any beneficiaries that are patients of the provider.⁹³ It is imperative that any purchaser undergoing a change of ownership, who refuses assignment of the provider agreement (and any corresponding liability), closely follow the necessary procedures. While less explicit, certified suppliers, who want to reject assignment to avoid pre-closing Medicare-related successor liability should follow this same procedure.

Disclaiming all such liability in the purchase agreement is not sufficient to avoid Medicare successor liability. In *United States v. Vernon Home Health, Inc.*, the Fifth Circuit Court of Appeals upheld the government's claim against the buyer of a home health agency for debts owed to Medicare by the prior provider.⁹⁴ Even though the buyer expressly stated in the asset purchase agreement that it was not accepting any of the seller's liabilities, the Fifth Circuit in *Vernon*

⁸⁹ CMS, Survey and Certification Letter: Acquisitions of Providers/Suppliers with Rejection of Automatic Assignment of the Medicare Provider Agreement: Implications for Timing of Surveys and Participation Effective Date, REF S&C: 13-60-ALL (Sept. 6, 2013) (hereinafter "CMS Survey & Certification Letter").

⁹⁰ While the term *provider* often is used generally to refer to all entities and persons who furnish healthcare services, in the Medicare statutory and regulatory scheme, *provider* is a term of art that is limited to hospitals, skilled nursing facilities, home health agencies, hospices and a few other less common entities. *See* 42 U.S.C.A 1395x(u) (West 2018); *see also* 42 C.F.R. § 489.2 (2017).

⁹¹ 42 C.F.R. § 489.18 (2017); *see also* CMS, State Operations Manual, CMS Pub. 100-07, Chap. 3, Sec. 3210.5A (Rev. 123, Oct. 03, 2014) (hereinafter "State Operations Manual").

⁹² 42 C.F.R. § 489.18(c); *see also* State Operations Manual.

⁹³ State Operations Manual.

⁹⁴ *United States v. Vernon Home Health, Inc.*, 21 F.3d 693 (5th Cir. 1994), *cert denied*, 513 U.S. 1015 (1994).

held that because the purchaser failed to reject assignment of the seller's Medicare provider agreement, it took on the seller's obligations to Medicare. Specifically, the Fifth Circuit held that an overpayment to the prior owner of the home health agency could be offset against post-closing Medicare payments to the new owner.⁹⁵ In addition, accepting assignment of a provider or certified supplier agreement could potentially subject the new owner to liability under federal fraud and abuse laws. In *Deebrook Pavilion, LLC v. Shalala*, the Eighth Circuit held that civil monetary penalties imposed on a prior operator of a skilled nursing facility could be asserted against the new operator.⁹⁶

Given this potential liability, why wouldn't every buyer or investor reject assignment and re-enroll in Medicare? In short, it is typically cost prohibitive to re-enroll in Medicare. As a result of CMS's concerns about (and maybe experience with) attempts to avoid obligations by setting up new entities and re-enrolling rather than paying overpayments, penalties and fines, CMS has made it quite unpalatable and impractical to not take assignment and, accordingly, the past liabilities.⁹⁷ If a new owner refuses to accept assignment and also wishes to participate in the Medicare program, Medicare will treat the new owner as a new applicant to the program. While that sounds positive at first blush, practically it results in termination of the existing provider agreement effective as of the change of ownership (or closing) date. The new owner will be unable to bill Medicare until it submits a new Medicare application and undergoes a new survey.⁹⁸ New surveys can take a long time to initiate (*e.g.*, 6-8 months) and the new enrollment will not become effective until after a satisfactory survey demonstrating that the "new" Medicare provider or certified supplier meets all of Medicare's conditions for participation.⁹⁹ As a result, the new owners will have no avenue to bill Medicare for any services provided to Medicare beneficiaries from the date of closing until the day it passes a successful survey, *i.e.*, not simply a cash flow delay but a loss of potential revenue.

As a result of the revenue losses likely associated with having to re-enroll in Medicare (and other commercial payor programs), most buyers prefer to keep the existing Medicare and other enrollments (*e.g.*, Medicaid, TRICARE and commercial payors) in place to avoid, or minimize, any disruption or delays in cash

⁹⁵ Thomas D. Vaughn, Medicare CMS 855 Enrollment Under the Patient Protection and Affordable Care Act (2015) (hereinafter "Vaughn Presentation").

⁹⁶ *Deebrook Pavilion, LLC v. Shalala*, 235 F.3d 1100 (8th Cir. 2000), *cert. denied*, 122 S. Ct. 454 (2001); *see also* *BP Care, Inc. v. Thompson*, 337 F. Supp. 2d 1021, 1029 (S.D. Ohio 2003), *aff'd on other grounds*, 398 F.3d 503 (6th Cir. 2005) (interpreting *Deebrook* and holding "Savvy purchasers likely take these liabilities into consideration" when negotiating a transaction.').

⁹⁷ CMS Survey & Certification Letter.

⁹⁸ State Operations Manual, Chap. 3, Sec. 3210.5A; *see also* CMS Survey & Certification Letter.

⁹⁹ 42 C.F.R. § 489.13 (2017).

flows. In that context, however, compliance diligence becomes incredibly important in evaluating whether successor liability risks are acceptable.

[B] The 60-day Repayment Rule

Another significant driver of increased diligence in recent years relates to what is commonly referred to as the “60-day Repayment Rule.” The 60-day Repayment Rule has the practical impact of making new owners responsible for actively investigating any potential billing issues that arise post-closing even if they relate to pre-closing activities; and, if substantiated, making repayments to Medicare or Medicaid. This rule was enacted in 2010 as part of the ACA and requires that entities submitting claims to Medicare or Medicaid report and repay Medicare and Medicaid overpayments by the later of: (1) 60 days after the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.¹⁰⁰ For purposes of Medicare, reporting and returning obligations (including the requirement to investigate) extend to all overpayments received within the last six years.¹⁰¹ In recent years several state Medicaid programs have enacted similar 60-day repayment requirements applicable to both traditional Medicaid program and managed Medicaid programs in the state.

An “overpayment” is defined as “any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled. . . .”¹⁰² An overpayment can include, among other things, receiving payments for non-covered services, duplicate payments, or payments in excess of the allowable amount for an identified covered service; making errors and including non-reimbursable expenditures in cost-reports; or, billing Medicare as primary when another payer had the primary responsibility for the beneficiary.¹⁰³ Billings tainted by Anti-Kickback Statute or Stark Law violations are also overpayments, necessitating repayment of the full amount paid for such claims.¹⁰⁴ The 60-day Repayment Rule applies regardless of whether the entity that submitted the claims caused the overpayment.¹⁰⁵

Typically, a provider or supplier has “identified” an overpayment when it has have, or should have, through the exercise of reasonable diligence: (1) determined

¹⁰⁰ 42 U.S.C.A. § 1320a-7k(d) (West 2018).

¹⁰¹ 42 C.F.R. § 401.305(e) – (f) (2017) (applicable to Medicare Parts A and B).

¹⁰² 42 U.S.C.A. § 1320a-7k(d) (in this context the term “person” means “a provider of services, supplier, Medicaid managed care organization (as defined in section 1396b(m)(1)(A) of this title), Medicare Advantage organization (as defined in section 1395w-28(a)(1) of this title), or PDP sponsor. . . .”).

¹⁰³ Reporting and Returning of Overpayments, 81 Fed. Reg. 7,654, 7,656 (Feb. 12, 2016) (to be codified at 42 C.F.R. Parts 401 & 405).

¹⁰⁴ 81 Fed. Reg. 7,654, 7,658–59.

¹⁰⁵ 81 Fed. Reg. 7,654, 7,656–57 (addressing Medicare Parts A and B).

that it received an overpayment; and (2) quantified the amount of the overpayment.¹⁰⁶ When an entity receives any credible information that an overpayment may have been received, it is obligated to conduct “reasonable diligence” to determine whether or not an overpayment actually occurred.¹⁰⁷ CMS has indicated that “reasonable diligence” includes (1) proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments; and (2) investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment.¹⁰⁸ CMS has noted the standard of “reasonable diligence” is not uniform and will vary based on the facts and circumstances involved, including the resources of the applicable provider. CMS expressly rejected that that identification of an overpayment would require actual knowledge.¹⁰⁹

Failure to repay an overpayment is grounds for liability under the False Claims Act, including penalties and treble damages.¹¹⁰ This theory was the basis for liability in *U.S. ex rel. Kane v. Healthfirst, Inc.* In *Kane*, the Southern District of New York denied the defendants’ motion to dismiss the United States’ claim that the defendant healthcare providers failed to timely report and refund government overpayments.¹¹¹ *Kane*, which eventually settled, is an important case for two reasons: it is the first “reverse false claims” case where the United States intervened, and the district court’s opinion denying the defendants’ motion to dismiss was the first published opinion to consider a healthcare provider’s obligations under the 60-day repayment provision.¹¹²

As a result of these repayment obligations, buyers need to understand that, if they identify a potential overpayments post-closing, they are required to investigate; and, if substantiated, quantify the overpayment and make repayments. Gone are the days when buyers could simply fix the problem and move forward. While representations and indemnifications may technically give buyers an avenue to seek funds from the sellers’ post-closing, most buyers recognize that is not an easy thing to do—particularly if the sellers are partners or employees in the post-closing entity. Moreover, any potential overpayments identified in the course of diligence related to federal health care programs must be fully evaluated to determine if they are actual overpayments, and then resolved in an appropriate manner. (See Section 3.06, Navigating Risk Identified in Due Diligence.)

¹⁰⁶ 42 C.F.R. § 401.305; *see also* 42 C.F.R. § 422.326 (addressing the same for Medicare Advantage organizations).

¹⁰⁷ 81 Fed. Reg. 7,654, 7,662–63, 7,665.

¹⁰⁸ 81 Fed. Reg. 7,654, 7,661 (applicable to Medicare Parts A and B); Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,923–24 (May 23, 2014) (to be codified at 42 C.F.R. Parts 417, 422, 423, & 424) (applicable to Medicare Advantage).

¹⁰⁹ 81 Fed. Reg. 7,654, 7,661; 79 Fed. Reg. 29,844, 29,923–24.

¹¹⁰ 31 U.S.C.A. § 3729(a)(1)(G).

¹¹¹ *United States ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015).

¹¹² *Kane*, 120 F. Supp. 3d at 377–78.

[C] Value-Based Payment Models and MACRA

In addition reviewing historical revenues to predict future revenues, buyers must also consider the target's reporting of quality data in connection with new value-based payment models, which can impact future reimbursement. Since the passage of the ACA, there has been a concerted shift by Medicare as well as other major payors to base reimbursement on value rather than volume.¹¹³ This shift has been largely driven by Alternative Payment Models (APMs) established by the CMS Innovation Center, including the various iterations of Accountable Care Organizations (ACOs),¹¹⁴ Episode-Based Payment Initiatives,¹¹⁵ and models focusing on Primary Care Transformation.¹¹⁶

The most substantial recent development toward more value-based payment was the passage and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) passed in 2015, which repealed the Sustainable Growth Rate Formula¹¹⁷ and established a new quality payment

¹¹³ Amy E. Sanders, *HHS Sets Explicit Goals to Shift Payments from Volume to Value . . . But How?*, AHLA Executive Summary (Feb. 2015), available at https://www.healthlawyers.org/Members/PracticeGroups/PALS/ExecSumms/Documents/HHS_Sets_Explicit_Goals_to_Shift_Payments.pdf.

¹¹⁴ The CMS Innovation Center established a number of ACO programs, including the Pioneer ACO Model, ACO Investment Model, Comprehensive ESRD Care Initiative, and Next General ACO Model. CMS, Innovation Models, available at <https://innovation.cms.gov/initiatives/index.html#views=models> (hereinafter "CMS Innovation Model List"). The Medicare Shared Savings Program is the largest ACO model, which has participants in all 50 states and adjusts reimbursement based on potential savings and risk apportionment. CMS, Shared Savings Program—About the Program, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.html>, 2018; see also CMS, Performance Year 2018 MSSP ACOs, available at <https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/Performance-Year-2018-Medicare-Shared-Savings-Prog/7zis-nzdf>.

¹¹⁵ Episode-Based Payment Initiatives tie reimbursement to a wide spectrum of providers involved in an "episode" of care for a specific procedure or category of treatment. Examples include Bundled Payment for Care Improvement (BPCI), the Comprehensive Care for Joint Replacement (CJR), and the Oncology Care Model (OCM).

¹¹⁶ See CMS, Innovation Center, available at <https://innovation.cms.gov/>; see also CMS Innovation Model List.

¹¹⁷ The Balanced Budget Act of 1997 made a number of significant changes to reimbursement, one of which was the adoption of the SGR adjustment. See Pub. L. No. 105-33, 111 Stat. 251(1997). The SGR was intended to control the growth of Medicare spending for physicians' services through annual adjustments to the MPFS payment rates. However, the SGR became extremely unpopular with providers; facing an annual outcry from the industry, Congress continually passed legislation to negate the yearly payment reductions mandated by the SGR, which only created additional uncertainty for providers and added to the SGR's unpopularity.

program.¹¹⁸ Specifically, MACRA establishes incentive payments or penalties based on provider participation in the Merit-based Incentive Payment System (MIPS) and certain “Advanced APMs.”¹¹⁹

MIPS consolidates components of three preexisting CMS programs—the Physician Quality Reporting System (PQRS),¹²⁰ the Physician Value-based Payment Modifier (VM Program),¹²¹ and the Medicare Electronic Health Record Incentive Program (EHR Incentive Program)¹²²—and largely sunset payment adjustments under these programs after 2018.¹²³ Under MIPS, eligible clinicians are required to submit data in four major categories: (1) quality performance; (2) practice or care delivery activities aimed at improving outcomes; (3) advancing care information performance; and (4) cost performance.

MIPS is broadly applicable to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and groups that include such clinicians, who bill under Medicare Part B.¹²⁴ Clinicians may be exempt from MIPS if they meet certain criteria, such as (1) being newly enrolled in Medicare, or (2) being below a low volume thresholds (*i.e.*, has less than \$90,000 Medicare Part B charges *or* provides care for 200 or fewer Part B beneficiaries).¹²⁵

Eligible clinicians and groups may earn positive or neutral payment adjustments based on achieving satisfactory or high final scores, whereas providers that fail to participate or perform poorly face negative payment adjustments. Under MIPS, eligible clinicians are evaluated based on performance during a calendar year (CY) on a two-year delay. For example, data submitted in CY 2017 will result in positive, negative, or neutral payment adjustments in payment year (PY) 2019. The maximum adjustment increases over time, starting at plus or minus 4

¹¹⁸ See CMS, Quality Payment Program Overview, available at <https://qpp.cms.gov/about/qpp-overview>.

¹¹⁹ As of early 2018, Advanced APMs include the MSSP (Tracks 2 and 3 only), the Next Generation ACO Model, Comprehensive ESRD Care, Comprehensive Primary Care Plus, Oncology Care Model (two-sided risk), CJR (CEHRT Track), and BPCI Advanced (begins October 1, 2018). See CMS, APMs Overview, available at <https://qpp.cms.gov/apms/overview>; see also CMS, Innovation Model: BPCI Advanced, <https://innovation.cms.gov/initiatives/bpci-advanced>.

¹²⁰ CMS, Physician Quality Report System, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/pqri>.

¹²¹ CMS, Value-Based Payment Modifier, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>.

¹²² CMS, Promoting Interoperability Program, available at <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html> (renamed from EHR Incentive Program to Promoting Interoperability Programs).

¹²³ Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM), 81 Fed. Reg. 77,008, 77,010–11 (Nov. 4, 2016) (to be codified at 42 C.F.R. Parts 414, 495).

¹²⁴ 81 Fed. Reg. 77,008, 77,014, 77,036.

¹²⁵ 81 Fed. Reg. 77,008, 77,037; see also CY 2018 Updates to the Quality Payment Program, 82 Fed. Reg. 53,568, 53,577 (Nov. 16, 2017) (to be codified at 42 C.F.R. Part 414) (adjusting thresholds).

percent in PY 2019 (based on CY 2017 performance) and gradually increasing to 9 percent in PY 2022 (based on CY 2020 performance).¹²⁶

The MIPS program identifies each eligible clinician based on a unique combination of TIN/NPI, and MIPS performance is assessed separately for each TIN under which an individual bills.¹²⁷ Eligible clinicians may report data required by MIPS individually, as part of a group,¹²⁸ or as a participant in an APM (e.g., the MSSP or Next Generation ACO Model). If a clinician opts to report data as part of a group, submissions are aggregated and judged collectively, and all TIN/NPIs participating in a group practice will typically receive the same MIPS score and payment adjustment.¹²⁹ Irrespective of whether clinicians submit data individually or as part of a group, MIPS payment adjustments are applied at the individual TIN/NPI level. This allows MIPS adjustments to follow the clinician if he or she changes practices.¹³⁰ CMS explained: “[I]f a MIPS-eligible clinician worked in one practice (TIN A) in the performance period, but is working at a new practice (TIN B) during the payment year, then [CMS] would use the final score for the old practice (TIN A/NPI) to apply the MIPS payment adjustment for the NPI in the new practice (TIN B/NPI).”¹³¹

Thus, buyers need to consider compliance with current reporting requirements and the quality of the data submitted in order to assess, to the extent possible, potential post-closing payment adjustments applicable to groups and eligible clinicians. In addition, the parties can consider having representations and warranties in the purchase agreement addressing future adjustments based on data submitted pre-closing. In the short-term, the parties should also consider how to ensure continuing data collection and reporting when the transaction falls part way through a reporting period.

[D] Buying Out of Bankruptcy: Special Considerations

Due to a combination of factors, including changes in the delivery of health care after the ACA, more significant expenditures in new technology and integration systems, and decreased revenues due to reduced availability of government funds, there has been an increase in “distressed” health care transactions.¹³²

¹²⁶ 81 Fed. Reg. 77,008, 77,332; *see also* 42 C.F.R. § 414.1405 (2017).

¹²⁷ 81 Fed. Reg. 77,008, 77,058.

¹²⁸ For purposes of MIPS, a “group” is defined by “TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have re-assigned their billing rights to the TIN.” 42 C.F.R. § 414.1305 (2017).

¹²⁹ 81 Fed. Reg. 77,008, 77,330.

¹³⁰ 81 Fed. Reg. 77,008, 77,330–32.

¹³¹ 81 Fed. Reg. 77,008, 77,330–32.

¹³² William P. Smith, *et al.*, *Limiting Successor Liability Under Assigned Medicare Provider Assignments*, Law Journal Newsletters (July 2015), available at <http://www.lawjournal>

Health care entities that are having financial trouble can present an attractive investment opportunity with lower purchase prices through a bankruptcy sale.

Bankruptcy sales can occur in two different ways. One way is using a plan of reorganization,¹³³ which involves an extensive process to prepare, negotiate and seek approval of the plan. Because of the lengthy process in reorganization, it is becoming increasingly more common for bankruptcy transactions to occur as an asset sale under Bankruptcy Code Section 363.¹³⁴ One of the most significant advantages of a bankruptcy sale of assets is that, except for those that are specifically set forth in the transaction documents, the sale is “free and clear” of liens, claims and encumbrances.¹³⁵

In a health care bankruptcy transaction, a significant debate generally involves whether the purchaser will assume the current Medicaid/Medicare participation agreement. Most courts have held that a Medicare participation agreement is executory in nature, such that an assumption of the agreement equals assumption of the associate liabilities.¹³⁶ Bankruptcy Code Section 365 permits a trustee or a debtor to “assume” or “reject” an executory contract of the debtor.¹³⁷ Assumption and assignment is then required to transfer the participation agreement to the buyer. Thus, one option in a bankruptcy sale is for the purchaser to have the debtor reject the existing participation agreement, so that the purchaser would not take any liabilities associated with the corresponding provider number. However, in turn, it would be necessary for the purchaser to obtain a new participation agreement, which (as discussed in the Section 3.04[A], (Successor Liability,)) is a burdensome process that would disrupt the target’s revenue stream.¹³⁸

On the other hand, assumption of the current participation agreement will allow the purchaser to continue operations of the target without interruption, which is beneficial for not disrupting the provision of care or revenue.¹³⁹ However, upon assumption of the participation agreement, the purchaser would remain liable for all outstanding known and unknown liabilities related to the distressed entity. These liabilities can include overpayments, Stark Law claims, False Claims

newsletters.com/sites/lawjournalnewsletters/2015/07/01/limiting-successor-liability-under-assigned-medicare-provider-agreements/?slreturn=20180329214914.

¹³³ 11 U.S.C.A. § 1101 *et. seq.* (West 2018).

¹³⁴ 11 U.S.C.A. § 363 (West 2018).

¹³⁵ 11 U.S.C.A. § 363.

¹³⁶ See *In re Vitalsigns Homecare, Inc.*, 396 B.R. 232, 239 (Bankr. D. Mass. 2008) (citing and discussing additional cases).

¹³⁷ 11 U.S.C.A. § 365.

¹³⁸ Lisa Atlas Genecov, *et al.*, *Sale of Distressed Healthcare Assets in Bankruptcy: Potential Acquisition Challenges and Opportunities* (2016), available at <http://www.nortonrosefulbright.com/files/20160121-sales-of-distressed-healthcare-assets-in-bankruptcy-136300.pdf> (hereinafter “Genecov, *et al.* Presentation”)

¹³⁹ Genecov, *et al.* Presentation.

Act claims, and other fraud and abuse claims.¹⁴⁰ The purchaser would also be responsible for rectifying any deficiencies related to Medicare conditions.¹⁴¹

It should be noted that some courts have taken the minority position that Medicare agreements are assets that can be transferred pursuant to a Section 363 sale “free and “clear” of any encumbrances.¹⁴² However, even in these instances there may be some circumstances where HHS could assert the equitable defense of recoupment.¹⁴³

Because of the risk associated with a Medicare participation agreement and the likelihood that well before bankruptcy the company was cutting corners due to extreme resource limitations, due diligence during a bankruptcy transaction becomes especially important in identifying these potential liabilities and non-compliance. Depending on what risks are identified during the diligence process, a purchaser may change its purchase price offer or change aspects of the proposed transaction to account for the risk.

§ 3.05 Conducting Diligence: Areas to Review

As discussed above, successor liability and future reimbursement implications increase the importance of performing thorough diligence to assess a health-care target’s pre-closing compliance with the applicable laws and regulations. The scope and areas of diligence will be highly dependent on what type of healthcare business is at issue and the rules and regulations that apply to that business. While there are too many health care sectors for us to review thoroughly in this chapter, below we discuss some of the more common and important areas of compliance diligence in the course of evaluating health care companies that bill and submit claims to state and federal health care programs.

[A] Ongoing Government Investigations or Qui Tam Litigation

Transactions are increasingly occurring despite ongoing governmental investigations—perhaps due to the competitive mergers and acquisitions environment or the general recognition that compliance missteps, particularly historic ones, are bound to impact almost every healthcare company at some point. For

¹⁴⁰ See *In re Our Lady of Mercy Med. Ctr.*, No. 07-10609 (Bankr. S.D.N.Y. May 15, 2008); see also Genecov, *et al.* Presentation.

¹⁴¹ Genecov, *et al.* Presentation.

¹⁴² *In re BDK Health Mgmt., Inc.*, Nos. 98-00609-61, 98-00610-6B1, 98-00612-6B1, 98-00613-6B1, 98-00614-6B1, 1998 WL 34188241 (Bankr. M.D. Fla. Nov. 16, 1998).

¹⁴³ *Newbury Corp. v. Fireman’s Fund Inc., Co.*, 95 F.3d 1292, 1400 (9th Cir. 1996); see also Genecov, *et al.* Presentation.

example, in 2015 Team Health Holdings (“Team Health”) acquired IPC Healthcare Inc. (“IPC”) for \$1.6 billion.¹⁴⁴ In February 2017, Team Health settled alleged False Claims Act violations involving up-coding by IPC for \$60 million and entered into a five-year Corporate Integrity Agreement with the OIG.¹⁴⁵ Team Health noted in a statement that it was aware of the DOJ’s investigation when it acquired IPC and worked closely with the government to resolve allegations.¹⁴⁶

Perhaps one of the most challenging diligence issues to assess is the risk associated with an active government investigation or ongoing qui tam litigation under the False Claims Act. The earlier in the process of an investigation, the harder to assess the scope of and credibility of the complaints or concerns raised. Nonetheless, a close look at the target’s internal review of the issues raised, its responses to any production requests, interrogatories, and subpoenas, along with a thorough understanding of the status of discussions with the government can help a buyer to assess the credibility of the allegations, the scope of the issues and, hopefully, the magnitude of any potential liability. It may or may not be evident whether there is a whistleblower making allegations. If there is a suspected whistleblower, it is helpful to understand the general role of that individual and their credibility as a complainant. For example, a disgruntled employee let go for poor performance (assuming there is credible evidence of that behavior) that has never raised any compliance concerns prior to being fired, may have less credibility than someone who left the compliance department of their own accord after raising repeated concerns. In addition, assessing the general compliance infrastructure of the company (as discussed below) can give insight as to whether the company may have ignored its compliance obligations such that investigators may find other skeletons in the closet.

If the parties elect to move forward despite an ongoing investigation, there are bound to be strong negotiations and debate over the scope of the potential liability, special indemnities and escrows to cover those liabilities. Assessing the liability is not an exact science and requires a solid understanding of the laws at issue and the penalties that can be imposed under those laws; however, perhaps more important is having some knowledge of the penalties typically imposed by, and the general approach and temperament of, the government investigators.

¹⁴⁴ Diana Jones, *Law 360: Health Care Co. to Pay \$60M To End Whistleblower Fraud Suit*, available at <https://www.law360.com/articles/888985/health-care-co-to-pay-60m-to-end-whistleblower-fraud-suit> (hereinafter “Jones Article”)

¹⁴⁵ Press Release, Dept. of Justice, Healthcare Service Provider to Pay \$60 Million to Settle Medicare and Medicaid False Claims Act Allegations (Feb. 6, 2017), available at <https://www.justice.gov/opa/pr/healthcare-service-provider-pay-60-million-settle-medicare-and-medicare-false-claims-act>; see also February 3, 2017, Corporate Integrity Agreement, available at https://oig.hhs.gov/fraud/cia/agreements/Team_Health_Hodlings_Inc_and_IPC_Healthcare_Inc_02032017.pdf.

¹⁴⁶ Jones Article.

[B] Compliance Program

One of the most telling indicators of whether or not an entity may have hidden compliance issues is having an effective compliance program. An effective compliance program allows a company to not only monitor its compliance, but to correct potential compliance problems before they become significant problems, *e.g.*, the subject of a whistleblower lawsuit.

Evaluating a compliance program should include a review of the target's compliance plan; policies and procedures; compliance committee reports and minutes; and compliance hotline logs and complaints. Most healthcare companies today should have a compliance program that is appropriate for the size of their organization and comports with the compliance guidance published by the OIG.¹⁴⁷ Though some guidance is specific to certain providers,¹⁴⁸ the OIG has consistently set out seven elements that should be a part of any compliance plan:

1. Written standards of conduct and detailed policies and procedures that promote compliance;
2. Compliance program administration, including a compliance officer and committee, that reports directly to the chief executive officer and the governing body;
3. Screening and evaluation of employees, physicians, vendors, and other agents;
4. Communication, education, and training on compliance issues;
5. Monitoring, auditing, and internal reporting systems, including a hotline capable of receiving anonymous complaints and protections against retaliation;
6. Discipline for noncompliance through well-publicized guidelines, including policies on corrective action that are effective and consistently followed; and
7. Prompt investigation and remediation of identified systemic problems.¹⁴⁹

¹⁴⁷ U.S. Sentencing Guidelines Manual § 8A1.2 (U.S. Sentencing Comm'n 1991), *available at* http://www.uscc.gov/sites/default/files/pdf/guidelines-manual/1991/manual-pdf/Chapter_8.pdf.

¹⁴⁸ *See* Off. of Inspector Gen., Compliance Guidance, *available at* <https://oig.hhs.gov/compliance/compliance-guidance/index.asp> (hereinafter "OIG Compliance Guidance").

¹⁴⁹ *See* OIG Compliance Guidance and Off. of Inspector Gen., Measuring Compliance Program Effectiveness: A Resource Guide, at 2 (Mar. 27, 2017), *available at* <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>; *see also* Off. of Inspector Gen., Health Care Compliance Program Tips, *available at* <https://oig.hhs.gov/compliance/provider-compliance-training/files/compliance101tips508.pdf>.

These elements can be used as a guide when assessing a target's compliance program.

In addition, review of reports and minutes from the target's compliance committee can demonstrate whether the target's compliance plan is actively followed, along with revealing how specific compliance problems have been previously handled. Similarly, evaluation of any regulatory complaints submitted via the target's compliance hotline, including the associated logs and documentation addressing the resolution the complaint, can give insight as to whether the compliance plan is working and whether issues that arise are appropriately handled.

Calibrating for the size of the organization and the nature of the problems, a reasonable number of compliance issues that have been appropriately identified and resolved likely indicate a healthy compliance program. Conversely, the failure to identify any issues may suggest a lack of compliance infrastructure or failure to adhere to applicable policies and procedures. That said, it is not uncommon for small healthcare providers and suppliers to either have a weak compliance program or not have a compliance program at all. In fact, this is often one of the facets of a small business that is driving the transaction—its inability to adequately assess and monitor compliance and its desire to align with an organization that is able to bring stability and infrastructure to their business. Not having a compliance program, or even a good one, is not a deal breaker. Rather, it is an indicator of risk and should inspire more expansive diligence in other areas, such as a larger sampling of claims and their supporting records, higher escrow amounts, and longer representation and warranty survivor periods.

[C] Evaluating Coding and Billing Practices

[1] Conducting an Audit of Target's Billings

Given that much of the potential liability in health care business relates to inappropriate coding and billing, a review of the target's historic coding and billing practices through a sampling process is almost essential in a transaction where the buyer will take on successor liability for historic billing practices. At the end of the day, if a provider's or supplier's medical records do not support the services that it billed, then the billed amounts will be perceived as an overpayment by most payors.

Assessing a health care provider's coding and billing compliance can be complex, especially because coding and billing issues often vary based on the provider, services, and payor involved. If the buyer is not capable of doing the coding and billing audit itself, it can consider engaging specialized coding consultants to conduct the review. These consultants generally analyze a sample of the target's past billing, collection, and coding practices and prepare a report identifying billing error rates, including both overpayments and underpayments. Such

information is extremely helpful to evaluate the integrity of the target's historic billings and prospective cash flow.

Any problematic results that could be the basis of a government enforcement action, including a lack of or insufficient medical record documentation, medically unnecessary services, and incorrect coding (including use of modifiers), must be evaluated for any potential liability and repayment obligations.

[2] Reviewing Third-Party Audits

Another indicator of the compliance health of a company is the number of private and governmental payor audits; and, perhaps more importantly, the success of the target in defending those audits. The types of audits, the auditors, the claims at issue and the results are all important indicators of how payors perceive the billing and collections of the company. Notable governmental auditors include: (1) Medicare Administrative Carriers (MAC); (2) CERT contractors, (3) Recovery Audit Contractors (RAC); (4) Zone Program Integrity Contractors (ZPIC); (5) Medicaid Integrity Contractors (MIC); (6) Unified Program Integrity Contractors (UPIC). While each type of auditor has a different focus, ZPIC, MIC, and UPIC audits are usually triggered by some indication of potential fraud, and as a result, are the most concerning. UPICs are a new type of auditing entity, which CMS is in the process of rolling out to combine the functions of ZPICs and MICs. UPICs will perform a variety of program integrity functions that focus on Medicaid, Medicare, and durable medical equipment and supplies.¹⁵⁰

While some audits are common—almost all providers and suppliers experience some type of audit from commercial and governmental payors—numerous audits with significant denials and any ongoing ZPIC, MIC, and UPIC, suggests the integrity of the company's billing is in question. Further, with respect to past audits, particularly any involving significant repayments, recoupments, or prepayment reviews, diligence efforts should evaluate whether the issues that arose in the audits have been fully resolved, including any necessary repayments.

[3] Credit Balances

Diligence efforts should also address any government program related credit balances. For purposes of Medicare, a “credit balance” is defined as “an improper or excess payment made to provider as a result of patient billing or claims processing errors.”¹⁵¹ If a credit balance is uncovered, the provider must submit Form

¹⁵⁰ See Noridian Healthcare Solutions, Unified Program Integrity Contractor, *available at* <https://med.noridianmedicare.com/web/jadme/cert-reviews/upic>.

¹⁵¹ CMS, Medicare Financial Management Manual, CMS Pub. 100-06, Chap. 12, Sec. 20 (Rev. 99 06-30-06) (hereinafter “Medical Financial Management Manual”).

CMS-838 to the government.¹⁵² If a provider improperly maintains a credit balance and fails to refund any money owed to Medicare (or other government payors), the provider can be subject to False Claims Act liability for retaining an overpayment, including potential criminal prosecution, civil monetary penalties, and administrative sanctions. For example, the day following the *Kane* decision discussed above, providers of pediatric home nursing services reached a joint False Claims Act settlement in two whistleblower investigations for \$6.88 million to resolve, in part, allegations the providers did not refund credit balances owed to TRICARE and 20 states' Medicaid programs between 2007 and 2013.¹⁵³

[D] Referral Source Financial Relationships

Understanding the target's relationships with referral sources is critical to evaluating compliance with state and federal self-referral and anti-kickback laws and ensuring the integrity of the post-closing structure. While Anti-Kickback Statute and the Stark Law only apply to state and federal healthcare programs (*e.g.*, Medicare, Medicaid, TRICARE), state kickback, fee splitting and self-referral laws often apply more broadly to all payors.¹⁵⁴

Generally, state and federal fraud and abuse laws define "financial relationship" very broadly. For example, the Stark Law defines "financial relationships" to include, in part, any direct or indirect "ownership or investment interest" or "compensation relationship" involving any payment or other benefit in cash or in kind.¹⁵⁵ Whereas any transfer of value could be "remuneration" within the purview of the Anti-Kickback Statute. Accordingly, diligence efforts must focus on direct and indirect ownership interests involving referral sources, such as ownership interests in labs, imaging centers, ambulatory surgery centers, durable medical equipment suppliers and physician group practices. Moreover, buyers should review all compensation arrangements involving individuals in a position to make or influence referrals, including medical director agreements, employment agreements, professional service agreements, leases, vendor relationships and even gifts and donations. To gain a better sense of these relationships, it is generally helpful to not only review relevant contracts and organizational charts but to also thoroughly discuss with management the existence of such relationships, particularly any such relationships that are not well documented.

¹⁵² Medicare Financial Management Manual.

¹⁵³ *United States ex rel. Odumosu v. Pediatric Servs. of Am. Healthcare*, N.D. Ga., No. 1:11-cv-1007, and *United States ex rel. McCray v. Pediatric Servs. of Am. Healthcare*, S.D. Ga., No. 4:13-cv-127; *see also* Anna Grizzle, Brian Roark & Julia Tamulis, *Providers Take Notice: Recent Cases Find Failure to Refund Overpayments Leads to FCA Exposure* (Aug. 12, 2015), available at <http://www.bassberry.com/publications/2015/08/recent-cases-find-failure-to-refund-overpayments>.

¹⁵⁴ *See, e.g.*, Cal. Bus. & Prof. Code § 650 (West 2018); Fla. Stat. Ann. § 456.054 (West 2018); Ohio Rev. Code § 3999.22 (West 2018).

¹⁵⁵ 42 U.S.C.A. § 1395nn; 42 C.F.R. §§ 411.351, 411.354.

Sometimes practitioners have financial relationships or conflicts of interest about which management is not even aware. The federal government has created certain tools to help assess financial relationships between the healthcare industry and providers, including drug and device companies, physicians, and hospitals. For example, pursuant to the ACA,¹⁵⁶ Congress enacted what is commonly referred to as the “Physician Payments Sunshine Law” which mandated that pharmaceutical and device manufacturers and group purchasing organization report annually certain information regarding physician ownership and transfers of value to CMS. In association, CMS implemented the Open Payments Program to capture and make the data publically available.¹⁵⁷ The Open Payments Search Tool enables anyone to search by the name of specific physicians, companies, or hospitals and identify previous financial relationships with these organizations.¹⁵⁸ These tools can be helpful in identifying potentially problematic relationships or arrangements, which may have otherwise gone unnoticed.

Financial relationships should also be evaluated in the context of any APMs. Specifically, CMS has issued model specific fraud and abuse waivers for certain APM programs (*e.g.*, Pioneer ACO Model and BPCI Model), which permit certain financial relationships that would otherwise be prohibited under fraud and abuse laws. These waivers must be analyzed when conducting diligence on transactions involving APMs, particularly given the importance of remaining within the bounds of the waiver to ensure ongoing compliance.¹⁵⁹ Past failure to adhere to the waivers amounts to historic risk under these laws. Further, proceeding with a transaction or operational change that would result in the entity’s failure to continue satisfying the elements of a previously relied upon fraud and abuse waiver could result in liability under the False Claims Act.

[E] Privacy and Security

Based on the prevalence and multitude of data security breaches in recent years and the potential cost of handling large scale incidents, it is critical that due diligence efforts include an evaluation of the target’s privacy and security compliance. Most health care providers are subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations regarding the privacy and security of protected health information (PHI).¹⁶⁰ Additional privacy and security standards often apply in the context of substance use

¹⁵⁶ ACA, Section 6002 (Pub. L. No. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152).

¹⁵⁷ See CMS, How Open Payments Works, *available at* <https://www.cms.gov/OpenPayments/About/How-Open-Payments-Works.html>.

¹⁵⁸ See CMS, Open Payments Data, *available at* <https://openpaymentsdata.cms.gov/search>.

¹⁵⁹ See generally CMS, Fraud and Abuse Waivers, *available at* <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

¹⁶⁰ Pub. L. No. 104-191, 110 Stat. 1936 (Jan. 3, 1996); 45 C.F.R. Parts 160 and Part 164

disorder treatment, including the strict standards set forth at 42 C.F.R. Part 2 that are commonly known as the “Part 2 Regulations.”¹⁶¹

Evaluation of an entity’s privacy and security compliance should include review of HIPAA policies and procedures; security risk assessments; government audits; improper uses or disclosures of PHI, security incidents or breaches of PHI and any related notifications; and business associate agreements. The diligence review should include understanding how the entity maintains, uses, receives, and discloses PHI and whether the target is a “covered entity” or “business associate” under HIPAA.¹⁶²

[1] Policies and Procedures Addressing Privacy and Security

An entity subject to HIPAA is required to have a broad range of policies and procedures addressing privacy and security. HIPAA Privacy Rule policies should address, among other items, permitted uses and disclosures, the minimum necessary standard, business associate agreements, de-identification of PHI, marketing involving PHI; the sale of PHI, authorizations, incidental disclosures, breach reporting, patient rights involving PHI (*e.g.*, access, amendment, restriction requests, privacy notices, confidential communications and accounting of certain disclosures), training, and designation of a privacy officer.¹⁶³ Policies addressing the HIPAA Security Rule should address, among other items, designating a security officer, security management, workforce training, sanctions for security violations, password management, access control, encryption, contingency planning (*e.g.*, disaster recovery), workstation use and security, audit controls, business associate agreements, and transmission security.¹⁶⁴

¹⁶¹ Generally, the Part 2 Regulations apply to “federally assisted” programs, including those that (1) participate in Medicare; (2) receive federal financial assistance in any form; or (3) are “carried out” under a license, certification or registration from a federal agency or authority to (a) conduct maintenance treatment or withdrawal management, or (b) dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders. 42 C.F.R. § 2.12 (2017). If subject to the Part 2 Regulations, the target would be restricted from certain disclosures of patient information that may otherwise be permitted under HIPAA or applicable state law.

¹⁶² *Covered entity* means a health plan (*e.g.*, health insurance company), health care clearinghouse, or a health care provider who transmits health information in an electronic form in connection with a transaction under HIPAA. *Business associate* means a person or entity that performs certain functions or activities that involve the use or disclosure of PHI on behalf of, or provides services to, a covered entity. See 45 C.F.R. § 160.103 (2017).

¹⁶³ See generally 45 C.F.R. Part 160 and Subparts A and E of Part 164 (2017).

¹⁶⁴ See generally 45 C.F.R. Part 160 and Subparts A and C of Part 164.

The U.S. Department of Health and Human Services Office for Civil Rights (OCR) has created an audit protocol that is a helpful reference when evaluating an entity's policies and procedures.¹⁶⁵

[2] Security Risk Assessments

Entities subject to HIPAA are expressly required to conduct an “accurate and thorough” assessment of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all ePHI held by the entity¹⁶⁶ Though there is no single method or best practice for security risk assessments, a typical analysis should assess data collection (*e.g.*, storage, receipt, maintenance, and transmission of ePHI), identification and documentation of potential threats and vulnerabilities, evaluation of current security measures, determination of the likelihood and impact of threat occurrence, and assignment of risk levels for all threat and vulnerabilities.¹⁶⁷ Review of security risk assessments conducted in the past six years by the target can also focus efforts on specific problem areas.

The requirement to conduct security risk assessments is ongoing and the frequency of performance varies among entities. To the extent the target has not conducted a recent security risk assessment, one should be completed prior to or as soon as possible post-closing. In enforcement actions involving penalties, OCR has frequently focused on the failure to perform these assessments, including a 2018 settlement for \$3.5 million with Fresenius Medical Care North America (FMCNA). Specifically, FMCNA experienced a number of breaches involving five of its subsidiaries, and OCR's investigation revealed FMCNA failed to conduct accurate and thorough risk analysis of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of its ePHI.¹⁶⁸

[3] Business Associate Agreements, Notices of Privacy Practices and Authorizations

Assessment of a target's security and privacy compliance should also address template business associate agreements (BAA), notice of privacy

¹⁶⁵ See Office for Civil Rights, Audit Protocol—Updated April 2016, *available at* <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/index.html>.

¹⁶⁶ 45 C.F.R. § 164.308.

¹⁶⁷ See Office for Civil Rights, Guidance on Risk Analysis Requirements under the HIPAA Security Rule (July 14, 2010), *available at* <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>.

¹⁶⁸ See Press Release, Office for Civil Rights, Five breaches add up to millions in settlement costs for entity that failed to heed HIPAA's risk analysis and risk management rules (Feb. 1, 2018), *available at* <https://www.hhs.gov/about/news/2018/02/01/five-breaches-add-millions-settlement-costs-entity-failed-heed-hipaa-s-risk-analysis-and-risk.html>.

practices, and authorization forms.¹⁶⁹ Buyer's should confirm that compliant BAAs are in place with vendors and other business associates of the target that create, use, maintain or transmit PHI on behalf of the target. OCR has imposed penalties on entities that have failed to maintain compliant BAAs and that have experienced breaches of PHI, including a 2016 settlement for \$1.55 million.¹⁷⁰

[4] Breaches, Improper Uses, or Disclosures and Security Incidents; OCR Investigations and Audits

Diligence efforts should also focus on reviewing any breaches of PHI, security incidents and improper uses and disclosure of PHI. The scope and frequency of these occurrences can be strong indicators of the sophistication of the target's compliance efforts as well as the risk of enforcement actions by state and federal regulators. Buyers should confirm that any patient, media, or governmental notices were appropriately submitted as required by HIPAA or state law. Failing to handle breaches in a compliant manner could result in penalties and fines. For example, in 2017, OCR settled with Presence Health for violations of the HIPAA breach notification rule for \$475,000 involving the failure to provide timely notices for a breach affecting 836 individuals.¹⁷¹

Lastly, diligence efforts should address any prior or ongoing OCR or state government privacy and security related investigations or audits, including government requests for information and correspondence between the target and regulators. If the investigation or audit is ongoing, diligence efforts should assess potential exposure and any necessary changes to bring the entity into compliance. If the investigation or audit is resolved, diligence should assess whether the organization has taken corrective action to protect against any ongoing issues.

[F] State and Federal Health Care Program Enrollments and Surveys

Most health care entities' ongoing operations are intricately tied to their ability to bill third-party payors, including state and federal health care programs.

¹⁶⁹ Review of template forms required by HIPAA should also be evaluated to ensure whether they comply with any heightened requirements imposed by state law. *See* 45 C.F.R. §§ 164.504, 164.520, 164.508 (2017) (addressing requirements for BAAs, notice of privacy practices, and authorization forms).

¹⁷⁰ *See* Press Release, Office for Civil Rights, \$1.55 million settlement underscores the importance of executing HIPAA business associate agreements (Mar. 16, 2016), *available at* <http://wayback.archive-it.org/3926/20170127185635/https://www.hhs.gov/about/news/2016/03/16/155-million-settlement-underscores-importance-executing-hipaa-business-associate-agreements.html>.

¹⁷¹ Press Release, Office for Civil Rights, First HIPAA Enforcement action for lack of Timely Breach Notification Settles for \$475,000, *available at* <http://wayback.archive-it.org/3926/20170127111957/https://www.hhs.gov/about/news/2017/01/09/first-hipaa-enforcement-action-lack-timely-breach-notification-settles-475000.html>.

As a result, assessing the compliance of the target's enrollments and participation in applicable state and federal health care programs is an important diligence step.

Buyers should confirm the target's state and federal health care program enrollments, including Medicare, Medicaid, and TRICARE, are in good standing. While a target may not think it receives any government reimbursement, it is often easy for health care companies to unknowingly receive government reimbursement indirectly through managed care organizations, such as managed Medicaid payors, Medicare Advantage organizations, or TRICARE Regional Offices (*e.g.*, Humana Military or Health Net). Thus, being aware of and identifying these alternative sources of government associated reimbursement is important in evaluating whether a provider truly has any state and federal health care program enrollments or contracts.

In addition, the buyer will want to ensure the state and federal health care enrollments are appropriate and current for all applicable groups/facilities and individual providers. For example, each separate durable medical equipment location must have a separate Medicare enrollment; billing under a different location's Medicare number is problematic.¹⁷² Similarly, providers and suppliers are required to update the applicable agency with changes to their enrollment information. Buyers will want to ensure that all prior changes of information or changes of ownership have been appropriately and timely filed.

One important indicator of licensure or enrollment health is how the target performed on past surveys upon which enrollment is dependent—*e.g.*, state surveyors and accreditation organizations. Significant survey deficiencies, particularly repeat deficiencies and failed plans of correction, may be a sign of mismanagement and risk of sanctions. Review of such surveys is particularly important with any Medicare providers enrolled in Part A and long-term care providers.

[G] Workforce and Investor Matters

[1] Avoiding Excluded or Sanctioned Employees and Investors

Because it is easily avoidable, there may not be anything worse than investing in a health care company only to find out that one of its employees has been excluded from participating in state or federal health care programs or is about to have his or her state license suspended. The same is true for a company seeking new investors; any investment by an excluded individual or entity can wreak havoc on the organization.

¹⁷² 42 C.F.R. § 424.57.

Exclusion from participation in federal health care programs means no federal health care program payment may be made for any items or services furnished by that person. Exclusion goes beyond professional services, meaning excluded individuals are also prohibited from furnishing administrative and management services involving federal healthcare programs, including consultants and executives.¹⁷³ As a result, even one excluded individual working in the billing department or other administrative role, creates liability and often requires a self-disclosure to the OIG.

Many health care companies today have screening infrastructure in place to confirm the exclusion status of all new employees, contractors and vendors upon hire and on a monthly, quarterly or annual basis. However, prior to finalizing any transaction, particularly where the target may not have checked such databases, buyers should review the exclusion database maintained by the OIG,¹⁷⁴ the System for Award Management (SAM),¹⁷⁵ and any state-specific exclusion sites.¹⁷⁶ Moreover, where the transaction involves ongoing investment by the sellers, sellers should similarly assess the buyers to ensure that the investment does not unwillingly establish an ownership interest in their organization by an excluded individual or company.

In addition to exclusions, diligence efforts should evaluate sanctions levied on licensed professionals within the target's workforce, including physicians, mid-level providers, and technologists. Buyers should evaluate the current licensure and disciplinary status of workforce members, including any past board actions. These items are often easily checked via online databases maintained by state regulatory agencies or professional boards.

[2] Potential Whistleblowers

While there is no direct way of determining who may be a whistleblower, keeping a look out for potential whistleblowers is prudent. For example, we generally inquire about employee turnover, circumstances of terminations, whether compliance issues were discussed at exit interviews, and how any concerns raised by employees generally have been addressed. In addition, any departing employees who have refused severance and a corresponding release may raise suspicion.

¹⁷³ Off. of Inspector Gen., Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013), *available at* <https://oig.hhs.gov/exclusions/files/sab-05092013.pdf>.

¹⁷⁴ Off. of Inspector Gen., Exclusions Database, *available at* <https://exclusions.oig.hhs.gov/>.

¹⁷⁵ System For Award Management, *available at* <https://www.sam.gov/portal>.

¹⁷⁶ Though the majority of states operate their own exclusion databases, examples of states with such lists include California and New York. *See* California Department of Health Care Services, Suspended and Ineligible Provider List, *available at* <http://files.medi-cal.ca.gov/pubsdoco/SandILanding.asp>; New York Office of the Medicaid Inspector General, List of Exclusions, *available at* <https://www.omig.ny.gov/index.php/fraud/medicaid-exclusions>.

Special attention should be paid to employees with the access to information and knowledge necessary to bring a qui tam action, including executives and managers, physicians, compliance personnel, and billing and coding experts. In the event diligence identifies potential whistleblowers, the buyer should assess the credibility of allegations raised in order to evaluate the risk.

[3] Employee Classification: 1099s versus W2s

Over the last 10 years, there has been increasing debate over the employee classification of health care professionals, particularly physicians. As a result, whether the target has appropriately classified its workforce as 1099 independent contractors or W2 employees is becoming a topic of discussion in health care transactions. The analysis will vary greatly depending on the nature of the entity involved and the specific circumstances. Inappropriate classification of employees as independent contractors can carry potential tax and employee benefit liability and impact whether coverage applies under a malpractice insurance policy.¹⁷⁷

[H] Reputation in the Market

Last but certainly not least, reputation in the market is an important lens into the general experience of patients, customers and the company as a whole. This aspect of due diligence is generally less regimented and often takes place outside of formal requests to the seller or target. Rather, both parties can typically access this type of information through research on standard online search engines to uncover national or local news stories, regulator press-releases, online reviews, and social media postings. It also generally good practice to extend these searches to important individuals associated with the buyer and seller, including members of management, owners, and key providers. This research can be particularly helpful when performed early in the diligence process to help reveal potential compliance issues and problems, which can focus subsequent reviews and follow-up requests.

§ 3.06 Navigating Risk Identified in Diligence

Depending on the nature of the risks identified during the diligence process, there are a number of ways that a buyer can address potential liability or compliance problems. These options range from simple fixes post-closing to an

¹⁷⁷ Kevin S. Little, *Medical Practices Beware Risks That Attend Improper Classification of Contracted Physicians*, Healthcare Law Blog (Mar. 20, 2017), available at <https://www.healthcarelawblog.com/2017/03/medical-practices-beware-risks-attend-improper-classification-contracted-physicians.html>.

overhaul of the proposed deal structure. Other options include repayments and indemnifications.

[A] Post-Closing Improvements

Relatively low risk issues identified in the course of diligence can typically be resolved with post-closing improvements. Post-closing improvements are generally addressed by the parties' counsel or the entity's internal compliance team. Examples of the type of issues that may be addressed post-closing include compliance program updates, implementation of a compliance hotline, revision of policies and procedures and additional workforce training. In the absence of troubling breaches or ongoing government investigations, it is also common for the purchaser to address any deficiencies in the target's HIPAA compliance infrastructure post-closing. Minor problems involving pre-existing facility licenses or certifications are often resolved post-closing, which can sometimes be addressed simultaneously with any other filings or notices triggered by the transaction. If necessary, the purchaser can consider enlisting an outside consultant to address certain issues post-closing, including engaging a third party to assist with future audits, HIPAA security risk assessments, and ongoing compliance involving the workforce (*e.g.* exclusion screening, licensure, and credentialing).

The most difficult aspect of post-closing improvement is often ensuring that the recommended steps are timely undertaken. As these items are lower risk, post-closing improvements can easily slip through the cracks during the chaos of a companywide integration of recently purchased groups or facilities. Ideally, buyer's counsel can remain involved in the process to ensure these items are resolved appropriately and in a timely manner.

[B] Overpayments and Resolutions

Increasingly, diligence efforts identify an issue that may require a repayment to payors. This situation is particularly challenging if the parties do not agree that repayment is necessary, perhaps due to a disagreement over billing and coding rules or whether the documentation supports the medical necessity of the care provided. Unlike other smaller diligence issues, potential overpayments must be thoroughly investigated and addressed, ideally pre-closing. As discussed in more detail above, the law places a burden on providers to investigate and address any Medicare or Medicaid overpayments in a short period of time; and, contractual obligations to commercial payors may dictate the same result. Given that failing to timely report or return a government program overpayment as required by the 60-day Repayment Rule can result in False Claims Act liability (including penalties, treble damages and even potential exclusion from federal health care programs), the only way to curb the risk is to ensure that adequate and timely

repayments occur.¹⁷⁸ Thus, it is important the parties work efficiently to determine how to resolve such these issues either before closing or shortly thereafter. In the event repayments will be made post-closing, appropriate escrows and indemnity provisions should account for sufficient estimated funds to make the appropriate refunds.

Perhaps as challenging as determining that a problem exists, is determining to whom the disclosure or repayment should be made. There are a variety of different methods to refund overpayments, each with their own advantages and disadvantages. The 60-day Repayment Rule notes that repayments can be made (1) to the applicable Medicare contractor or (2) by making a disclosure under the OIG's Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol.¹⁷⁹ The deadline to return overpayments will be tolled when the OIG or CMS acknowledges receipt of a submission under either entity's respective self-disclosure protocol.¹⁸⁰ Providers also have the option to self-disclose to additional entities such as the DOJ, which is usually done at the local U.S. Attorneys' Office level. Though not addressed in detail here, overpayments involving Medicaid require evaluation of whether to report to the applicable managed Medicaid plan, the state Attorney General, or Medicaid Fraud Control Unit.

The best repayment or disclosure option will vary depending on the nature of the transaction, the goals of the parties, and the specific overpayment(s) involved. It is typically straightforward to determine how to repay routine overpayments, but the process is much more burdensome where the situation is complex and civil or criminal liability is involved. Where an investigation has determined that there is little exposure under fraud and abuse laws overpayments are generally repaid to the Medicare contractor or state Medicaid agency. These situations include brief or routine billing errors, small overpayments, or inadvertent errors.¹⁸¹ Voluntary repayments to Medicare contractors are perhaps the quickest and most efficient; however, the parties will not receive any sort of liability release.

When an overpayment involves potential civil or criminal liability providers should consider the OIG's Self-Disclosure Protocol,¹⁸² the CMS Voluntary Self-Referral Disclosure Protocol,¹⁸³ or disclosure to the DOJ.¹⁸⁴ Self-disclosure can

¹⁷⁸ 42 U.S.C.A. § 1320a-7a(a)(10); 31 U.S.C.A. § 3729(a)(1)(G).

¹⁷⁹ 42 C.F.R. § 401.305(d).

¹⁸⁰ 42 C.F.R. § 401.305(b).

¹⁸¹ See Tony Maida, *Disclose Smart: Strategic Considerations in Making a Government Disclosure*, AHLA Weekly (Mar. 13, 2015), available at https://www.mwe.com/~media/files/thought-leadership/publications/2015/03/disclose-smart-strategic-considerations-in-makin_/files/ahlaweekly031315/fileattachment/ahlaweekly031315.pdf (hereinafter "Maida Article").

¹⁸² See OIG, Self-Disclosure Information, available at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>.

¹⁸³ See CMS, Self-Referral Disclosure Protocol, available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

¹⁸⁴ See Maida Article.

provide the certainty of a resolution and arguably reduce applicable penalties, as well as cut off the ability of a relator to file a False Claims Act *qui tam* action. Below are the common avenues of self-disclosure along with some comparison.

- *CMS Voluntary Self-Referral Disclosure Protocol.* The CMS Voluntary Self-Referral Disclosure process allows resolution of noncompliance with the federal Stark Law and does not require a minimum settlement amount. The major benefit of utilizing the CMS protocol is the relatively modest settlement amounts, particularly with respect to technical non-compliance matters. Unfortunately, it takes many years to resolve a matter, by which time the underlying facts and data may be somewhat stale. CMS is backlogged about four years, meaning a disclosure filed in 2014 is just being processed in 2018. Disclosure to CMS only releases civil liability or risk of administrative actions, including exclusion.¹⁸⁵
- *OIG Self-Disclosure Protocol.* OIG's Self-Disclosure Protocol applies to a wider scope of providers and can address both Anti-Kickback Statute and Stark Law violations, but requires a minimum settlement of at least \$50,000 for kick-back related conduct and \$10,000 for all other matters. Comparatively, the OIG Self-Disclosure Protocol may be slower than going to the DOJ, but likely result in a lower settlement amount.¹⁸⁶ Like the CMS process, self-disclosure to the OIG only releases civil liability or risk of administrative actions, including exclusion.¹⁸⁷
- *DOJ.* There is no set process for approaching the local Assistant United States Attorney (AUSA). Often the local AUSA can be more nimble in arriving at a resolution, but in general the quick resolution comes at a financial cost—a higher settlement amount. Self-disclosure to the DOJ is generally reserved for cases with more complex or extensive inappropriate conduct that require a release for liability under the False Claims Act.

Parties to a transaction must work together to determine what option is best to resolve any identified overpayment, including self-disclosure or repayment. To the extent self-disclosure or repayment are not feasible, *e.g.*, sellers fundamentally disagree with buyers analysis of the potential liability, the parties can, as discussed further below, consider whether there is a means to restructure the deal such that buyers do not take on successor liability.

¹⁸⁵ See Maida Article.

¹⁸⁶ See Maida Article; Thomas Crane *et seq.*, AHLA Healthcare Compliance Legal Issues Manual, Chapter 3.4 (4th ed. 2015).

¹⁸⁷ See Maida Article.

[C] Indemnification, Escrows, and Survivability

Typically buyers will seek to hold back a portion of the purchase price for a period of time (*e.g.*, one to three years) to fund any indemnification claims under the purchase agreement. Assuming the parties have not purchased representations and warranties insurance (see discussion in Section 3.03[C]), the parties can negotiate who should retain the risk for certain pre-closing liabilities. The buyer will often look to the seller to cover risks associated with pre-closing activities through either general representations and warranties or through special indemnity provisions. In conjunction with specific indemnities, the parties may negotiate special indemnity caps and baskets, escrows or holdbacks to cover liabilities. For example, if the target is in the midst of negotiating a settlement with the government, the parties may estimate the likely financial risk to the company and place that amount in a special escrow funded by the purchase price. The special escrow will be used to fund the settlement upon final resolution. This same approach is sometimes used for pending repayments, self-disclosures, potential employment disputes and other noncompliance scheduled by the seller or identified by the buyer.

[D] Reassessing Deal Structure

Short of walking away from a transaction all together, one of the last options to navigate diligence risks involves renegotiation of the deal structure. These options are often disfavored by the parties because it may be time-consuming, create tax liability, or otherwise impact the business-model originally envisioned by the buyer. Nevertheless, restructuring a transaction can be a very effective method to reduce historic compliance and regulatory risks that would otherwise make the transaction infeasible.

Generally, the most common restructuring involves conversion from a stock or equity purchase into an asset purchase. As noted above in more detail in Section 3(I) above, asset transactions provide the buyer the ability to leave problematic assets behind, including refusing assignment of Medicare provider agreements and enrollments (assuming the appropriate procedure is followed). Though conversion to an asset deal provides more certainty regarding potential regulatory risks, asset transactions have their downsides. Depending on the type of facility and jurisdiction, an asset transaction may trigger the need for completely new licenses and payor enrollments. This can be time-consuming, leading to closing delays and creating cash flow disruptions or losses. Though a delayed closing is not ideal, closing a transaction without obtaining necessary licenses or payor enrollments could result in additional regulatory exposure or financial losses. In evaluating alternative transaction structures, the parties will need to thoroughly research and weigh the benefits and disadvantages of any proposed changes.

Though not always possible, a potential alternative to conversion to an asset deal involves carving out or spinning out a troublesome business line or entity from the scope of a transaction. Sellers, however, may not prefer this option. As a result of diligence discussions, most sellers become aware of any regulatory issue uncovered and may not want to operate that aspect of business going forward and retain the associated liability. More importantly, however, anything that lowers the initial purchase price could prompt the seller, in this competitive market, to look for another buyer.

§ 3.07 CONCLUSION

Ultimately, every health care transaction is different. The transaction and its diligence process will be driven by the items and services the target offers, how those services are reimbursed, and the regulations that govern the business. Given the differences in the regulations applicable to different sectors of the health care industry, there is no one-size-fits-all mechanism to evaluate compliance in diligence. However, one thing is universally true given the complexity of health care: there are risks involved. Understanding, evaluating, and handling those risks is an increasingly important aspect of handling mergers and acquisitions in health care.

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