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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

MAY 2018

QUICK SHOTS

Recent developments provide guidance to evaluate FCA Lawsuits.

Read more (subscription required).

Fifth Circuit opens door to injunctive relief for providers awaiting ALJ hearing on alleged overpayment.

Read more.

2018 Bipartisan Budget Act gives HHS Secretary greater authority to grant waivers or exceptions to the Stark Law.

Read more.

Healthcare Hazards Involving Medical Records During Bankruptcy

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Companies in the healthcare industry face many unique challenges when undergoing a bankruptcy, including challenges arising due to the federal and state law framework governing the use and disclosure of medical information. In February 2018, the U.S. Department of Health and Human Services (HHS) announced that it had reached a settlement with the receiver appointed to liquidate the assets of Filefax, Inc., a medical record storage and transportation company, resolving claims against Filefax for potential violations of the Health Insurance Portability and Accountability Act (HIPAA). The HHS investigation, which commenced in 2015, indicated that Filefax impermissibly disclosed the protected health information (PHI) of 2,150 individuals by leaving the PHI in an unlocked truck in the Filefax parking lot, or by granting permission to an unauthorized person to remove the PHI from Filefax and leaving the PHI outside the Filefax facility for collection in an unsecured manner. During the investigation, Filefax stopped operating and was involuntarily dissolved. As part of the settlement, the receiver agreed to pay $100,000 out of the receivership estate and to properly store and dispose of the remaining medical records in compliance with HIPAA.

Medical Record Storage and Maintenance

While HIPAA requires covered entities (i.e., health plans, healthcare providers, and healthcare clearinghouses) and their business associates (generally, persons or entities providing services that involve the use or disclosure of PHI to or on behalf of a covered entity) to maintain the privacy and security of PHI during maintenance, storage, and disposal of PHI, state laws typically govern the length of time the medical records must be kept. For example, in Texas, a hospital must maintain medical records for 10 years from the date of last treatment of the patient, or, if the patient was under 18 when last treated, for the longer of

10 years or until the patient reaches the age of 20. State laws can vary based on the type of person or entity and record involved, although often these record maintenance laws apply only to specific types of healthcare providers. In addition, certain other statutes may apply. For example, the Centers for Medicare & Medicaid Services ("CMS") require hospitals to maintain medical records for five years.

Maintenance and storage of medical records may be complicated further if the covered entity or business associate is undergoing a bankruptcy and lacks the financial resources required for proper maintenance and storage of the patient records. The United States Bankruptcy Code (the "Bankruptcy Code") permits a "health care business" that is a debtor in bankruptcy to dispose of patient records in a certain manner if the debtor/trustee has insufficient funds to pay for storage of the patient records as required by federal or state law. Specifically, the healthcare business must publish notice in a newspaper of the intent to destroy the records and must attempt to contact directly each patient and the patient's insurance provider. The records must be kept for at least one year, and if no one claims the records, the trustee must offer them to the appropriate federal agency. Records that are not accepted by the appropriate federal agency may then be destroyed as set forth in the Bankruptcy Code. A "health care business" is defined in the Bankruptcy Code to include any public or private entity that is primarily engaged in offering to the general public facilities and services for the diagnosis or treatment of injury, deformity, or disease, and surgical, drug treatment, psychiatric, or obstetric care, including, but not limited to, any hospital, emergency or surgical treatment facility, hospice, home health agency, and nursing, assisted-living, or long-term care facility.

While the definition of "health care business" in the Bankruptcy Code covers many healthcare providers, it does not cover every healthcare provider.[1] Further, if there is no applicable federal or state law requiring the healthcare business to maintain the patient records for a certain period of time, courts have some discretion to develop procedures on a case-by-case basis. For example, after finding no relevant state law requiring the debtor to maintain the patient records and noting that the trustee had no funds to store patient records, the court in *In re LLSS Mgmt. Co., Inc.* ordered the trustee to keep a compact disk (for no cost) that contained the names and addresses of patients to whom a prescription mixture was given and for whom anti-depressants were prescribed, and to notify patients that their medical histories would be shredded after sixty days.[2]

Disclosure of Records During Sale or Winding Up

Part of the bankruptcy or winding up process may involve the sale of some or all of the debtor's assets, and potential purchasers may have access to medical information during the due diligence process. HIPAA has certain exceptions to allow for the disclosure of PHI during the due diligence process, but the exceptions are limited in nature and must be analyzed carefully to ensure compliance. For example, a covered entity may disclose PHI for due diligence related to a sale, transfer, merger, or consolidation without obtaining patient consent if the transaction is between two covered entities, or between a covered entity and an entity that will become a covered entity following the transaction.

Best Practices

Given the complexity of the federal and state laws applicable to medical record privacy and security during a bankruptcy or winding up, companies in the healthcare industry should take certain steps to limit their exposure (e.g., earmarking funds for medical records management in liquidation or restructuring budgets, and ensuring appropriate privacy and security policies and procedures are continued during this process). Healthcare providers and their vendors should also proactively address medical

record storage, destruction, and ownership in their agreements and consider adding specific provisions to address "wrapping up" services in the event of a bankruptcy. Finally, companies in the healthcare industry should carefully consider disclosures made during a potential purchase and engage legal counsel to help determine whether HIPAA, state laws, and applicable exceptions apply.

[1] See In re 7-Hills Radiology, LLC, 350 B.R. 902 (Bankr. D. Nev. 2006) (finding that a Chapter 11 debtor was not a "health care business" because its radiological services were performed only at the request of a referring physician and were not offered to the general public).

[2] *See No. 07-02678-5-ATS, 2008 WL 395184 (Bankr. E.D.N.C. Feb. 11, 2008).*

Ninth Circuit Decision Impacts Settling FCA Defendants

Stacy Brainin and Taryn McDonald

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The False Claims Act (FCA) contains a number of provisions designed to prevent follow-on or parasitic lawsuits. One such provision is the government action bar, which prohibits a person from bringing an FCA action "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party."[1] In a 2-1 decision, the Ninth Circuit recently held that the government action bar prohibited a subsequent suit based on allegations that were made in a previously settled suit in which the government intervened, settled some of the claims, and dismissed the case, even though the previously-settled suit was no longer active.[2] The Ninth Circuit's decision is a big win for settling FCA defendants concerned about future suits based on similar allegations. Under the Ninth Circuit's decision, as long as the government intervenes and settles some of the claims, then the government action bar would prohibit any future relator from bringing a later suit based on the same allegations. It should be noted, however, that the government continues to take an active stance against the Ninth Circuit's decision, urging other courts to instead hold that the government action bar only applies while the government remains a party to an active suit.

Case Summary

In *United States ex rel. Bennett v. Biotronik, Inc.*, the relator brought an FCA suit based on allegations in a previously settled suit in which the government intervened and settled the case. Upon settlement, the entire first suit was dismissed—with prejudice as to the "covered conduct" and without prejudice with respect to all other conduct.

The defendant moved to dismiss the case under the government action bar. The relator argued that the bar should not apply for two reasons. First, the relator argued that the statutory language of the government action bar, which is written in the present tense, should not prohibit his subsequent suit because the first suit was no longer pending and therefore the government no longer "is" a party to it.[3] Second, the relator argued that the government action bar does not apply to the claims in the first suit, which the government did not settle and which were dismissed without prejudice.[4] The district court rejected both arguments, and the Ninth Circuit affirmed.

As to the relator's first argument, the Ninth Circuit explained that the government is and remains a "party" to an action even after the suit is concluded. The court explained that such a reading is consistent with both common sense and the statutory language of the government action bar.[5] Had Congress intended a different interpretation, the court

reasoned, it could have used the word "pending" as it did in other sections of the FCA—but it did not.[6]

As to the relator's second argument, the Ninth Circuit again disagreed, explaining that the government action bar precluded the *entire* second suit, even though the government had intervened in the first suit and settled only the claims "related to certain 'covered conduct.'"[7] The court reasoned that "[t]here is nothing in the FCA which indicates that, upon joining and settling a lawsuit, the government becomes a party to the suit with respect only to those claims which it settles, but it is not a party to the suit with respect to those claims which it does not settle."[8]

The dissenting judge stated he was "most impressed" by the position of the United States in its amicus brief.[9] That brief argued that the interpretation of the statute hinges on the words "are" and "is," which would lead the dissenter to conclude that the statute refers to the present tense.[10] In addition, the majority's interpretation of the government action bar would discourage relators from bringing forward evidence of fraud following a settled case, and there is "no reason to read the government-action bar to preclude a relator who is an original source, not parasitic, from proceeding on claims that were not resolved before the government was dismissed as a party."[11]

The Government's Position

Following *Biotronik*, the government has urged at least one other court not to follow the Ninth Circuit. In March, the government filed a Statement of Interest in a case pending in the District of Massachusetts, and it made the same arguments about the government action bar made in its amicus brief in *Biotronik*. The government expressly urged the district court not to follow the Ninth Circuit's decision.[12]

Conclusion

Under *Biotronik*, the government action bar protects FCA defendants from future relators where the government has previously settled related conduct, even if the conduct at-issue was not part of the release. While it does not eliminate the risk that the *government* might later pursue a case as to the unreleased conduct, the Ninth Circuit's decision in *Biotronik* does mean that another relator cannot later bring a suit regarding alleged conduct that the government might have been unwilling to release. We will continue monitoring this area of the law and will report any developments.

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[1] 31 U.S.C. § 3730(e)(3).
[2] See United States ex rel. Bennett v. Biotronik, Inc., 876 F.3d 1011 (9th Cir. 2017).
[3] Id. at 1015.
[4] Id.
[5] Id. at 1016.
[6] Id. at 1018.
[7] Id. at 1020.
[8] Id.
[9] Id. at 1021 (Siler, J., dissenting).
[10] Id. at 1022.
[11] Id.
[12] United States ex rel. Herman v. Coloplast Corp., et al., No. 11-cv-12131. [need to cite pleading – Dkt. 333]

An Update on Telehealth in Texas and Beyond

Michelle "Missy" D. Apodaca and Neil Issar

Telehealth Initiatives on the Rise in Texas

Michelle "Missy" Apodaca

Neil Issar

As published in the **June 2017 issue of *Health Law Vitals***, Texas passed a new law (S.B. 1107) last year that enables healthcare providers to establish a doctor-patient relationship by telehealth—that is, using a telecommunications system without an initial face-to-face meeting.

Accordingly, telehealth provider Teladoc voluntarily dismissed its lawsuit against the Texas Medical Board, which revised its rules to conform to the new law. The Texas Health and Human Services Commission is also in the process of amending the Texas Medicaid Telemedicine Services Medical Policy to implement S.B. 1107. The major proposed amendments include:

- Revised definitions of telehealth services and telemedicine medical services;
- Removal of patient site presenter requirements, with an exception for school-based telemedicine medical services;
- Removal of requirements for initial in-person, face-to-face visits between physicians and patients prior to telemedicine medical services; and
- Alignment of telehealth service delivery modalities and operational requirements with those for telemedicine medical services.

Unsurprisingly, the post-S.B. 1107 environment has seen several telehealth initiatives emerge across the state in recent months. We highlight three such initiatives below.

In December, first responders in Harris County, the most populous county in Texas, began a pilot program called Emergency Mobile Psychiatric Assessment via Telehealth (EMPATH). The program arms law enforcement officers with tablets to provide a real-time video connection with psychiatrists available around-the-clock. This allows officers to obtain emergency telepsychiatry evaluations when encountering mental health patients in crisis. The project is a joint effort of the Harris County Sheriff's Office and three companies: Houston-based JSA Health Telepsychiatry, which provides the program's psychiatrists; Cloud 9, an Austin-based startup that developed a mobile app that allows psychiatrists to securely video chat with clients; and Verizon, which provided free use of mobile devices and its cellular network.

In January, Methodist Family Health Centers launched an online diagnosis and treatment service called **Methodist NOW**. The service provides asynchronous store-and-forward technology. Consumers first fill out an online questionnaire with clinical information. A Methodist physician then reviews the information, communicates with the patient via a real-time chat function, if necessary, and quickly provides a diagnosis and treatment plan. The service is powered by Minneapolis-based telemedicine vendor Zipnosis, which has delivered "virtual care" solutions to nineteen other health systems across the country. Hospitals in other states have similarly partnered with healthcare startups to launch asynchronous store-and-forward services. For example, Cambia Health Solutions in Portland, Oregon, **recently partnered** with San Francisco-based Lemonaid Health to help provide employees with online medical advice and prescriptions for common non-acute health issues.

Finally, the Northwest Texas Healthcare System recently received a federal Distance Learning and Telemedicine (DLT) grant worth $427,113 to fund the Texas Panhandle Specialty Telemedicine Project—a new telehealth platform that will link the system's acute care hospital to a network of seven healthcare facilities in the Texas panhandle. The U.S. Department of Agriculture issues DLT grants to finance telehealth projects that seek to improve healthcare access for rural and underserved populations.

Federal Legislative and Regulatory Changes Increasing Telehealth Access

The Bipartisan Budget Act (H.R. 1892) signed into law in February includes key portions from several telehealth bills—namely, the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act, Furthering Access to Stroke Telemedicine (FAST) Act, and Increasing Telehealth Access to Medicare Act—that increase access to and reimbursement for telehealth services. For example,

the new law allows Accountable Care Organizations to include a patient's home as an eligible originating site for telehealth services;[1] eliminates geographic restrictions on reimbursement for telestroke consultation services, beginning in 2019; and adds freestanding dialysis facilities, without geographic restriction, to the list of originating sites for patients' monthly telehealth assessments with a nephrologist, beginning in 2019.

The law also allows Medicare Advantage plans to provide additional telehealth benefits, beginning in 2020. These benefits include benefits that are available under Medicare Part B but are ineligible for payment due to current Medicare restrictions on telehealth and services that are identified as clinically appropriate to furnish using electronic information and telecommunications technology when a physician or practitioner is not at the same location as the patient.

Additionally, the CMS Medicare Physician Fee Schedule final rule for CY 2018 expanded the list of telehealth services that can be reimbursed as "Medicare services" by adding seven new codes:

- HCPCS code G0296 (visit to determine low dose computed tomography (LDCT) eligibility);
- CPT code 90785 (Interactive Complexity);
- CPT codes 96160 and 96161 (Health Risk Assessment);
- HCPCS code G0506 (Care Planning for Chronic Care Management); and
- CPT codes 90839 and 90840 (Psychotherapy for Crisis).

The final rule also decreased providers' administrative burdens in billing the government for telehealth services by eliminating the required reporting of telehealth modifier GT (via interactive audio and video telecommunications systems) for professional claims. This modifier was deemed redundant since providers are also required to report a place-of-service code describing services furnished via telehealth.

Legislative changes expanding access to care via telemedicine continue to be explored by Congress. For example, the Senate recently passed the bipartisan Veterans E-Health & Telemedicine Support (VETS) Act (S. 925), which expands telehealth services—including mental health treatment—for disabled or rural veterans by allowing Department of Veterans Affairs officials to practice telemedicine across state lines. Additionally, several members of Congress are identifying legislative vehicles to eliminate the restrictions on Medicaid reimbursement for substance abuse treatment to be provided via telehealth and to provide remote patient monitoring.

We will continue to monitor telehealth activities at a state and national level and provide updates.

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[1] 1 An "originating site" is the location of an eligible Medicare beneficiary at the time a telehealth service is furnished. The originating sites traditionally authorized by law are physicians' offices, hospitals (including critical access hospitals), rural health clinics, federally qualified health centers, hospital-based renal dialysis centers, skilled nursing facilities, and community mental health centers. Medicare beneficiaries are eligible for telehealth services only if the originating site is located in a rural Health Professional Shortage Area or in a county outside of a Metropolitan Statistical Area.

Guidance to Avoid FCA Liability for Firms Investing in Healthcare Companies

Chris Rogers and Neil Issar

Chris Rogers

Neil Issar

The United States recently intervened in a lawsuit alleging that a pharmacy violated the False Claims Act, 31 U.S.C. §§ 3729 et seq. (FCA), by paying millions in kickbacks to

marketers and submitting false claims for medically unnecessary prescriptions. Notably, the lawsuit named as a defendant the private equity firm that owns the pharmacy based on the firm's involvement in the alleged kickback scheme and the pharmacy's management. The government's intervention indicates that firms investing in healthcare companies could be liable under the FCA and, therefore, must exercise best practices and conduct due diligence with respect to the management of portfolio companies.

Key Points

In an unusual case, the government filed a complaint against a pharmacy, its private equity firm majority owner and two principals of that firm based on a kickback scheme conducted by the portfolio company.

The private equity firm's conduct was directly related to the scheme – its partners allegedly directed the change in strategy to focus on high reimbursing product lines such as compounded pain creams, scar creams, and vitamin supplements and directly funded commission payments that led to medically unnecessary claims.

The conduct alleged demonstrates the high legal bar for a portfolio healthcare company to create FCA liability for its owners but highlights the risk that exists for investors in this industry. That risk can be minimized by taking some key precautions when investing in healthcare companies.

Background

On March 7, 2016, two former employees of Diabetic Care Rx, LLC d/b/a Patient Care America (PCA), a compounding pharmacy located in Florida, filed a *qui tam* suit alleging that PCA violated the FCA by paying approximately $40 million in kickbacks to marketing agencies in exchange for securing TRICARE patients.[1] The defendants allegedly paid telemedicine doctors to issue medically unnecessary prescriptions for compounded pain creams, scar creams, and vitamins and waived patients' copayments to induce them to accept the prescriptions. After two years of investigation, the government filed a complaint in intervention against the defendants on February 16, 2018.

Notably, the government's complaint named two pharmacy executives and the private equity firm that owns a controlling interest in PCA as defendants in the action.[2] The government's complaint alleges that the private equity firm conspired with PCA, approved and bankrolled the alleged kickback scheme, and was actively involved in PCA's management. For example, after it purchased PCA for $25 million in 2012, the complaint alleges that the private equity firm shifted the pharmacy's focus towards compounded topical drugs to take advantage of high federal reimbursement rates and installed two of its partners as PCA officers and board members. These partners were allegedly involved in the payment of independent marketers as well as the selection and hiring of PCA executives.

Practical Takeaways

The government's intervention in the case against PCA should serve as a reminder that FCA liability may apply to any person or entity that "causes" a false claim to be submitted, and not just to those that submit claims themselves. The press release accompanying the government's complaint noted that the Department of Justice sought to hold liable all entities that paid kickbacks to maximize reimbursement at the expense of taxpayers and federal healthcare beneficiaries, including pharmacies *and those companies that manage them*.[3]

This means private equity firms, venture capitalists, and individual owners should be particularly conscientious about FCA compliance if they actively manage their portfolio companies' strategies, operations, or board decision-making. Taking preventative steps in the purchase, sale, and

management of these companies can minimize this risk.

These include:

- When conducting due diligence, obtaining legal analysis of business structures, particularly those involving sales, marketing, payment of commissions, and financial relationships with healthcare providers or referral sources.
- Ensuring portfolio companies have adequate internal compliance policies and procedures to identify problematic conduct or business relationships, especially if the healthcare company participates in federal government programs.
- Carefully scrutinizing relationships with healthcare providers, marketing agents, or company executives that are based on revenue or referral volume.
- Comparing portfolio companies' product or service offerings to published government enforcement priorities.
- Obtaining experienced legal counsel with healthcare expertise, whether in-house or externally, to support management and board members.

While the PCA case is likely an unusual case that will remain an outlier in healthcare enforcement, taking appropriate measures to ensure compliance and being proactive in due diligence will help protect investors against FCA liability while still allowing them to add value to their portfolio companies through control and oversight.

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[1] The case is United States ex rel. Medrano v. Diabetic Care Rx, LLC, No. 15-CV-62617 (S.D. Fla.).
[2] The complaint did not name as defendants' minority owners of PCA.
[3] See Press Release, Dep't of Justice, United States Files False Claims Act Complaint Against Compounding Pharmacy, Private Equity Firm, and Two Pharmacy Executives Alleging Payment of Kickbacks (Feb. 23, 2018).

UPCOMING SPEAKING ENGAGEMENTS

CMS Final MACRA Rule Webinar
Lorman Education Services
Kenya Woodruff
May 22, 2018
Register here

Value-Based Payments and CMS Bundled Payment Initiatives in a Fee-For-Service World
AHLA Annual Meeting
Kenya Woodruff
June 26, 2018
Chicago, Illinois

False Claims Act Mid-Year Update
Dallas Bar Association Meeting
Chris Rogers and Nicole Somerville
June 20, 2018
Dallas, Texas

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

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