

Health Care Liability & Litigation

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Looking Into the Future: Emerging Areas of False Claims Act Liability for Government- Sponsored Health Plans

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Medicare Advantage and Medicaid managed care are growing. One by-product of this growth is that Medicare Advantage organizations (MAOs) and Medicaid managed care organizations (Medicaid MCOs) are increasingly becoming the focus of False Claims Act (FCA) investigations and qui tam lawsuits. The recent spate of FCA lawsuits relating to Medicare Advantage (MA) risk adjustment is just an example of this sharpened focus on FCA claims against health plans—and likely promises to be just the beginning because qui tam counsel and the government are becoming more comfortable with health plan data. This article examines emerging areas of potential FCA liability for government-sponsored health plans with a particular focus on FCA theories predicated upon the alleged false certification of data and express and/or implied certification of program compliance.

Data Certification Is the Foundation of Payments to Government-Sponsored Health Plans

MA (Medicare Part C) is an alternative to the traditional government-administered fee-for-service program. Under MA, the Centers for Medicare & Medicaid Services (CMS) contracts with private health insurers (referred to as MAOs) to administer Medicare benefits to beneficiaries. CMS pays MAOs capitated payments on a per-member/per-month (PMPM) basis that are determined by annual bids that the MAO submits to CMS. In the bidding process, MAOs provide actuarial estimates of their costs to CMS, including medical claims costs, for the following year.¹ In doing so, the MAO uses past medical expense experience and applies that experience to actuarial assumptions to derive the bid amount.² CMS then applies the bids to a “benchmark”

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—from a declaration of the American Bar Association

based by 2020, but that deadline is likely to be extended. EDS is a complete 837 (encounter) file for every service episode. EDS data is more complex than RAPS data because it is a complete encounter in a more sophisticated “loop and segment structure” that contains header and line level detail for all claims. As a result, EDS provides more opportunity for inaccuracies and can be difficult for plans to remediate. Like the bid submission data, the CEO, CFO, (or their authorized delegate) of the MAO must personally attest to the accuracy, completeness, and truthfulness of the risk adjustment data, including encounter data, as CMS moves to 100% EDS.¹⁰ In addition, given the data flow, providers must also certify the accuracy, completeness, and truthfulness of risk adjustment data.¹¹

Medicaid managed care shares similar traits as MA. Like MAOs, states contract with private health plans (referred to as Medicaid MCOs) to administer Medicaid benefits in lieu of the state fee-for-service Medicaid program.¹² Under those contracts, states usually pay the Medicaid MCOs a PMPM capitated payment and most states risk adjust those payments just like MA.¹³ Moreover, states have increasingly implemented quality-based holdbacks where the state will withhold a portion of the PMPM capitated payment that the state will only pay if the plan meets certain quality metrics, which are usually based on Healthcare Effectiveness Data and Information Sets (HEDIS) data. However, all of the payments to the Medicaid MCOs must be actuarially sound.¹⁴ To develop actuarially sound capitation rates, states are required to take into account historical medical expenses and make adjustments in accordance with generally accepted actuarial standards to account for medical trends and utilization.

The basis for payment to Medicaid MCOs, like MAOs, is data. For instance, Medicaid MCOs must submit to the state enrollee encounter data that may be used to identify services rendered and set capitation rates, determine risk adjustment, and evaluate MCO quality and cost performance. Like in MA, the CEO, CFO, or an individual who reports directly to the CEO or CFO with delegated authority, must attest that, based on best information, knowledge, and belief, the encounter data is accurate, complete, and truthful.¹⁵ States must ensure that Medicaid MCOs submit accurate data in the appropriate format and CMS has the authority to withhold federal funds to states for failure to comply with encounter data submissions—which means that the regulations expressly condition federal payments on the accuracy of encounter data.¹⁶ Beyond encounter data, Medicaid MCOs must submit data to demonstrate the plans’ medical loss ratio (MLR), as well as any other data required by the state to determine actuarially sound rates—all of which must be certified as accurate.¹⁷

Emerging FCA Theories Against Plans

The FCA is not a new threat to government-sponsored health plans. However, historically there have been relatively few FCA cases against health plans when compared to hospitals and physicians. This was likely due to the complexity of the managed

care business and the fact that plans do not submit “claims” to the government in the traditional sense. Nevertheless, many of the FCA cases brought against plans over the past 10-15 years resulted in large recoveries to the government.¹⁸ Those early cases against plans tended to allege that the plan falsely represented that it paid for services that were not, in fact, performed, or another alleged fraud in the administration of Medicaid benefits such as marketing violations.

In recent years, however, there has been an uptick in FCA cases targeting health plans based upon data submissions. The most notable example is the onslaught of cases against MAOs related to alleged false RAPS data for MA risk adjustment payments. As explained earlier, CMS uses RAPS data to make increased payments to MAOs based upon the actual medical claims experience for enrollees. In conjunction with criticism from government oversight agencies and inquiries into risk adjustment data from certain members of Congress, as well as increased CMS risk adjustment validation audits,¹⁹ the Department of Justice has increased its efforts at targeting MAOs for submitting allegedly false risk adjustment data.²⁰ Importantly, as the Ninth Circuit explained in the seminal 2016 case of *Swoben v. United Healthcare Insurance Company*, the false claims are the false certification by the MAOs under the applicable Medicare Advantage regulation (42 C.F.R. § 422.504(l)) that the RAPS data is accurate.²¹ Thus, the focus was on what the MAO did to validate (or allegedly not validate) the risk adjustment data.

We can expect that FCA cases over risk adjustment data will become a fixture in the industry due to the inherent uncertainty of that data and easy ability of relators’ counsel to argue false certification. MAOs need to be particularly wary as they move towards 100% EDS because that data is much more complex and difficult to manage than RAPS data. Exacerbating those difficulties, at least one study has concluded that EDS encounter data has the potential to reduce payments to MAOs compared to RAPS data, which may cause MAOs to look to creative but compliant ways to remediate the EDS data to ensure there is no revenue leakage.²² In doing so, plans should note that the 2017 Office of Inspector General Work Plan includes evaluating the integrity of MA encounter data.²³

These MA risk adjustment cases are likely just the beginning of FCA cases against government-sponsored health plans based upon false certification theories because data certification is the foundation to all payments to MAOs and other government-sponsored managed care plans. As explained above, the government pays government-sponsored health plans almost solely upon the plans’ submission of data that the plan attests is accurate and complete. The applicable MA and Medicaid managed care regulations and contracts contain a laundry list of data sets and other submissions that plans must make to the government while certifying their accuracy. Beyond risk adjustment data, MAOs must certify the data and information upon which they submit their bids to CMS and one could easily see relators and their counsel

arguing that MAOs certified that data without taking appropriate steps to validate it or that the plan relied upon data that it should have known is not valid.

Medicaid encounter data is another good example because it is used to set capitation rates and, if applicable, risk adjustment payments for Medicaid MCOs. Yet, it is widely known that Medicaid encounter data is problematic and possibly inaccurate. As states start to feel more pressure from CMS to ensure the Medicaid encounter data is accurate, that pressure will flow downstream to the MCOs, which provides a perfect storm for potential whistleblowers to assert claims relating to the plans' efforts to certify the accuracy of their data. Again, the Ninth Circuit's decision in *Swoben* is important because it establishes the foundation for relators and their counsel to argue that any certified data set must be properly validated and any operational or compliance wrinkle in the validation process will provide an argument that the certifications are false.

Beyond data and false certifications, government-sponsored health plans will almost certainly see an uptick in other alleged program violations re-cast as FCA cases by whistleblowers and relators' attorneys. Although government-sponsored health plans do not submit traditional "claims" to the government for payment, they are nevertheless prime targets for "legally" false claims because plans either expressly or impliedly certify compliance with all program requirements. Thus, relators and their counsel have many opportunities to argue that non-compliance could ostensibly give rise to FCA liability. Those types of cases will likely turn on a "materiality" analysis as recently articulated by the U.S. Supreme Court in *Universal Health Services v. U.S. ex rel. Escobar*.²⁴ Of some help to health plans is the fact that the U.S. Supreme Court explained that the "materiality" standard is "demanding" and "garden-variety breaches of contract or regulatory violations" should not translate into FCA liability.²⁵

Conclusion

As government-sponsored health plans look forward, one reality is clear: MAOs, Medicaid MCOs, and Medicare Part D plans are increasingly becoming targets of diversified FCA claims that may pose significant risk. The focus of future FCA claims against government plans will almost certainly involve false certification theories, as well as express or implied certification theories based upon program non-compliance. While plans have extensive arguments to combat these cases, they will nevertheless continue to become an increasing component of government-sponsored plans' risk profile.

- 1 See 42 U.S.C. § 1395w-24(a)(1)(A).
- 2 42 U.S.C. § 1395w-24(a)(6)(A)(i), (iii).
- 3 42 U.S.C. § 1395w-23(j)-(k) (2014); 42 C.F.R. 422.312 (2014).
- 4 42 U.S.C. § 1395w-23(a)(1)(B)(i).
- 5 CMS, Medicare Managed Care Manual, Chapter 8, § 60.4; 42 U.S.C. § 1395w-23(a)(1)(B)(ii) (2014).
- 6 42 C.F.R. § 422.504(l)(4); see also 42 C.F.R. § 422.254.
- 7 Medicare Part D plans also receive risk adjustment payments. See, e.g., CMS, Medicare Managed Care Manual, Chapter 7, § 30.
- 8 See CMS, Medicare Managed Care Manual, Chapter 7, §§ 20 & 30.
- 9 See CMS Medicare Managed Care Manual, Chapter 7, Risk Adjustment, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf>.
- 10 42 C.F.R. § 422.504(l)(2); see also 42 C.F.R. § 422.310.
- 11 42 C.F.R. § 422.504(l)(3).
- 12 See 42 U.S.C. § 1396b(m).
- 13 See 42 C.F.R. § 438.4; see also 42 C.F.R. § 438.6.
- 14 See id.
- 15 See 42 C.F.R. § 438.604; see also 42 C.F.R. § 438.606.
- 16 See 42 C.F.R. § 438.818.
- 17 See 42 C.F.R. § 438.604(a).
- 18 See, e.g., *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill. 2007) (The federal and state government intervened in an FCA case and, after a four week jury trial, the court entered a judgment against Amerigroup for a total of \$334 million, which Amerigroup ultimately settled at \$225 million); *United States ex rel. Kerr v. APS Healthcare, Inc.*, Case No. 2:11-cv-01454-MMD-GWF (D. Nev. Jan. 30, 2013).
- 19 See, e.g., Center for Public Integrity, *Why Medicare Advantage Costs Taxpayers Billions More than it Should*, available at <https://www.publicintegrity.org/2014/06/04/14840/why-medicare-advantage-costs-taxpayers-billions-more-it-should>; see also GAO, *Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments*, at p. 2, available at <http://www.gao.gov/assets/680/676441.pdf>.
- 20 See, e.g., *United States v. Janke*, No. 2:09-cv-14044-KMM (S.D. Fla.), Docket No. 1, ¶¶ 38-39 (applying sampling and alleging that the MAO falsely submitted risk adjustment data and claiming over \$90 million in damages plus civil penalties); *Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. Dec. 16, 2016), remanded to district court as *Swoben v. SCAN Health Plan*, No. 2:09-cv-05013 (C.D. Cal.) (DOJ intervened as to United defendants and action the DOJ's intervening complaint was dismissed without prejudice in October 2017 and the DOJ chose not to amend); *Poehling v. United Healthcare Ins. Co.*, No. 2:16-cv-8697 (C.D. Cal.) (DOJ intervened as to United and other defendants but declined to intervene as to remaining defendants and action pending); *Sewell v. Freedom Health, Inc.*, No. 8:09-cv-1625 (M.D. Fla.) (\$32.5M settlement on May 30, 2017); *Silingo v. Mobile Medical Examination Services, Inc.*, No. 8:13-cv-1348-FMO-JC (C.D. Cal.) (DOJ declined to intervene; settlement by some defendants; dismissal as to other defendants and on appeal to 9th Circuit, No. 16-56400 with briefing underway); *Valdez v. Aveta, Inc.*, No. 3:15-cv-01140-CCC (D.P.R.) (DOJ declined to intervene; case pending with Quinn Emanuel Urquhart & Sullivan, LLP as relators' counsel); *Graves v. Plaza Medical Centers, Corp.*, No. 10-23382-CIV-MORENO (S.D. Fla.) (settled weeks before trial with the defendants paying the United States \$3 million).
- 21 *Swoben*, 848 F.3d at 1173-1175.
- 22 See Deana Bell, David Koenig, Charlie Mills, *Impact of the Transition from RAPS to EDS on Medicare Advantage Risk Scores*, available at <http://www.milliman.com/insight/2017/Impact-of-the-transition-from-RAPS-to-EDS-on-Medicare-Advantage-risk-scores/>.
- 23 <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000265.asp>.
- 24 *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).
- 25 *Id.* at 2003.

Discovery Pertaining to the Authenticity and Integrity of Electronic Medical Records and Its Impact in Medical Malpractice Cases

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An increasingly common discovery request in medical malpractice claims are requests directed to the authenticity and veracity of an injured or deceased patient's electronic medical record (EMR or EHR). The shift from paper to electronic medical records¹ was hastened for many providers by the American Recovery and Reinvestment Act's requirement² that all public and private health care providers eligible for reimbursement from Medicare or Medicaid make "meaningful progress" towards the adoption of EMR. According to recent statistics from the Department of Health and Human Service's Office of the National Coordinator of Health Information Technology, as of the end of 2016, more than 95% of hospitals and over 60% of all U.S. office-based physicians have demonstrated meaningful use of certified health information technology through the Centers for Medicare and Medicaid Services' (CMS) EHR Incentive Programs.³

The widespread adoption of EMR by even the smallest health care providers has had excellent results in terms of patient care. This transition from paper to electronic medical records also has helped ensure that patients and other providers outside of a medical system now can more easily access (and read) a patient's records from other providers.

However, one unintended consequence of the nearly-universal use of EMR has been to open up a patient's medical record as an avenue of attack against a health care provider or facility in the event of an adverse medical incident. With EMRs, it is easier for attorneys to determine when, how, and by whom a patient's records are created, accessed, modified, and altered. Thus, certain types of discovery requests are becoming commonplace in medical malpractice claims. The discovery requests often include requests for production for all metadata associated with a patient's EHR and audit trails of that same EHR.

A patient's EMR, particularly if it shows changes made by health care providers

after an adverse medical incident, can be a powerful tool for a patient's attorney in a medical malpractice claim. It can range from a minor headache to a complete nightmare for a defense attorney. It can force settlement on terms that might not be otherwise warranted given the facts of the case. Therefore, attorneys for both sides in such cases need to focus not only on what the records themselves show, but also on what underlying information the patient's EMR may also contain.

What is Metadata and What Does It Show?

Metadata refers to the data regarding creation, subsequent changes, and other identifying information associated with a particular electronic file. In the words of one Pennsylvania state court, "[m]etadata is data typically stored electronically that describes characteristics of ESI [electronically stored information], found in different places and different forms, and while some metadata such as file dates and sizes, can easily be seen by users, other metadata can be hidden or embedded and unavailable to computer users who are not technically adept."⁴ The metadata for a patient who received care from multiple services in a hospital setting, for instance, would reflect each of the different computers from which the particular patient's EMR was edited and/or accessed.

The reason metadata is so important, particularly in medical malpractice litigation where the veracity or authenticity of a patient's medical record may be in question, is that it cannot be changed or "scrubbed" even if the electronic document is later edited or altered. The metadata remains, no matter what happens to the document. Therefore, in cases where the authenticity or



veracity of an electronic document is in question, the metadata can assist either side, depending on what it shows.

Upon a request from a patient's attorney, courts typically will order production of metadata associated with a patient's electronic medical record.⁵

What is An Audit Trail?

In contrast to metadata, which exists as an intrinsic part of the electronic file itself, most commercial EMR programs offer the ability to run a report on command that lists every user who has ever accessed a patient's EHR and what actions each provider performed in the chart. "The audit trail is the metadata for a patient's chart that changes every time the chart is accessed or altered" and "provides direct evidence of exactly what was done--when, where and by whom--to a patient's EMR."⁶

An audit trail can be a useful device due to the information it reveals about who accessed a patient's medical records and what each person that accessed those records did inside the patient's chart. It can show not only which health care providers at a particular facility accessed the patient's chart, but can also potentially reveal inconsistencies between the contents of the EHR and a health care provider's testimony as to what occurred during a particularly critical time period.

Much like requests for metadata, courts are increasingly electing to order production of audit trails when requested to do so by a patient's attorney.⁷

What Problems Can Changes to, or a Lack of Information in, the EMR Cause Each Side in a Professional Liability Action?

Changes to the EHR can leave a defense attorney struggling to articulate a credible explanation, particularly if it appears the health care providers were attempting to "cover their tracks" after an adverse medical incident. For example, an audit trail may show no one even entered a patient's chart to document on a critically ill patient despite the patient complaining of severe, life-threatening symptoms.

This was exactly the allegation in a 2016 New York case in which a patient's estate alleged she had presented to a hospital's Emergency Department complaining of severe abdominal pains, nausea, and vomiting. The patient was at the hospital for 5-6 hours before being discharged, allegedly without ever being evaluated by a physician. The next day, the patient collapsed and died from what a subsequent autopsy determined was a twisted loop of intestine, which can (and did) lead to a small bowel infarction and perforation of the small intestine.⁸ Over the hospital's objection, the court ordered production of the complete audit trail of the patient's EHR.⁹ Given the patient's attorney was seeking discovery of the audit trail because the medical records produced by the defendant hospital did not indicate whether an ED physician ever reviewed the patient's medical records prior to discharge, the information revealed in the audit trail could provide the key evidence on which the case would turn.

On the other hand, digging into the electronic medical record can also bolster the defense position. Sometimes, an audit trail may show there was no "smoking gun" like a nurse attempting to cover her tracks as a patient may allege in his or her complaint. This lack of a smoking gun can leave a patient's attorney struggling to prove medical malpractice occurred.

Challenging Discovery Requests Directed to the Accuracy and Authenticity of the EMR

Although courts¹⁰ are more and more often declaring discovery regarding the accuracy and the authenticity of a patient's EMR to be discoverable in civil litigation, there are potential avenues for defense counsel to limit such discovery requests. In the event a patient's attorney requests an audit trail, the case law discussed above is not very friendly to a challenge by the defendant health care providers to such a request. This would stand to reason, as the patient is seeking information regarding his or her *own records*. Any applicable privilege is typically found by the courts to be inapplicable or else outweighed by the patient's right to access his or her own medical records if challenged by a health care provider or facility.

The objection most likely to be successful to a patient's request for an audit trail is an objection based on burdensomeness. Medical malpractice cases typically turn on a particular key time period during what sometimes may be a long course of treatment. A limited challenge to the time period over which metadata or an audit trail is sought is more likely to meet with success than a blanket objection to performing an audit trail at all. If the time period during which the case will turn is a thirty minute period before, after, or during a surgery, then a limited objection to the scope of a requested audit trail for the entire length of the patient's six week pre- and post-surgical hospital stay is more likely to be successful than a blanket objection to performing an audit trail at all.

Conclusion: Ensure Your Audit Trails and Metadata Line Up with the Stories Each of Your Witnesses Are Telling You and Proactively Use the Technological Tools at Your Disposal to Provide Your Client with the Best Advice Possible

Unfortunately for health care providers, both state and federal courts generally are agreeing with patients who claim they need metadata or audit trails of their own electronic medical records to prove their claims. Under the weight of this authority, there is little a health care provider or facility can do to challenge a request once made by the patient's attorneys besides seeking to limit the scope of the request. Therefore, in addition to seeking to limit the scope of the audit trail to as limited a period as possible, defense counsel for health care providers and facilities should consider utilizing the audit trail and metadata functions available in whatever EHR software their client uses to determine what the particular patient's EHR reflects immediately upon being assigned a medical malpractice claim. Knowing what potential skeletons are in the closet on the front end (and before the inevitable discovery requests roll in) will prove much more useful in not only developing a defense strategy for the case but also will assist

defense counsel in advising clients whether there are serious problems with the case that merit potential early resolution.

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1 A *New England Journal of Medicine* article found that in 2008, the following statistics applied to the implementation of electronic health records by health care professionals across the United States:

In 2008, a total of 11% of nonfederal U.S. hospitals had implemented basic EHR systems, and less than 2% had implemented comprehensive systems in at least one clinical unit. A much larger proportion of hospitals had implemented or begun implementation of key EHR functionalities; for example, 56% had implemented or initiated implementation of electronic systems for entry of physicians' notes, and 52% had implemented or initiated implementation of clinical-decision support systems involving practice guidelines. Among physicians whose primary practice setting was not a hospital, 21% had a basic system and 6% had a comprehensive system in 2009.

See Sandeep Mangalmurti, Lindsey Murtagh, and Michelle M. Mello, *Medical Malpractice Liability in the Age of Electronic Health Records*, 363 N. ENG. J. MED. 2060-2067 (Nov. 2010), available at <http://www.nejm.org/doi/full/10.1056/NEJMhle1005210>.

- 2 As a part of this legislation, all public and private health care providers were required to adopt and demonstrate "meaningful use" of electronic medical records by January 1, 2014 to maintain their existing Medicaid and Medicare reimbursement levels.
- 3 See The Office of the National Coordinator for Health Information Technology, Health IT Dashboard, Quick Stats, available at <https://dashboard.healthit.gov/quickstats/quickstats.php>.
- 4 *Brogan v. Rosenn, Jenkins & Greenwald, LLP*, 32 Pa. D. & C. 5th 454, 459 n.1 (Pa. D. Ct. 2013) (internal citations and quotation marks omitted).
- 5 See, e.g., *Hall v. Flannery*, No. 3:13-cv-914-SMY-DGW, 2015 WL 2008345, at *4 (S.D. Ill. May 1, 2015) (ordering production of all metadata associated with patient's electronic medical record).
- 6 Jennifer Keel, *Follow the Audit Trail*, J. LEGAL NURSE CONSULTING, Vol. 26, No. 2 at p. 26 (Summer 2015).
- 7 See, e.g., *Picco v. Glenn*, No. 12-cv-02858-RM-MJW, 2015 WL 2128486, at *9 (D. Colo. May 5, 2015) (ordering production of a complete audit trail of a patient's medical records); *Borum v. Smith*, No. 4:17-CV-00017-JHM, 2017 WL 3014487, at *5 (W.D. Ky. June 14, 2017) (ordering production of a complete audit trail of a patient's records upon the patient's request); *Baker v. Geisinger Community Medical Center*, No. 16 CV 2946, 2017 WL 1293251, at *5 (Pa. Com. Pl. Apr. 7, 2017); *Gilbert v. Highland Hospital*, 31 N.Y.S. 3d 397, 400 (N.Y. Sup. Ct. 2016); *Osborne v. Billings Clinic*, No. CV 14-126-BLG-SPW, 2015 WL 1412626, at *4 (D. Mont. Mar. 26, 2015); *Fernandez-Rajotte v. Dartmouth Hitchcock Medical Center*, No. 215-2011-CV-00455, 2014 WL 12540494, at *4-5 (N.H. 2014).
- 8 *Gilbert v. Highland Hosp.*, 31 N.Y.S.3d 397, 400 (N.Y. Sup. Ct. 2016).
- 9 *Id.*
- 10 See notes 7 and 8 *supra* and sources cited therein.

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Health Care Provider Liability and Litigation Topics at AHLA's *Fundamentals of Health Law*

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Health law is incredibly broad and intersects with several practice areas including corporate, labor and employment, administrative, real estate, privacy, and contracts. The additional layer of compliance and regulatory laws that govern medical providers make business transactions and relationships complex and can cause significant legal implications and liability for health care providers.

During AHLA's *Fundamentals of Health Law* conference in Chicago, IL on November 6-8, 2017, the speakers addressed a variety of health law topics, including physician employment contract litigation, and potential liability under federal health care laws, including the Stark Law, Anti-Kickback Statute (AKS), False Claims Act (FCA), and the Health Insurance Portability and Accountability Act (HIPAA).

Stark and AKS Liability

Stark Law and AKS liability was the focus of Marc D. Goldstone and Donn H. Herring's presentation and is an area where litiga-

tors may be involved to defend provider clients against claims of non-compliance. As the speakers explained, the Stark Law is a federal law (42 U.S.C. § 1395nn), prohibiting a physician from referring certain designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, absent the presence of a statutory exception.

They also discussed the federal AKS (42 U.S.C. § 1320a-7b(b)), which prohibits a provider from "knowingly and willfully" soliciting or receiving any remuneration in exchange for federal health care program referrals. The Stark law is a strict liability statute whereas the AKS requires unlawful intent.¹

Identifying a Stark Law Violation

Although best-practice dictates that a provider consult with his or her attorney before engaging in certain business relationships to avoid unintended Stark Law violations, an attorney may be notified after a Stark Law violation has occurred (or after there is an allegation of a Stark Law violation). Due to the strict liability nature of the Stark Law, physicians who have innocent intentions, but nonetheless violate the law could be held accountable for severe and significant penalties, including exclusion from participation in federal health care programs.²

As a threshold matter, the Stark Law applies only to physicians.³ To implicate the Stark law, the physician must make a "referral" for designated health services.⁴ A referral does not include the physician personally performing designated health services. Designated health services include: (1) clinical laboratory services, (2) physical therapy, occupational therapy, and



outpatient 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.⁵ Last, the physician (or an immediate family member) must have a financial interest (compensation and/or ownership or investment interest) in the entity to which the physician referred the designated health service, and that entity must submit a claim to Medicare or Medicaid.⁶

If each of the aforementioned criteria are present, the relationship at issue must fall squarely within a Stark Law exception to avoid liability.⁷ In the *deeper dive* break-out session, the speakers discussed common Stark Law exceptions, such as the in-office ancillary services exception, the physician recruitment exception, and the isolated transactions exception.⁸

If the provider does not fall within a Stark Law exception, sanctions could include civil penalties, FCA liability, and possible exclusion.

Identifying an AKS Violation

In contrast to the strict liability Stark Law, the AKS is a criminal statute that requires unlawful intent to establish liability.⁹ The AKS makes it a felony to knowingly and willfully solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for federal health care program referrals.¹⁰

Although it is a defense to a claimed AKS violation that the individual in question lacked the requisite intent to commit a violation, the speakers explained that under the “One Purpose” test, if one purpose of the payment was to induce future referrals, a violation has occurred and the entire transaction is tainted.¹¹ As a result, the speakers explained that a prosecutor need only establish that one of the purposes of the remuneration was to induce a referral. Consequently, prevailing on a “lack of intent” defense could be difficult. Moreover, because intent is a factual issue, an AKS case could proceed to trial as opposed to resolving at summary judgment. There are several other defenses to an AKS claim that attorneys should consider such as whether the transaction falls under a safe harbor.¹²

Medicare/Medicaid Reimbursement Disputes

Disputes also arise when Medicare/Medicaid refuses to pay physicians for services. James Flynn and Thomas Barker discussed Medicare Parts A-D at the *Fundamentals* conference and highlighted two areas in which litigators and/or administrative attorneys may be utilized to assist providers. First, with respect to Medicare Part B, there has been a proliferation of reimbursement disputes over what constitutes “reasonable and necessary” medical services. Under Section 1862(a)(1) of the Social Security Act (42 U.S.C. § 1395y), Medicare excludes from payment services that are not “reasonable and necessary for the diagnosis and treatment of illness or injury.” However, the Centers for Medicare &

Medicaid Services (CMS) has not precisely defined what is “medically necessary” or the documentation required to prove that a physician’s medical decision was in fact “medically necessary.” As such, CMS may decline payment for a service that it deems not medically necessary and a provider may dispute, challenge, and/or appeal the denial.

Second, Medicare requires health care providers to certify on Form 1500 that a service was “medically necessary” for the care of the patient when submitting a claim for payment.¹³ As a result, with more sophisticated computer programming and data mining software, it has become substantially easier for CMS and government enforcers to study the trends of submitted claims and potentially target providers who have a higher rate of utilization. Consequently, providers should consult their attorneys to ensure adequate representation, protection, and compliance in the event of an audit or investigation.

False Claims Act

All of the concepts discussed during the federal regulatory and compliance presentations potentially translate to liability under the FCA, which was addressed by Scott R. Grubman and W. Taylor McNeill at the *Fundamentals* conference.

The FCA (31 U.S.C. § 3729) provides that any person who, among other things, (1) knowingly presents, or causes to be presented, to the federal government, a false or fraudulent claim for payment or approval, (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government, (3) conspires to defraud the federal government by getting a false or fraudulent claim paid or approved by the federal government, or (4) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the federal government, is liable for a violation of the FCA.¹⁴

The penalties for violating the FCA could be catastrophic for providers. The liability for each individual claim submitted ranges from \$10,957 to \$21,916, per claim, plus treble damages.¹⁵

A substantial majority of the provider liability topics discussed at the *Fundamentals* conference were potential theories of liability under the FCA. For example, the Form 1500 provider certification, which requires providers to attest that certain physician services were “medically necessary” for a patient’s care, could be a false claim if in fact such services were not medically necessary. Therefore, “medical necessity” could be the predicate for a reimbursement dispute, but could also be the impetus of an FCA violation.

Physician Employment Contracts and Restrictive Covenants

Physician Employment Contracts was a break-out session led by Lisa M. Gora and Kim Harvey Looney. There are a host of potential liability issues that can arise with respect to physician employment agreements, including the breach of restrictive covenants, which is a heavily litigated area.

Non-competition agreements are regulated by the individual states because they restrict an individual's right to work. For example, Florida is a pro-employer state and reasonable non-competes are valid and enforceable.¹⁶ However, as discussed by Carla Hartley during a break-out session on Employment Issues, California, by contrast, is a "right to work" state and non-competes are illegal and void.¹⁷ As a result, while Florida litigators may devote their entire practice to the enforcement and/or defense of restrictive covenants, attorneys in other states, such as California, may lack the specialty.

In Florida, a non-compete clause that restricts or prohibits competition during or after the term of the restrictive covenant is enforceable if it is reasonable in time, area, and line of business.¹⁸

The primary purpose of a non-competition clause in a physician-employment agreement is to protect the employer when a physician-employee leaves the practice. For a restrictive covenant to be enforceable, the physician-employer must have a "legitimate business interest" to protect. In Florida, "legitimate business interest" includes, but is not limited to: (1) trade secrets, (2) valuable confidential business or professional information, (3) substantial relationships with specific prospective or existing customers, patients, or clients, (4) customer, patient, or client goodwill associated with: (i) an ongoing business or professional practice, by way of trade name, trademark, service mark, or "trade dress," (ii) a specific geographic location, or (iii) a specific marketing or trade area, and (5) extraordinary or specialized training.¹⁹

However, the statutory list of delineated "legitimate business interests" is not exhaustive and the law continues to evolve in this area. Thus, an employer in the health care field may establish other protectable legitimate business interests. For example, referral sources and relationships were not previously considered protectable business interests in Florida,²⁰ however, a recent Florida Supreme Court decision held that referral sources may be a "legitimate business interest" depending upon the context and proof adduced.²¹ In that recent decision, the Florida Supreme Court concluded that home health care referral sources are protectable interests under Florida's non-compete statute and opined that a fact-based inquiry is necessary to determine whether a non-enumerated interest is indeed a protectable "legitimate business interest."²²

HIPAA Compliance

Litigators representing providers must be cognizant of maintaining the protection of protected health information (PHI). Deanna S. Mool discussed compliance with HIPAA at the *Fundamentals* conference. Attorneys who act as general counsel or even special litigation counsel to health care providers must be cautious to avoid innocently disclosing PHI.

A physician may receive a subpoena requiring production of a patient's billing or medical records. The physician may unknowingly commit a HIPAA violation by producing the records without confirming that the subpoena was accompanied by a disclosure authorization (or HIPAA release). Improperly releasing a patient's medical records or PHI that appears on invoices can result in a

civil lawsuit by the patient, an administrative fine by the federal government, or disciplinary action by the state medical board.

If the subpoena does not contain a HIPAA release or an authorization signed by the patient, the physician should contact the attorney who issued the subpoena to obtain satisfactory assurance that the attorney made a good faith attempt to contact the patient and afforded the patient an opportunity to raise an objection to the court, prior to releasing PHI.

Abundant Liability Concerns

Health care providers are subject to a heightened level of scrutiny from government regulators, payers, and the public, and therefore must be cognizant of more than providing quality medical care to their patients. A conservative and cautious approach is always advisable and employing professionals such as health care attorneys to advise and guide providers is always recommended.

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1 Compare 42 U.S.C. § 1395nn with 42 U.S.C. § 1320a-7b(b).

2 <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (last accessed on Jan. 3, 2018).

3 See 42 U.S.C. § 1395nn(a). A physician is defined as "a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctrine of podiatric medicine, a doctor of optometry or a chiropractor, as defined in section 1861(r) of the Act" 42 C.F.R. § 411.351.

4 A general exception to both ownership and compensation arrangement prohibitions applies to physician services provided personally by (or under the personal supervision of) another physician in the same group practice as the referring physician. See 42 U.S.C. § 1395nn(b)(1).

5 42 U.S.C. § 1395nn(h)(6).

6 42 U.S.C. § 1395nn(a).

7 See 42 U.S.C. § 1395nn(b).

8 *Id.*

9 42 U.S.C. § 1320(b) (requiring "knowing[] and willfull[]" solicitation or acceptance of remuneration (including any kickback, bribe or rebate) in return for referring a patient).

10 42 U.S.C. § 1320a-7b(b).

11 *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

12 42 C.F.R. § 1001.952.

13 <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> (last accessed Jan. 3, 2018).

14 31 U.S.C. § 3729(a).

15 28 C.F.R. § 85.3(a)(9); 28 C.F.R. § 85.5.

16 See FLA. STAT. § 542.335.

17 Section 16600 of the California Business and Professions Code makes unlawful contracts "by which anyone is restrained from engaging in a lawful profession, trade or business of any kind."

18 FLA. STAT. § 542.335(1)(b).

19 § 542.335(1)(b), Fla. Stat.

20 See *Florida Hematology v. Tummala*, 927 So. 2d 135 (Fla. 5th DCA 2006); see also *UF v. Sanal*, 837 So. 2d 512 (Fla. 1st DCA 2003).

21 *White v. Mederi Caretenders Visiting Serv. of Southeast Florida, LLC*, 226 So. 3d 774, 786 (Fla. 2017).

22 *Id.*

Resource Corner

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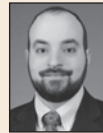
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