Federal Bar Association

Turning Square Corners

The Newsletter of the Federal Bar Association Qui Tam Section

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Leadership Lane

By Megan Mocho, Partner, Holland & Knight LLP

As Chair of the Federal Bar Association Qui Tam Section, I am pleased to present the newest edition of Turning Square Corners, the bi-yearly newsletter published by this great Section. Our newsletter is rich with in-depth analysis and diverse viewpoints, a hallmark of all our Qui Tam Section programs and benefits.

Members of the Section receive access to several monthly programs, each dedicated to the nuanced practice of whistleblower statutes. Programs all convey the perspective of relators, defense and government counsel alike. Whether you want to listen to our bi-monthly lunchtime webinars, hear about the bespoke practice in a particular jurisdiction during FCA Today, or learn from thought leaders during our award-winning annual conference, we'd welcome your perspective and involvement.

On the latter, registration for the Annual Conference is now open. This year's theme is Hard-Won Wisdom: FCA Pitfalls and Best Practices. We have two days of panels poised to deliver compelling debate from all sides. This year we are proud to have DOJ Senior Trial Counsel Diana Cieslak and Choate Hall & Stewart partner, Danielle Pelot as our Co-Chairs. I hope to see you there February 20-21, 2025 here in Washington, DC. https://www.quitamconference.com/

This edition focuses on healthcare fraud, which should come as no surprise given the extensive intersection of healthcare fraud and the False Claims Act. Both sides of the aisle contributed in different articles having summarized new cases, addressing emergency room fraud, and traverse valuation issues in Stark Law cases. And of course, no current edition would be complete without a discussion about the effect of Loper in this area. I hope you enjoy this edition as much as I did.

A significant thank you to editor Rachel Rose as well as the members of the Education Committee and the authors who have dedicated significant time to this effort; your hard work makes our section shine. We welcome submissions from members and non-members, please reach out if you have any suggestions for future edition articles. Next edition's theme will be: procurement fraud.

With every good wish,
Megan

Also in This Issue

FBA Member Spotlight: Scott Oswald

By Rachel V. Rose

You were a founding member of the Federal Bar Association's Qui Tam Section, and its second chair. Tell us about the evolution of your legal career.

I'm a third-generation lawyer. My grandfather was first Chief Justice of the South Dakota Supreme Court and my mother was one of the first women to graduate from her law school — so I had big shoes to fill. It took a few years for my path to lead me to plaintiff-side law. I started out as an immigration lawyer, then branched out into employment matters. Even then, I was doing mostly defense-side work. In 2002, I joined with two colleagues to create The Employment Law Group with the intention of helping individual employees. Our practice took a turn in 2004 when we represented Sheila Kalkunte, our first whistleblower client, and made new law in the process. Before I knew it, we had built a reputation as whistleblower lawyers. From there, moving into False Claims Act work came naturally. I've never looked back, and a mix of employment and qui tam cases feels like my natural element.

Within the Section, you're known for your belief in programming that brings members together, both in-person and online. How did that evolve?

From the start, the purpose of the Section was to create spaces where members on *all* sides of the FCA equation — relator-side counsel, defense counsel, government, judiciary — could come together and learn from each other. Just hearing from people on the other side of the "v" is educational, the key to our mission. Our annual conference was the first expression of that, and it's still the anchor for our programming. We love getting everyone into the same room. Then we added the "FCA Today" series, focusing on individual jurisdictions, because so much qui tam work happens in U.S. Attorney's Offices, each with its own nuances. We did those in-person for years. When the COVID pandemic pushed us online, we expanded to include Zoom Roundtables, which focus on specific FCA topics, and "The Rounds," our video series that analyzes recent FCA cases. Moving online allowed us to do far more events and to involve a lot more Section members, who now take a primary role in suggesting and running their own events. The annual conference is still my favorite program, though. Zoom is great, but seeing people in person is better.

What is the most memorable False Claims Act case that you have been involved in?

For me it was *U.S. ex rel. Manieri v. Avanir Pharmaceuticals, Inc*. Our client had joined Avanir as a high-level executive, and he was horrified to learn that his new employer was essentially paying doctors to overprescribe one of its drugs to dementia sufferers, a very vulnerable population that had little use for it. Our FCA complaint led to a $103 million settlement that benefited taxpayers and stopped this predation of older people. Dementia has affected my own family, and this outcome means a lot to me. But really I'm proud of *all* the FCA cases I've filed, including the ones that never led to recoveries. Our whistleblower clients make the world a better place by triggering these investigations. I'm honored to be a part of that.

Any suggestions for cultivating civility across the aisle?

Civility is a baseline, but my true goal is amity across the aisle. I treat opposing counsel as my colleagues on a case, and I assume their good faith. If they ask for an accommodation, let's say a continuance, I always try to cooperate. What goes around, comes around — that's my adage. Do unto others. The Qui Tam Section is a perfect reminder. I've been opposed to many of my fellow members, but we have so much in common. That's the important stuff. When we meet at our Annual Conference, I am happy to see them. I want them to be happy to see me, too, no matter who won the last battle. This is a small community and we're in it together.

Rachel V. Rose, JD, MBA (Houston, Texas), advises clients on compliance, transactions, government administrative actions, and litigation involving healthcare, cybersecurity, corporate and securities law, as well as False Claims Act and Dodd-Frank whistleblower cases. She also teaches bioethics at Baylor College of Medicine in Houston. Rachel holds a variety of leadership positions within the FBA, including serving on its National Board of Directors and can be reached through her website, www.rvrose.com.

Noteworthy Case Summaries

By John T. Vaughan and Parker Reynolds, Holland & Knight LLP

No discussion of cases from the final half of 2024 would be complete without a discussion of the Middle District of Florida's decision in *United States ex rel. Zafirov v. Florida Medical Associates LLC*, No 8:18-cv-01136 (M.D. Fla. Sept 30, 2024), holding that the qui tam provisions of the False Claims Act (FCA) are an unconstitutionally impermissible infringement on the Executive Branch's powers under Article II of the United States Constitution.

Because two Florida District Courts reached opposite conclusions on the qui tam provisions, it is likely that the Eleventh Circuit will need to clarify their constitutionality: the Florida Middle District Court decision raises the question of whether relators can ever litigate a matter on behalf of the federal government, while just a few weeks earlier, in *United States ex rel. Butler v. Shikara, et al*., No. 9:20-cv-80483, slip op. at 25-26 (S.D. Fla. Sept. 6, 2024), the Florida Southern District Court declined to find the qui tam provisions unconstitutional, consistent with long-standing precedent.

In contrast to the dueling decisions out of Florida, the Ninth Circuit clarified the legal standards for establishing a prima facie case of retaliation in *Mooney v. Fife, et al*, D.C. Nos. 23-16328 and 23-15158 (9th Cir. Sept 30, 2024).

One Florida District Court Determines the Qui tam Provisions Are Unconstitutional…

Relator Clarissa Zafirov filed a qui tam action alleging that Florida Medical Associates and other defendants misrepresented patients' medical conditions to Medicare, thereby committing fraud. For five years, she prosecuted various corporate entities on behalf of the United States.

Defendants attacked the qui tam provision itself, arguing that a relator is an improperly appointed Officer of the United States under Article II's Appointments Clause, Take Care Clause, and Vesting Clause.

The Court agreed. The court pointed out that the Appointments Clause preserves accountability in the Executive Branch by creating a two-track system for appointing "Officers of the United States" who must be nominated by the President and confirmed by the Senate. The Appointments Clause does not apply to a mere employee or inferior officers, but those that (1) "exercise significant authority pursuant to the laws of the United States," and (2) occupy a continuing position established by law.

In applying this test, the court concluded that an FCA relator is an Officer of the United States subject to the Appointments Clause because (1) a relator's civil enforcement authority is significant, and (2) a relator's statutory duties, powers, and emoluments mirror that of a special prosecutor or bank receive in its duration and non-personal nature.

1. ***Significant Authority:*** In coming to this conclusion, the court relied on the Supreme Court's significant authority standard in Buckley, which articulated two independent reasons for designating someone an Officer of the United States. (*Buckley v. Valeo*, 424 U.S. 1, 126 (1976)). First, the Court explained that an official vested with the power to conduct civil litigation for vindicating public rights must be an Officer. Second, broad administrative powers that represent the performance of a significant governmental duty exercised pursuant to a public law also mark an Officer. The district court found that a relator's power to file a complaint without oversight and prosecute an action to final judgement when the government does not intervene, including litigating appeals that can become binding precedent on the government, is "textbook significant authority." Further, the court emphasized that enforcement authority and charging discretion are core executive powers, especially when coupled with the authority to impose a punitive sanction.
2. ***Continuous Position:*** Additionally, a FCA relator occupies a continuing position established by law much like a special prosecutor. The continuing position inquiry stresses ideas of tenure and duration and asks whether the individual's duties are occasional or temporary rather than continuous and permanent. A relator's statutory duties, powers, and emoluments prove the office is continuous, even if it is not continually filled. The court reasoned that the office of relator persists by operation of the FCA even if the position is not filled. The court analogized that relators are akin to special prosecutors or bank receivers, both of which are treated as Officers despite an expiration term at the end of a single matter.

Although the court acknowledged the historical use of qui tam provisions, the court emphasized that the Constitution prevails over practice, especially when the text is clear. Therefore, the court dismissed the case, reasoning that Zafirov lacked the authority to prosecute the action on behalf of the United States because she was self-appointed.

The Supreme Court has signaled some receptiveness to the court's reasoning. In his dissent in *United States ex rel. Polansky v. Executive Health Resources, Inc*., 599 U.S. 419 (2003), Justice Thomas stated "[t]here are substantial arguments that the qui tam device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." Although Justices Kavanaugh and Barrett ultimately agreed with the majority, they wrote a concurrence specifically to agree with Justice Thomas's statement.

With at least three Supreme Court justices receptive to the District Court's reasoning in Zafirov, members of the qui tam bar will be reckoning with the constitutionally of the qui tam provisions for the foreseeable future. At the time of this writing – one month after publication – defendants are already citing Zafirov in motions to dismiss similar actions around the country.

...While Another Florida District Court Reaches the Opposite Conclusion

Conversely, in *United States ex rel. Butler v. Shikara*, the Southern District of Florida declined to conclude that FCA's qui tam provision violated Article II in a similar challenge. In *Butler*, the court determined the constitutionality of the FCA's qui tam provisions while considering a motion to dismiss a Relator case concerning allegations of a doctor entering into many quid quo pro relationships for monetary gain, running afoul of the FCA's rules against kickbacks.

In *Butler*, one Defendant argued that the qui tam provision of the FCA is unconstitutional. The Defendant's argument, similar to that in *United States v. Florida Medical Associates LLC*, was that the the qui tam mechanism violates the separation of powers principles embodied by the Appointments and Take Care Clauses of the Constitution. The Defendant emphasized that constitutional concerns are especially pronounced where the United States chooses not to intervene. The court ultimately disagreed, pointing to the numerous district and circuit courts that have all rejected the unconstitutionality argument presented and similarly relied on historical analysis in finding the mechanism to be constitutionally sound. Additionally, the court independently examined the Appointments Clause and Take Care Clause arguments as summarized below.

1. ***Appointments Clause Analysis:*** Regarding the Appointments Cause, the court also concluded that a Relator is not an officer under the purview of the Appointment clause because a Relator do not have the defining qualities of an officer such as tenure, duration, emolument and duties. The court further reasoned that Relators also lack the qualities of an inferior officer seeing as they are not in an employment-like relationship and do not have permanent or continuing duties.
2. ***Take Care Clause Analysis:*** Regarding the Take Care Clause, the court determined that Relators do not hold unchecked power overing prosecuting qui tam claims because the United States exercises significant control over all aspects of the lawsuit, from commencement to disposition, pointing to the Governments power to elect to pursue a remedy, opportunity to intervene, ability to seek dismissal, and authority to settle.

Broader Implications for the Qui Tam Provisions

United States v. Florida Medical Associates LLC is a departure from Butler v. Shikara's decision upholding the constitutionality of qui tam provisions. Notably, the Eleventh Circuit has yet to consider the issue of an Article II challenge to the FCA's qui tam provisions. With these two Florida district courts coming to opposite conclusions, an appeal of *United States v. Florida Medical Associates LLC* to the Eleventh Circuit is more than likely to come.

The Ninth Circuit Adopts McDonnell Douglas Burden-Shifting Framework

Another decision from the Ninth Circuit clarified the legal standards for establishing a prima facie case of retaliation, and how a relator can satisfy the requirement that an employee provide her employer with proper notice of an attempt to stop or prevent an actionable violation of the False Claims Act.

Mooney v. Fife provides litigants with greater clarity on the requirements for establishing a prima facie claim for retaliation by formally adopting the McDonnell Douglas burden-shifting framework in the nation's largest Circuit.

Mooney v. Fife involved a healthcare employee, Mooney, who alleged wrongful termination after repeatedly raising concerns about improper billing practices for Medicare and Medicaid. Mooney was under a three-year employment agreement with Vivida Dermatology ("Vivida") that included a confidentiality clause. The company claimed Mooney breached the confidentiality clause by exposing plans of a prospective acquisition of another dermatologist's practice, which resulted in his termination. Mooney, conversely, contended he was terminated for notifying Dr. Fife, the sole owner of the practice, of the company's noncompliance with Medicare and Medicare regulations during their weekly one-on-one meetings.

After he was terminated, Mooney filed an FCA qui tam action against Vivida, that he subsequently voluntarily dismissed. Mooney then moved to file a Second Amendment Complaint that added claims for retaliation under the FCA, breach of contract, and breach of the implied covenant of good faith and fair dealing.

The district court granted summary judgment to Vivida on Mooney's three claims. The district court found that Mooney's retaliation claim failed because ensuring compliance with billing regulations and reporting irregularities were activities in Mooney's job description, and his reporting did not put Vivida on notice of potentially protected conduct.

Based on these facts and procedural history, the 9th Circuit held that a False Claims Act retaliation claim requires proof of three elements: (1) protected conduct; (2) notice; and (3) causation. Before turning to these three elements, the court clarified its approach between two retaliation frameworks – the McDonnell Douglas framework and the Mt. Healthy framework. The court favored the McDonnell Douglas burden shifting framework, which provides that once an employee has established a prima facie case of retaliation, the burden shifts to the employer to produce a legitimate, non-retaliatory reason for the employee's termination (McDonnell Douglas Corp. v. Green, 411 U.S. 792 (1973)). Then, if the employer produces such a reason, the burden shifts to the employee to show that the proffered explanation was pretextual. The McDonnell Douglas framework is often relied upon in other retaliation contexts such as Title VII, ADEA, and ADA. In relying upon McDonnell Douglas, the court rejected Mt. Healthy' s framework, commonly applied to First Amendment retaliation claims (*Mt. Healthy City School District Board of Education v. Doyle*, 429 U.S. 274 (1977)).

The court then turned to the three elements required to establish a prima facie case of retaliation:

1. ***Protected Conduct:*** In 2009, Congress amended 31 U.S.C. § 3730(h) to clarify that, in addition to protecting lawful acts done by the employee, the False Claims

Act also protects employees from being discharged because of efforts to stop violations of the Act. Prior to this amendment, this court held that, under the Moore test, an employee engaged in protected activity where (1) the employee in good faith believed, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer was possibly committing fraud against the government. (*Moore v. Cal. Inst. of Tech. Jet Propulsion Lab'y*, 275 F.3d 838, 845 (9th Cir. 2002)). In U.S. ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996), the 9th Circuit also held that the employee must be investigating matters that were calculated, or reasonably could lead, to a viable action under the False Claims Act.

Agreeing with the 11th Circuit, the 9th Circuit found that the "investigating" requirement does not apply when the employee alleges that he was discharged because of efforts to stop violations of the Act. However, the court determined the *Moore* test to still be appropriate under the 2009 amendment. Here, the court found that Mooney engaged in protected conduct that satisfied the first element of the retaliation claim because he subjectively and objectively believed that Vivida was possibly committing fraud against the government.

2. ***Notice:*** The Appeals Court also found that Mooney met the notice requirement of a prima facie case by showing that the employer knew the employee was engaging in protected conduct. Departing from sister courts, the 9th Circuit concluded that it was irrelevant that it was a part of Mooney's regular job duties to ensure compliance with billing regulations and report irregularities. The court found that the determination is not whether an employer is on notice of a potential qui tam sui but rather whether the employer is on notice of other efforts to stop one or more violations of the FCA. Employees with compliance duties are not held to a different standard in meeting the notice requirement of an FCA retaliation claim.
3. ***Causation:*** Vivida did not challenge the third element of a prima facie case, causation.

With the three elements for a prima facie case of retaliation met, the burden shifted to Vivida to produce a legitimate, non-retaliatory reason for Mooney's termination under the *McDonnell Douglas* framework. The 9th Circuit held that Mooney established genuine issues of material fact whether the reasons proffered by Vivida were pretextual and remanded that claim for trial.

Key Takeaways From *Mooney*

This decision underscores the need for corporations to exercise heightened caution when interacting with employees who report possible violations of federal laws or regulations. The satisfaction of the notice element through an employee ensuring compliance through his or her regular job duties leaves healthcare companies more vulnerable to retaliation claims by making it easier for employees to establish a prima facie case for retaliation.

The application of *McDonnell Douglas* emphasizes the importance of documenting legitimate, non-retaliatory reasons for any adverse employment action to withstand scrutiny and re-shift the burden under the *McDonnell Douglas* framework if a prima facie case is established.

Ultimately, *Mooney* reinforces protections for employees in the regulated industries (most notably healthcare and life sciences), encouraging whistleblowers to report potential compliance issues without jeopardizing their employment status, which could lead to a more transparent environment -- but will also prompt increased compliance costs for their employers.

John Vaughan is a public policy and regulation attorney in Holland & Knight's Los Angeles office. Mr. Vaughan is an accomplished legal officer and strategic adviser with a robust background in regulatory affairs, corporate governance and compliance across diverse industries, including healthcare, life sciences, biotech and technology. He has in-depth experience in the application of healthcare uses for emerging technologies, such as artificial intelligence (AI) and machine learning (ML). Mr. Vaughan has developed legal, regulatory and legislative strategy for life sciences and technology companies ranging from the Fortune 50 to start ups. He has played a pivotal role in obtaining favorable resolutions from the U.S. Department of Justice (DOJ) and U.S. Securities and Exchange Commission (SEC) in enforcement proceedings.

Parker Reynolds is an attorney in Holland & Knight's Washington, D.C., office and a member of the firm's Public Policy & Regulation Group. Ms. Reynolds focuses her practice primarily on legislative and regulatory issues related to healthcare and technology. She also has a deep understanding of matters related to the U.S. Food and Drug Administration (FDA), privacy, energy, financial services, corporate and non-profit governance, and compliance. Prior to joining Holland & Knight, Ms. Reynolds served as senior legislative assistant to former Rep. Liz Cheney (R-Wyo.), where she handled the healthcare issue portfolio. Ms. Reynolds is a member of the District of Columbia Bar.

Ambulatory Surgery Center (ASC) Ownership Transaction Considerations to Mitigate Risk

By Don Barbo, CPA/ABV, Ingrid Aguirre, CFA, and Rachel V. Rose, JD, MBA

As the United States Department of Health and Human Services – Office of the Inspector General (HHS-OIG) states, "[t]he five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark [L]aw), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL)."[1] Understanding the regulatory landscape is critical to mitigating risks during ownership transactions, particularly in the context of multi-specialty Ambulatory Surgery Centers (ASCs). Two (2) fundamental laws – the federal AKS, 42 U.S.C. §§ 1320a-7b(b) and the Stark Law, 42 U.S.C. §1395nn - must be read *in pari materia* to ensure compliance and avoid running afoul of fraud, waste, and abuse laws. At the core of the AKS and Stark Law is the Congressional intent to "prohibit the submission, or causing the submission, of claims in violation of the law's restrictions on referrals."[2] A fundamental comparison of the two laws appears in Table A.

ASCs provide efficient outpatient surgical services, but ownership structures and transactions must adhere to specific regulatory frameworks, particularly under the AKS. This article outlines the key ASC safe harbors and important considerations to mitigate risk during ownership transactions.

Overview of Applicable ASC Safe Harbors

Under the AKS, 42 U.S.C. § 1320a-7b(b), any remuneration for patient referrals reimbursed by federal healthcare programs is prohibited. However, there are safe harbors under 42 CFR § 1001.952 that allow certain ASC ownership structures to avoid penalties, provided they meet specific conditions. Like the Stark Law's exceptions (42 CFR § 411.357), AKS safe harbors must be squarely met or the protection does not apply. Two (2) questions and answers posed by HHS-OIG related to safe harbors cannot be overlooked.[3] Specifically,

When an arrangement does not satisfy a safe harbor under the Federal anti-kickback statute, does that mean it's automatically illegal? If an arrangement satisfies most of a safe harbor's conditions, does that mean it is lower risk?

- The safe harbor regulations at 42 CFR § 1001.952 describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. Compliance with a safe harbor is voluntary; failure to satisfy a safe harbor does not mean that an arrangement is illegal.
- There is no safe harbor protection for partial compliance with the conditions of a potentially applicable safe harbor. To receive the benefit of safe harbor protection,

Table A

	AKS	Stark Law
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals of general Federal health care program business.	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies. • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral.
Referrals	Referrals from anyone.	Referrals from a physician.
Items/Services	Any items or services.	Designated health services.
Intent	Intent must be proven (knowing and willful).	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties for knowing violations.
Penalties	Criminal and/or Civil.	Civil Only.
Exceptions	Voluntary safe harbors.	Mandatory exceptions.
Federal Health Care Programs	All.	Medicare/Medicaid.

an arrangement must squarely satisfy each condition set forth in the applicable safe harbor. The risk of any arrangement that implicates the Federal anti-kickback statute and does not meet all of the elements of a safe harbor would be assessed based on the totality of its facts and circumstances, including the intent of the parties. (emphasis added).

Healthcare providers may seek Advisory Opinions from the HHS-OIG prior to entering into the contemplated business arrangement pursuant to section 205 of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191 (Aug. 21, 1996) (HIPPA).

The AKS safe harbor related to the ASC investment and one-third of income requirement (r)(3), is crucial and must be verified by the ASC.[4]

For multi-specialty ASCs, safe harbor provisions are particularly relevant when structuring ownership agreements. The seven safe harbor standards for multi-specialty ASCs include the following:

i. Ownership interest terms offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from an investor to the ASC.
ii. At least one-third of each physician-investor's income from all sources for the previous year medical practice must be derived from performing procedures eligible to be performed in an ASC.
iii. At least one-third of the procedures performed by each physician-investor for the previous year must be performed at the ASC.
iv. The ASC or any investor in the ASC (or other individual or entity acting on behalf of the ASC or investor) must not loan or guarantee a loan to an investor for the purpose of the investor obtaining an investment interest in the ASC.
v. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment of that investor.
vi. All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the ASC and none may be separately billed to Medicare or other Federal healthcare programs.
vii. The ASC and any physician investors must treat patients receiving medical benefits under any Federal health care program in a nondiscriminatory manner.By ensuring compliance with these safe harbor provisions, ASCs can significantly reduce their legal exposure under the AKS.

Key Issues in ASC Ownership Transactions

1. Prices at Fair Market Value (FMV)

Ensuring that all ownership transactions, including the sale and purchase of interest, occur at fair market value (FMV) is paramount. Any deviation from FMV can raise concerns under the AKS, particularly if it suggests inducement for referrals. Obtaining independent, third-party valuations can help substantiate the FMV of a transaction and mitigate the risk of regulatory challenges.

2. Number of Units Offered or Prices Should Not Be Based on Volume/Value of Referrals

In accordance with ASC safe harbor standards, the number of ownership units offered to investors or the price of those units must not be tied to the volume or value of referrals made by the physician. Ownership terms should be uniform and not vary based on the ability of an investor to generate business for the ASC.

3. Ownership Distributions Based on Ownership Interest, Not Productivity

Distributions of profits to investors must be based solely on ownership interest and not on the productivity or revenue generation of individual physicians. Structuring distributions in this manner ensures compliance with AKS regulations, which prohibit compensation models that incentivize referrals. Profit-sharing arrangements based on ownership percentages align with safe harbor provisions. It is equally important to assess the type of ownership in an AKS from the outset (e.g., physician-hospital owned, single specialty or different specialties) because the relevant safe harbors and exceptions vary depending on the ownership structure.

Potential Risks in ASC Transactions

1. Buying Controlling Interest from Physicians Above FMV
Acquiring controlling interest from physician-owners at prices exceeding FMV can raise concerns under the AKS. Paying above FMV might be viewed as a way to induce future referrals, which could trigger regulatory action. Thus, it is essential to document each transaction with FMV valuations to avoid potential risks.

2. Selling Non-Controlling Interest to Physicians Below FMV
Selling non-controlling interests to referring physicians at prices below FMV may similarly be viewed as an inducement for increased referrals. To mitigate this risk, all sales of ownership interests should occur strictly at FMV, with identical terms offered to all investors, regardless of their referral potential.

3. Buying Out Physicians Slowing Down Their Practices; Selling Units to Physicians Growing Their Practices

As physicians approach retirement or reduce their clinical activities, ASCs may face the challenge of buying back ownership interests. To avoid potential conflicts, these transactions should be conducted in a consistent, transparent, and appropriate manner. Operating agreements should clearly described the buyout process, including how the FMV transaction prices will be determined. Similarly, selling ownership units to physicians with growing practices should not be perceived as an inducement for their referrals and consistent with the operating agreement's process and determination of FMV transaction prices.

Conclusion: Key Takeaways

To effectively mitigate risks in ASC ownership transactions, several key considerations must be kept in mind:

1. ***Ensure FMV Compliance:*** All ownership transactions should be consistent with the ASC's operating agreements and based on FMV, supported by independent valuations to avoid potential regulatory challenges under both the AKS and Stark Law, as well as the FCA.
2. ***No Referral-Based Terms:*** Ownership units and distributions must not be linked to the volume or value of physician referrals. This concept is consistent in the AKS, Stark Law, and FCA cases.
3. ***Structured Buyout and Buy-in Agreements:*** Operating agreements should clearly define the process for buying out retiring or inactive physicians and buy-ins of new physicians, with provisions to ensure the transaction prices are consistently determined and compliant with FMV Safe Harbors. As a "best practice" buyouts should be done within a reasonable time frame and in accordance with corporate documents of a physician retirement, transition to inactive status, to avoid failure to meet the requisite AKS safe harbor or Stark Law exception. Failing to do so, especially if a physician is still able to refer, whether directly or indirectly can lead to liability under the FCA for Stark Law and/or AKS violations.

By adhering to these strategies, ASC owners and operators, including physicians, can protect themselves from legal risks while maintaining compliant and profitable business operations within the framework of federal healthcare regulations. Failing to do so can result in Government enforcement actions, monetary fines, and potentially exclusion from participating in Medicare and Medicaid.

Note: The legal analysis in this article are those of Rachel Rose, Esq. The other co-authors of this article, Don Barbo and Ingrid Aguirre, are not attorneys and therefore, are not expressing any legal analysis. Their opinions are limited to the valuation and business planning opinions expressed herein. Nothing in this article is meant to constitute legal or valuation advice, as the application of laws, regulations, and methods varies as to specific facts and circumstances.

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Rachel V. Rose, JD, MBA (Houston, Texas), advises clients on compliance, transactions, government administrative actions, and litigation involving healthcare, cybersecurity, corporate and securities law, as well as False Claims Act and Dodd-Frank whistleblower cases. She also teaches bioethics at Baylor College of Medicine in Houston. Rachel holds a variety of leadership positions within the FBA, including serving on its National Board of Directors and can be reached through her website, www.rvrose.com.

Endnotes

[1]See https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/#:~:text=The%20Stark%20law%20prohibits%20the,the%20Federal%20health%20care%20programs. (last visited Nov. 10, 2024).

[2]*Id.*

[3]See https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/ (last visited Nov. 10, 2024).

The Emergency Room—The Front Door to the Hospital (Fraud Schemes)?

By Pamela Coyle Brecht

Fraud related to hospital services – both inpatient and outpatient – has led to over $511 million in damages and hundreds of millions of dollars in False Claims Act (FCA) settlements over the past 15 years. The ER has been aptly called the "front door" to the hospital.[1] ER patients account for 70% of all hospital admissions.[2] It is no surprise that the ER is also the locus of lucrative fraud schemes. Many ER patients are also beneficiaries of government healthcare programs. In 2021, 58% of all ER patients were covered by Medicare or Medicaid.[3] This percentage does not include other government healthcare programs such as Tricare, Champus/VA, the federal employee health benefits program (FEHBP) or private payors. The ER is a place rife for opportunistic fraudsters to cause mischief at taxpayers' expense.

Medical Necessity

Fraud schemes focused on charging payors for medically unnecessary services have been the subject of FCA cases and DOJ settlements since at least 2000.[4] The government's settlement with Hospital Corporation of America (HCA) in 2003 was a landmark recovery for the DOJ. ER patients have long been (and continue to be) exploited for common schemes in healthcare fraud, over-admitting ER patients for lucrative in-patient stays,[5] billing for services not performed or billing for medically unnecessary services.

Anti-Kickback Violations

What is lesser known, but even more insidious, is the prevalence of Anti-Kickback Statute (AKS) or Stark Law violations that impact ER operations. Clearly, ER care, like every other type of medical care, is highly regulated and must comply with the AKS, Stark Laws, and the FCA. However, to understand the way hospitals and ER staffing companies have become more sophisticated in schemes to violate federal and state laws aimed at preventing fraud, waste, and abuse through emergency care, a brief primer on how emergency treatment is provided to patients is helpful.

How Hospitals Provide for ER Treatment

Hospitals operate the ER as a department of the hospital. The nurses, technicians, physical building, equipment, and supplies are all provided by the hospital. The medical care in the ER is rendered by an emergency physician group, made up of physicians or advanced practice clinicians ("APCs", including NPs or PAs). Hospitals rarely employ the physicians and APCs who actually provide the medical care in the ER. Instead, the hospital enters into exclusive contracts with emergency physician groups who provide 24/7 the medical care for all patients entering the hospital through the ER. Over the past two decades, these contracts have increasingly been held by large, national staffing companies who compete with community-based emergency groups for ER contracts with both national and more regional health systems.

Exclusive ER Contracts are Streams of Referrals by Hospitals to Contracted ER Groups

Once these ER contracts are in place between the hospital and the ER group, each patient who enters the hospital ER is referred by the hospital to the contracted ER physician group to provide medical care. The referral that takes place between the hospital and the ER group is physically demonstrable: the hospital nursing staff literally delivers the ER patient to a treating room to receive care by the contracted ER group with the exclusive right (by contract) to treat every ER patient who enters the hospital.

The federal AKS and similar statutes under state laws "prohibits the knowing and willful payment of 'remuneration' to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients)."[6] Hospital-based medical services like anesthesia, hospital medicine, cardiac catheterization, etc., have long been susceptible to liability under Stark laws, the AKS, and of course, the FCA. Emergency medicine is no different from these other hospital-based services in terms of the reach of the FCA, AKS, and Stark.

Tainted ER Patient Referrals that Violate the AKS Carry Significant FCA Liability

In 2019, the DOJ resolved both civil and criminal liability against one of the country's largest hospital companies based on the hospital system using ER contracts as inducements in violation of the AKS.[7] In that case, the hospital provider, Health Management Associates, Inc. (HMA), which was later absorbed by Community Health Systems, Inc. (CHS), used lucrative ER contracts to induce a large contract management group EmCare (later a part of Envision) to participate in a scheme to admit ER patients to HMA facilities for inpatient hospital care without regard to medical necessity.[8] In that case, the government's settlements with EmCare for $29.8 million[9] and with HMA for $260 million[10] was based on the fact that both referrals in this scheme (ER patients referred under exclusive ER contracts by the HMA hospital to Emcare physicians and patients referred by Emcare physicians to the HMA hospital for outpatient ER services and inpatient care) were tainted by AKS violations. HMA's non-prosecution agreement was based on detailed factual admissions, including the admission that the conspirators had used ER contracts in violation of the AKS. The

ER group had induced the hospital system to obtain or maintain the ER patient referrals by promising to cooperate in the hospital's fraud scheme to increase admissions without regard to medical necessity.

Fraud schemes that employ creative use of inducements to acquire exclusive ER contract referral streams are properly the focus of enforcement activities. Both parties to the ER contract, the hospital granting the ER contract and the ER group receiving the contract have been on the receiving end of DOJ scrutiny. Tainted referrals for ER care can lead to hundreds of millions of dollars in civil recoveries and criminal penalties paid by hospitals or ER providers to the DOJ.

Conclusion

ER patients enter the front door of the hospital more frequently than any other type of patient. The ER patient referral stream from the hospital leading to contracted ER groups is the largest referral relationship a hospital has by volume. Like any other type of patient care, this high-volume referral relationship between hospitals and ER groups is and should be scrutinized for compliance with the AKS, Stark laws, and, of course, the FCA. The proliferation of large contract management groups (often owned by private equity) in the emergency medical space has added a level of complexity and sophistication to government oversight of this significant area of healthcare.

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Endnotes

[1]A new front door -Expanding the hospital's reach with freestanding Eds: "A hospital's emergency department (ED) often is referred to as the facility's "front door" because of the large number of patients who arrive through that department." Available at https://www.hfmmagazine.com/articles/397-a-new-front-door.

[2]For-Profit Hospitals Admit at Higher Rates from Emergency Departments Than Nonprofit. Available at https://ldi.upenn.edu/our-work/research-updates/for-profit-hospitals-admit-at-higher-rates-from-emergency-departments-than-nonprofits/#:~:text=Admitting%20is%20Profitable,come%20from%20the%20emergency%20department.

[3]Emergency Department Visit Rates by Selected Characteristics: United States, 2021. Available at https://www.cdc.gov/nchs/products/databriefs/db478.htm

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[5]New Report Indicates America's Largest Hospital Corporation, HCA Healthcare, May Have Ripped Off Nearly $2 Billion From Taxpayers Nationally, Over $44 Million In California Available at https://www.seiu-uhw.org/press/seiu-hca-investigation-unsafe-staffing-unnecessary-admissions

[6]The contracted ER physicians determine the care needed, i.e. tests or treatments or admission to the hospital. The hospital care ordered by the ER physicians is mostly within the hospital where the ED is located. The ER physician's act of ordering tests or other care for ER patients is also a "referral" to the hospital. This reality is confirmed by the language of the physician self-referral laws (Stark laws), which specifically list "outpatient services" (which include ED services, except when performed outside the United States) and recommendations for admission to the hospital ("inpatient services") in the definition of "designated health services under Stark. 42 CFR § 411.351.

[7]Hospital Chain Will Pay Over $260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary Agrees to Plead Guilty. Available at https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one

[8]*Id.*

[9]EmCare, Inc. to Pay $29.8 Million To Resolve False Claims Act Allegations. Available at https://www.justice.gov/usao-wdnc/pr/emcare-inc-pay-298-million-resolve-false-claims-act-allegations

[10]Hospital Chain Will Pay Over $260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary Agrees to Plead Guilty. Available at https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one

The Effects of *Loper Bright* on Stark Law Enforcement and Compliance for Health Care Providers

By Michael Goldsticker and LauraLee Rawley

The Physician Self-Referral Law, also known as the Stark Law, is an important tool in the government's arsenal of fraud and abuse laws. Compliance with the Stark Law often depends on a lengthy, interconnected series of regulations describing permissible types of remuneration, including multiple exceptions and safe harbors for health care organizations to avoid violations. Previously, under the *Chevron* deference regime, courts deferred to the Centers for Medicare & Medicaid Services (CMS) when questions arose over the meaning and validity of such regulations. Now, in the wake of the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, uncertainty exists over the validity and significance of the Stark regulations and the extent to which CMS's Stark Law interpretations will continue to receive any deference.

Applicable Legal Framework

The Stark Law (42 U.S.C. § 1395nn) prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician has a financial relationship, absent an applicable exception. Although a seemingly straightforward prohibition on physician self-referrals, the Stark Law encompasses a broad range of financial relationships, including both physician ownership interests in health care providers and physician compensation arrangements. It has become complex, nuanced, and heavily reliant on agency regulations to define key terms and safe harbors.

The False Claims Act can be implicated when health care organizations falsely certify Stark Law compliance in connection with a claim submitted to a federally funded insurance program.

In such lawsuits, defense challenges to the validity of the applicable regulations were often met with little success. That is because, for decades, federal courts were instructed to give *Chevron* deference to agency interpretations of ambiguous statutory language.

That administrative landscape recently changed, however, with the Supreme Court's decision in *Loper Bright* and overruling of *Chevron* such that agencies are no longer entitled to deference based on the mere fact that a statute is ambiguous. Now, "courts must exercise independent judgment in determining the meaning of statutory provisions" to decide whether an agency has acted within its statutory authority.

Effect of Loper Bright on the Stark Law

A. Litigation

In the wake of *Loper Bright,* courts are likely to see an uptick in litigation over Stark regulations, especially with respect to False Claims Act litigation against health care providers premised on Stark violations. As one court in the Southern District of West Virginia put it, "[o]ver time the Stark Law (and accompanying regulations) has evolved into a labyrinth of multipart compliance requirements where the exception-to-the-exception-to-the-exception is the norm." *United States ex rel. Kyer v. Thomas Health Sys., Inc.*, No. 2:20-CV-00732, 2024 WL 4165082, at *4 (S.D.W. Va. Sept. 12, 2024). In light of this maze of regulations, courts may question the effect of Loper Bright on the Stark Law landscape: "Inevitably, *Loper Bright* will begin to ripple through the Stark Regulations. The only question for courts is when and how." *Id*.

A likely effect is that False Claims Act defendants will attempt to challenge the validity of the applicable regulations that give rise to the violation, arguing that such regulations have become divorced from the underlying promulgating Stark Law statute and are thus unenforceable. That is, defendants may argue that the nature of the alleged violation cannot be squared with the statutory language of the Stark Law, regardless of any corresponding Stark regulation. Indeed, as compared to its web of regulations, the statutory text of the Stark Law itself is more bare. For example, it does not define key statutory terms, such as "financial relationship," "compensation arrangement," "referral," and "remuneration," nor does the Stark Law delegate authority to the secretary of the Department of Health and Human Services to establish additional terms and conditions or take action in any way with respect to these terms.

Given that Stark regulations are now on less certain ground, litigants will be more likely to focus their efforts on whether the conduct violated the Stark Law itself, such that courts need not further analyze the regulations. For example, in *United States ex rel. Sheldon v. Forest Lab'ys LLC*, the relator alleged that his former employer, a pharmaceutical manufacturer, failed to include certain customer price concessions in its calculation of "Best Price," as that term is defined in connection with the Medicaid Drug Rebate Statute in violation of the False Claims Act. No. CV ELH-14-2535, 2024 WL 4544567, (D. Md. Oct. 22, 2024). While recognizing that the web of regulations at issue may be implicated by *Loper Bright*, the court sidestepped the issue by holding that the court need only interpret the rebate statute for itself. *Id*. at *33.

Notwithstanding uncertainty over the prohibitions contained in Stark regulations, however, defendants should still be able to avail themselves of the regulatory exceptions and safe harbors in litigation. Although Stark Law is a strict liability statute, Stark-based violations are typically asserted through fraud-based statutes that require a showing of scienter. Even if a safe harbor were deemed inconsistent with the statute during litigation, defendants will still be able to describe their good-faith subjective belief of compliance. Indeed, as the court noted in *Sheldon*, "[t]he Court's conclusions that [defendant] did not act with the requisite scienter . . . in no way depend on or involve the exercise of deference to CMS's interpretation

of the Rebate Statute." *Id*. at *33.

Moreover, as a practical matter, relators and the government will continue to be less inclined to bring claims in the face of an applicable regulatory exception, regardless of its ultimate validity.

Finally, the Stark Law itself expressly delegated authority to the agency to create permissible exceptions pertaining to financial ownership and compensation arrangement prohibitions "[i]n the case of any other financial relationship, which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). This express delegation comports with language in *Loper Bright* allowing courts to defer to such agency regulations insofar as they are within the scope of the statutory delegation. *Loper Bright*, 144 S. Ct. at 2263 (noting in cases involving express statutory delegation that "the statute's meaning may well be that the agency is authorized to exercise a degree of discretion"). In a related vein, the agency has express statutory authority to enforce many of the Stark Law exceptions through regulation, such that the Stark regulations pertaining to these exceptions are more likely to survive judicial scrutiny. *See, e.g.*, 42 U.S.C. § 1395nn(e)(2)(D).

B. Compliance

From a compliance perspective, health care organizations should continue to abide by all existing Stark regulations and interpretative guidance notwithstanding *Loper Bright* or doubts about the validity of any such provisions. The Supreme Court itself made clear that the *Loper Bright* decision does "not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful . . . are still subject to statutory stare decisis . . . ." 144 S. Ct. at 2273. As the Sixth Circuit recently explained, "while *Loper Bright* opens the door to new challenges based on *new* agency actions interpreting statutes, it forecloses new challenges based on specific agency actions that were already resolved via *Chevron* deference analysis." *Tennessee v. Becerra*, 117 F.4th 348, 363 (6th Cir. 2024). Thus, health care organizations should remain compliant with all existing Stark guidance, including *Chevron*-era guidance.

Moreover, as a threshold matter, *Loper Bright* did not result in the invalidation of any specific Stark regulations. It instead changed the scheme whereby courts no longer defer to agencies in evaluating whether such regulations are reasonable interpretations of ambiguous statutes. And, although deference is not required, the Supreme Court still explained that courts should give agency interpretations "due respect," while exercising their "independent judgment" to seek out the best meaning of a statute. *Loper Bright*, 144 S. Ct. at 2257.

At this preliminary juncture, to ensure Stark Law compliance in the wake of *Loper Bright*, health care organizations must place added emphasis on compliance with the statutory text of the Stark Law, including its prohibitions and permissive compensation arrangements. An organization should evaluate added risks associated with compensation structures that, although grounded in CMS regulatory exceptions, lack a firm statutory basis. The principal inquiry for Stark Law compliance must be the statute itself.

However, in light of *Loper Bright*, there will likely be future opportunities for health care providers to challenge CMS interpretations of the Stark Law where such interpretations are not clearly supported by the statute itself.

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Loper: A Perspective from the Relator's Side

By Rachel V. Rose, JD, MBA

Overview

On June 28, 2024, the United States Supreme Court delivered its anticipated Opinion in *Loper Bright Enterprises v. Gina Raimondo*, 144 S.Ct. 2244 (2024) ("*Loper*"), which consolidated two cases alleging that the Magnuson-Stevens Fishery Conservation and Management Act ("MSA") did not authorize a government agency to promulgate final rules "requiring Atlantic herring fishery to fund costs for on-board observers required by fishery management plan." At issue was whether or not courts, under the Administrative Procedure Act ("APA"),[1] either "need not" or "may not, defer to an agency's interpretation of the law simply because a statute is ambiguous." In doing so, the Court seemingly overruled forty (40) years of precedent under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984) ("*Chevron*"). The question before the Court in *Chevron* was "whether the agency's answer is based on permissible construction of the statute." *Id*. The Court held that "[t]he EPA's plantwide definition is a permissible construction of the statutory term, 'stationary source.'" *Id*., at 842.

One key item to note is that *Chevron* never addressed the APA, which requires agency to go through certain steps, including a public notice and comment period conjunctively with a notice of proposed rulemaking ("NPR") before a Final Rule is published in *The Federal Register*.

But did it really overrule *Chevron* completely and wipe out the two (2) factors comprising the Chevron framework – (1) is the statute clear (or has Congress spoken to it in the legislative history) and (2) is the agency's interpretation reasonable?

The answer is no. The rest of this article is dedicated to substantiating this position, as well as addressing recent False Claims Act, 31 U.S.C. §§3729-3733 ("FCA") cases where *Loper* came into play.

Analysis

Let's start with the *Loper* holding. "The [APA} requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and courts may not defer to an agency interpretation of the law **simply because a statute is ambiguous**." *Id*. at 2247. (emphasis added). Writing for the (6-3) Majority, Chief Justice Roberts articulated,

> 'The interpretation of the meaning of statutes, as applied to justiciable controversies,' remained 'exclusively a judicial function.' *United States v. American Trucking Assns., Inc.*, 310 U.S. 534, 544, 60 S.Ct. 1059, 84 L.Ed. 1345. **The Court also continued to note that the informed judgment of the Executive Branch could be entitled to 'great weight.'** *Id*., at 549, 60 S.Ct. 1059. 'The weight of such a judgment in a particular case' the Court observed, would 'depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.' *Skidmore v. Swift & Co*., 323 U.S. 134, 140, 65 S.Ct. 161, 89 L.Ed. 124. *Loper* at 2247. (emphasis added).

As the Dissent stated on page 2307 of Loper,

> *Chevron* is by now much more than a single decision. This Court alone, acting as *Chevron* allows, has upheld an agency's reasonable interpretation of a statute at least 70 times. See Brief for United States in No. 221219, p. 27; App. To id, at 68a-72a (collecting cases). Lower courts have applied the *Chevron* framework on thousands upon thousands of occasions.

This is keeping with APA Section 706, which says it is the responsibility of a court to decide whether the law means what the agencies said. Therefore, to the extent there are facts within an agency's expertise, the agency can inform — but not bind — a court, which is consistent with long standing precedent.

If "Congress has spoken to the precise question at issue [and] [i]f and only if, congressional intent is 'clear,' that is the end of the inquiry." *Loper* at 2254 (internal citations omitted). In essence, in *Loper* like in *Chevron*, if Congress's intent is clear or if Congress has not spoken to in Congressional hearings or in related laws, which should be read *in pari materia*, then the inquiry ends. Stated another way, when Congress gives an agency express rulemaking authority on a given subject related to a particular law – the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[2] for example - then it is incumbent upon the agency to follow the APA's procedures in promulgating the related rules and regulations, which are eventually published in *The Federal Register*. HIPAA Subtitle F §261 effectuates Congress' intent,

> **It is the purpose of the subtitle** to improve the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system by encouraging the development of a health information system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

Similarly, HIPAA §262 – Part C, requires the United States Department of Health and Human Services ("HHS") to adopt standards and administrative simplification with the context of §262's general requirements set forth by Congress.

If the statute is ambiguous, then a court may defer to an agency's interpretation. This is more consistent with *Skidmore v. Swift*, 323 U.S. 134, 139-140 (1944) where "an agency's interpretive judgements as to particular issues are entitled to some degree of deference in view of several factors, including the agency's 'specialized' knowledge, the 'thoroughness' of its consideration of the issue, 'the validity of its reasoning,' and its consistency with the agency's other decisions." A related consideration is whether the item at issue is a final agency action.

In *Chemours Company FC, LLC v. United States Environmental Protection Agency*, 2024 WL 3505119 (3rd Cir. 2024), the court addressed whether or not the Environmental Protection Agency's (EPA) health advisory for hexafluoropropylene oxide dimer acid and its ammonium salt (HFPO-DA) found in drinking water did not impose legal consequences under CERCLA, and thus agency actions under CERCLA did not make the health advisory a "final agency action" subject to judicial review under the Safe Drinking Water Act (SDWA), **where nothing in CERCLA or its implementing regulations required authorities to incorporate the health advisory in their hazardous substance clean-up plans**. (emphasis added).

Chemours contended that the Health Advisory was unlawful. The Third Circuit dismissed the petition for lack of subject matter jurisdiction because the Health Advisory was not a final agency action. In its analysis the Court of Appeals stated that in enacting the SWDA, Congress expressly stated that one possible action is regulation.[3] Moreover, consistent with the APA's requirements, the SWDA expresses that prior to promulgating a regulation for drinking water, **EPA must undergo notice-and-comment procedures. Id. §§ 300g-1(b)(1)(A)–(E)**. (emphasis added). The SWDA also enabled the agency to issue a health advisory in lieu of regulating the item.

As the Third Circuit stated, "[t]he health advisory also does not give rise to any 'direct and appreciable legal consequences.' *Bennett*, 520 U.S. at 178, 117 S.Ct. 1154. Congress foreclosed the possibility of direct legal consequences when it stated that "health advisories ... are not regulations[ ]." WL at *4. Furthermore,

> Because we view the finality requirement as jurisdictional, *see W.R. Grace & Co.*, 261 F.3d at 338, and we are free "to choose among threshold grounds for denying audience to a case on the merits," *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 584, 119 S.Ct. 1563, 143 L.Ed.2d 760 (1999), we need not address the other jurisdictional issue raised in this matter: whether Chemours has standing. Additionally, because we decide this case on jurisdictional grounds, the Supreme Court's recent decision in *Loper Bright Enters. v. Raimondo*, ––– U.S. ––––, 144 S. Ct. 2244, ––– L.Ed. 2d –––– (2024), does not affect our analysis.

Therefore, bringing us back to whether or not Congress has spoken and whether the item at issue is a regulation as threshold questions regarding when parties should raise *Loper* in relation to agency interpretation. From the Relator's side, here are items to address when opposing counsel raises *Loper* in a case.

- *Loper* **only** affects rules or agency action that was based on a **statutory ambiguity or silence**.
- Consideration must be given when Congress requires an agency to promulgate related rules and regulations and whether or not the agency went through the rule making process in accordance with the APA.
- Clear grants of power by Congress to an agency remain in place, because these never needed the protections of *Chevron* deference.
- *Loper* **does require** a court to exercise its independent judgment when considering an agency's interpretation of an ambiguous statute, **it does not require the court to *disagree* with the agency**. Courts in the exercise of their own judgment may still conclude that the agency has the best reading of an ambiguous statute.

So, what is happening in FCA cases post-*Loper*? A recent Westlaw search highlighted two cases – *United States ex rel. Sheldon v. Forest Laboratories, LLC*, -- F. Supp.3d – (2024), which is on appeal to the Fourth Circuit and *United States ex rel. Liesa Kyer v. Thomas Health System, Inc.*, Case No. 2:20-c-00732 (D. W.V. Sept. 12, 2024) (asking the parties to brief the Stark Law claim in light of *Loper* so that the judge can "ensure that the Stark regulator scheme is consistent with the power given by Congress and the statute as it was signed into law."). One take-away is that moving forward both sides of the aisle should be exacting in where the authority comes from, much like how agencies outline their regulatory authority in final rules. Another take-away is that not all regulations can or should be challenged because there is ample case law and Congressional language, as well as verbiage in the NPRs related to the APA.

Conclusion

Chief Justice Roberts stated that cases decided under *Chevron* are not automatically invalidated because of *Loper*. This means that prior cases interpreting the statute should be considered. Another issue, which may make interpretation tricky, is when different U.S. District Courts and in turn different circuits interpret a regulation and reach a divergent outcome. Which opinion does a company follow, how does it impact its compliance program, and how is this best addressed at trial? At least *Chevron*'s required deference created more uniformity.

The FCA remains the United States Government's number one tool to recover monies for the Federal Fisc. Relators and the Government should be able to meet most defense challenges or court requested briefings and overcome any objections. Still, there are some instances, just as there were under *Chevron*, where agencies overstep, or Congress has not spoken. This is where a court's role is the same as it has always been – to interpret the law.

Rachel V. Rose, JD, MBA (Houston, Texas), advises clients on compli-

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Private Equity Throws FCA Enforcement Off-Kilter

By Alexander M. Owens

Private Equity's Expanding Role in Healthcare

Over the last 15 years, private equity ("PE") firms have invested hundreds of billions of dollars in the healthcare sector, infiltrating every corner of the industry from emergency rooms and labs to billing providers and dental practices. Relators and the Department of Justice ("DOJ") have taken close notice. PE firms are increasingly being named in False Claims Act ("FCA") lawsuits. A growing number of settlements with PE firms and mounting case-law finding that PE firms can, in the right cases, be held liable under the FCA[1] will ensure that the trend continues.

Yet PE liability under the FCA remains the exception, not the rule. In most cases where a PE firm's portfolio company has violated the FCA, the PE firm will not be held liable. That reflects a couple of basic realities. Relators typically work at the portfolio company, which offers limited visibility into the conduct of the PE firm. Further, the PE firm may have no relevant connection to the fraud anyway, and mere ownership of a fraudulent enterprise is not enough for FCA liability.

Overleveraged Corporate Defendants

PE firms use leveraged buyouts ("LBOs") to purchase companies. In an LBO, a PE firm borrows large sums of money to finance the acquisition of a company on behalf of one of its funds. A $200 million buyout might be financed with $50 million in equity and $150 million in debt. Significantly, service of that debt falls, not on the PE firm or fund, but on the portfolio company. With interest rates having spiked in recent years, these debt obligations have risen further still.

A growing roster of overleveraged defendants is not good for FCA recoveries and enforcement. The FCA's treble damages and civil monetary penalty ("CMP") provisions allow the government to not just make itself whole but penalize fraudsters. That serves critical public policy aims, chief among them, deterrence. Yet with healthcare companies increasingly owned by PE, FCA cases are often being settled (e.g., on an ability-to-pay basis) for well below the double damages figures that have become the gold standard for FCA resolutions. The government may not even be made whole through a single damages settlement – and, in such cases, *fraud pays* given that the wrongdoer makes more from the fraud than it pays via settlement.

This dynamic is even more concerning because PE firms can financially benefit from fraud. Fraud-driven revenue at a portfolio company services that company's debt. As debt falls, the value of the PE fund's equity stake in the portfolio company grows. When the portfolio company is sold, the PE fund and firm (e.g., through carried interest) then gets a bigger slice of the sale proceeds. Meanwhile, fraud-driven revenue can help to pay for dividend recapitalizations where the portfolio company takes on debt to finance generous dividend payments.

If, in a given case, a PE firm can profit from fraud but cannot be held liable, while the portfolio company is too debt-laden to pay a fair settlement, what options does DOJ have to obtain an adequate resolution? There are two key avenues.

Fraudulent Transfers

The Federal Debt Collection Procedures Act ("FDCPA")[2] allows the government to obtain relief, including prejudgment remedies, premised on fraudulent transfers made by one owing a debt to the federal government.

Fraudulent transfers can occur where, inter alia, an FCA defendant which is insolvent (or will become insolvent due to an asset transfer) transfers assets without receiving reasonably equivalent value in return. FCA liabilities (including treble damages and CMPs) are "debts" under the FDCPA which arise at the time of overpayment.[3]

As a result of the FCA's treble damages and CMP provisions, a PE-owned company engaged in significant fraud can easily find itself *legally* insolvent under the FDCPA. FDCPA liability can then arise if the portfolio company makes a payment to a related entity. For example, portfolio companies often pay dividends to PE funds or so-called monitoring fees to PE firms. This creates fraudulent transfer risk if the payments occur after significant FCA debts arise.

A recent settlement involving healthcare investors is instructive. In January 2024, DOJ settled FCA claims against Silver Lake Hospital for $18.6 million. DOJ did not bring FCA claims against the hospital's investors but obtained a $12 million FDCPA settlement with those parties. DOJ alleged that the investors received fraudulent transfer distributions from the hospital.

The FDCPA, however, is not a cure all for the complicating financial dynamics that PE introduces to the FCA arena. Much of the revenue from a portfolio company will not be distributed to PE firms or funds but instead will be used to pay down pre-existing loan debts. Such payments would typically not be fraudulent transfers as they would be made for legitimate, antecedent debts. And even when DOJ pursues an FDCPA case, unless the relator can establish that the relief is an alternative remedy under the FCA, the relator will not share in the recovery.

Individual Liability

Despite longstanding DOJ policy calling for FCA enforcement against individuals, most FCA cases still do not result in any meaningful individual accountability. This is due to practical difficulties, most pertinently, the fact that individuals tend to lack deep pockets – or at least their pockets are not nearly as deep as those of their employers.

When FCA violations occur before a buyout, that dynamic can reverse. Attendant to a buyout, the prior owners' illiquid equity stakes turn into large cash payments. If

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2024 False Claims Act Settlements and Judgment Record-breaking Year: The Standout

By Jay Holland, Veronica Nannis, and Gia Grimm

False Claims Act ("FCA") settlements exceeded $2.68 billion in the Department of Justice's ("DOJ's") fiscal 2023 reporting. 2024 settlements show no signs of slowing down.[1] In 2023, over $1.8 billion of the $2.68 billion related to matters involving the health care industry, including managed care providers, hospitals, pharmacies, laboratories, long-term acute care facilities, and physicians. In 2023, the government and whistleblowers were party to 543 settlements and judgments, the highest number of settlements and judgments in a single year.[2]

With that background, this article looks at some standout settlements that were announced in late 2023 and so far in 2024. As usual, the largest FCA settlements are in the healthcare space, and kickback allegations continue to dominate, including many of the following:

On November 15, 2023, DOJ announced that Prema Thekkek, her management company, Paksn Inc., and six skilled nursing facilities owned by Thekkek and/or operated by Paksn entered into a **$45.6 million** ability-to-pay consent judgment to be paid out over the next five years. This settlement resolved allegations that the defendants submitted or caused the submission of false claims to Medicare by paying kickbacks to physicians to induce patient referrals in violation of the AKS. Allegations included that some doctors were paid $2,000 per month in exchange for patient referrals. The case was brought under the qui tam provisions of the FCA by the defendant's former Vice President of Operations and Chief Operating Officer, Trilochan Singh.

On December 19, 2023, DOJ and the USAO for Indiana announced the largest FCA settlement ever based on the Stark Law when Community Health Network, Inc. ("Community") agreed to pay **$345 million** to settle the United States' allegations that it violated the FCA by knowingly submitting claims to Medicare for services that were referred in violation of the Stark Law. Community also entered into a strict, five-year Corporate Integrity Agreement with close monitoring by HHS-OIG. Before Community's settlement in December, the Adventist Health case had been the largest Stark Law based FCA settlement at $115 million in 2015.

In its Complaint In Intervention, the United States alleged that the compensation Community paid to its employed physicians from three different physician specialties was above fair market value, that Community awarded bonuses to physicians that were tied to the number of their referrals, and that Community submitted claims to Medicare for services that resulted from these unlawful referrals. The United States alleged that beginning as far back as 2008, senior management at Community, including its CEO, decided to pursue an illegal scheme to recruit physicians for the purpose of capturing their lucrative "downstream referrals," often paying them salaries that were significantly higher — sometimes as much as double — what they were receiving in their own private practices.

The lawsuit was brought by Community's former Chief Financial Officer and Chief Operations Officer, Mr. Tom Fischer, as a relator under the qui tam provisions of the FCA through a complaint he filed in 2014. After six years of investigation and four years of hard-fought litigation, the $345 million settlement represented only the two claims on which the United States intervened. Relator continued pursuing the four non-intervened claims on his own, with the authors of this article as Relator's Lead Litigation Counsel. There will be more to report on this part of lawsuit at a later date.

On January 4, 2024, the DOJ announced that ChristianaCare, a healthcare facility operator in Delaware, agreed to pay **$42.5 million** to resolve allegations that the company provided ancillary service providers—including nurse practitioners and physician assistants—to assist with patients as an inducement to non-employee doctors to refer patients to the company's hospitals. The complaint alleged that these arrangements violated the Anti-Kickback Statute ("AKS") and the Stark Law. This lawsuit was brought by ChristianaCare's former chief compliance officer, who filed suit as a relator under the FCA in 2017.

On February 29, 2024 opioid manufacturer Endo Health Solutions, Inc. agreed to pay **$475.6 million** to resolve civil FCA allegations related to its marketing schemes and sale of opioid drugs targeted to providers that Endo knew were prescribing for non-accepted uses. A former Endo employee-turned-relator filed this lawsuit. DOJ alleged that the company marketed its opioid drugs to providers the company knew prescribed the drug for non-medically accepted indications, and that the company incentivized such targeting through sales goals, employee incentive compensation plans, and employee performance reviews. In resolution of a parallel criminal investigation, the comprehensive settlement also required a debtor affiliate of the manufacturer to plead guilty to a misdemeanor violation of the Food, Drug and Cosmetic Act ("FDCA") based on allegations that it introduced misbranded drugs into interstate commerce.

A parallel criminal resolution included the second-largest set of criminal financial penalties ever levied against a pharmaceutical company, including a criminal fine of $1.086 billion and an additional $450 million in criminal forfeiture. Prescribing for unapproved uses drastically contributed to the opioid epidemic and resulted in countless deaths. The criminal guilty plea and penalties reaffirm DOJ's commitment to holding accountable those

whose illegal conduct contributed to the opioid crisis.

Moreover, after Endo filed for bankruptcy in 2022, this omnibus settlement also resolved the government's claims under the bankruptcy agreement, and it will be paid up to $464.9 million over 10 years.

On June 21, 2024, DOJ announced that Sikorsky Services Inc. and Derco Aerospace Inc. (aerospace and parts companies) agreed to pay **$70 million** to resolve allegations that they overcharged the Navy for spare parts and materials for repairing and maintaining aircraft used to train naval aviators. The government alleged that Sikorsky entered an improper cost-plus-percentage-of-cost subcontract with Derco in violation of both a federal statute and Sikorsky's prime contracts with the Navy. According to the government, based on Sikorsky's failure to disclose the nature of the non-compliant contract, the Navy reimbursed Sikorsky for improper markups on the cost of parts Sikorsky purchased from Derco. Two former Derco employees filed suit as relators at different times, the first in 2011 and the second in 2014. They were consolidated and the United States intervened in both before the second case was dismissed. For her part, the relator was awarded $13,976,900 in addition to a portion of the interest.

On May 13, 2024, DOJ announced that Kabbage Inc., a now-bankrupt lender agreed to pay up to **$120 million** to resolve allegations that it submitted false claims for loan forgiveness, loan guarantees, and processing fees to the government under PPP. The company agreed to pay up to $63.2 million to resolve allegations that the company inflated PPP loans, causing the Small Business Administration to guarantee and forgive greater loan amounts than borrowers were entitled to receive. And then the company agreed to pay up to $56.7 million to resolve allegations that the company knowingly failed to implement adequate fraud controls to comply with its regulatory obligations to prevent fraudulent borrowers from seeking PPP benefits.

These claims were the result of two separate cases brought by relators under the FCA. The first was brought in 2020 by an accountant who submitted PPP loan applications to Kabbage and other lenders, and the other in 2021 by a former analyst in Kabbage's collections department.

This settlement highlights the Attorney General's COVID-19 Fraud Enforcement Task Force, first announced in May 2021, which marshals and coordinates federal resources to combat and prevent pandemic-related fraud.

On September 13, 2024, DOJ announced that Walgreens Boots Alliance Inc. and Walgreen Co. agreed to pay **$106.8 million** to settle charges that it violated the FCA by billing government health care programs for prescriptions never dispensed. The government specifically alleged that, between 2009 and 2020, Walgreens submitted false claims for payment to federal health care programs for prescriptions that it processed but that were never picked up by beneficiaries, and not returned to the government by Walgreens. This settlement was the result of three different cases brought by relators under the qui tam provisions of the FCA. The largest relator share went to the first to file, a former Walgreens pharmacy manager, who was awarded $14,918,675 for his efforts.

On October 13, 2024, DOJ announced that Teva Pharmaceuticals USA Inc. and Teva Neuroscience Inc. agreed to pay **$450 million** to resolve two matters that allege Teva violated the AKS and the FCA. The government alleged Teva (1) violated and conspired to violate the AKS and FCA by paying Medicare patients' cost sharing obligations (copays) for the multiple sclerosis drug Copaxone from 2006 through 2017, while steadily raising Copaxone's price; and (2) conspired with other generic drug manufacturers to fix prices for pravastatin, clotrimazole, and tobramycin. This massive civil settlement is in addition to a $225 million criminal penalty for admitting to conspiracy to fix prices on certain generic drugs with three other companies.

On July 10, 2024, DOJ announced that Rite Aid Corporation and Rite Aid subsidiaries, Elixir Insurance Company, RX Options LLC and RX Solutions, LLC, agreed to pay **$101 million** to resolve allegations that they violated the FCA by failing to accurately report drug rebates. The government alleged the defendants improperly reported to CMS portions of rebates received from manufacturers as bona fide service fees, even though manufacturers did not negotiate with the defendants to pay such fees. The settlement resolved allegations initially brought by a relator under the qui tam provisions of the FCA. Defendants RX Options and RX Solutions granted the United States an allowed, unsubordinated, general unsecured claim for a total of $20 million in Rite Aid's bankruptcy case pending in the District of New Jersey. This is an ability to pay settlement.

On September 18, 2024, DOJ announced that Oak Street Health agreed to pay **$60 million** to resolve allegations that it violated the False Claims Act by paying kickbacks to third-party insurance agents in exchange for recruiting seniors to Oak Street Health's primary care clinics. This settlement was the result of an FCA case filed by a relator, who was awarded a $9.9 million relator share for his contributions.

On October 16, 2024, DOJ announced that Raytheon Company will pay over $950 million in connection with foreign bribery, export control and defective pricing schemes. As part of the agreement, Raytheon entered a **$428 million** settlement to resolve allegations that it violated the FCA when it provided untruthful certified cost or pricing data when negotiating prices with the DOD for numerous government contracts and double billed on a weapons maintenance contract.

We are eager to see how the 2024 fiscal year wraps up and will continue monitoring FCA settlements and legislative activity.

Jay Holland and Veronica Nannis are shareholders and Gia Grimm is an associate at Joseph Greenwald and Laake PA, with nationwide experience representing whistleblowers and litigating False Claims Act cases. Holland, Nannis and Grimm are lead counsel representing the relator in the Community Health Network case, which partially settled in 2023 for a record-breaking $345 million. They can be reached via email at jholland@jgllaw.com; vnannis@jgllaw.com; and vgrimm@jgllaw.com.

Endnotes

[1]See Office of Public Affairs | False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023 | United States Department of Justice
[2]Office of Public Affairs | False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023 | United States Department of Justice

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ance, transactions, government administrative actions, and litigation involving healthcare, cybersecurity, corporate and securities law, as well as False Claims Act and Dodd-Frank whistleblower cases. She also teaches bioethics at Baylor College of Medicine in Houston. Rachel holds a variety of leadership positions within the FBA, including serving on its National Board of Directors and can be reached through her website, www.rvrose.com.

Endnotes

[1]5 U.S.C.A. § 551 et seq. ("enact[ing] the APA as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices, and as the culmination of a comprehensive rethinking of the place of administrative agencies in a regime of separate and divided powers.)".
[2]Pub. L. 104-191 (Aug. 21, 1996).
[3]Congress enacted the Safe Drinking Water Act (SDWA), 42 U.S.C. § 300f et seq., to protect the quality of drinking water. To further that goal, the statute authorizes EPA's Administrator to take various actions against contaminants in waters. Id. § 300g-1.

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the prior owners were engaged in the fraud, DOJ now has individuals who can be held liable and have the ability to pay a sizable resolution. In fact, those individuals, compared to the heavily indebted corporate defendant, may have the deepest pockets of all.

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Endnotes

[1]*E.g., U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Centers*, No. 15-CV-13065, 2021 WL 2003016, at *17-18 (D. Mass. May 19, 2021) (denying PE firm's motion for summary judgment).
[2]28 U.S.C. § 3001, *et seq*.
[3]*U.S. ex rel Doe v. DeGregorio*, 510 F. Supp. 2d 877, 883-84 (M.D. Fla. 2007).

Medicare Advantage Fraud and Enforcement Policies

By Ellen London and Allison Cook

It's impossible to attend a health care law conference, or even read a newspaper, these days without encountering the topic of Medicare Advantage. Why the sudden interest? After all, the program has been around for over 25 years. The answer, as is often the case, is in the numbers. In 2010, only 25 percent of Medicare beneficiaries were enrolled in a Medicare Advantage Plan. Now, that number has shot to 54 percent and is expected to rise in the coming years. This translates into well over $450 billion in government spending and, it turns out, what the government believes to be billions of taxpayer dollars in overpayments to Medicare Advantage's private insurers.[1]

What is Medicare Advantage?

Medicare Advantage, also known as Medicare Part C, allows beneficiaries to receive Medicare benefits via plans offered by private companies. CMS pays the Medicare Advantage plans capitated payments—i.e., a per-member-per-month figure—to provide care to beneficiaries. To avoid disincentivizing Medicare Advantage plans from enrolling "sicker" individuals, CMS offers "risk adjustment" payments based on those individuals' diagnoses. For a Medicare Advantage program to receive such payments, the program must submit claims that include, among other things, (1) the beneficiary's diagnosis; (2) that the diagnosis was treated by a qualified provider; (3) that treatment occurred during the relevant treatment year; and (4) treatment was provided in a face-to-face visit.

Combatting Fraud in the Medicare Advantage System – Risk Adjustment

As numerous news outlets have reported over the past few years, this system is not without risk.

In fact, estimates suggest that tens—if not hundreds—of billions of dollars may have been lost to fraud, waste, and abuse in the system.[2]

It is thus not surprising that combatting fraud in the Medicare Advantage program is a top priority for both the HHS OIG and the Department of Justice. Last year, HHS-OIG highlighted this issue in its Strategic Plan: Oversight of Managed Care for Medicare and Medicaid, explaining that "more must be done to address risks of fraud, waste, and abuse in managed care programs," and that "[i]nsurance companies must be held accountable if they game the system."[3]

Top DOJ officials have emphasized the same, with Deputy Assistant Attorney General Brian M. Boynton stating, "[DOJ is] committed to rooting out illegal practices committed by Medicare Advantage providers, insurance agents and brokers . . . ."[4]

Front and center in this fight is the submission of false and inaccurate diagnosis codes which make a patient appear sicker than they are. This results in a higher payment from the government to the insurer. DOJ and relators have pursued numerous False Claims Act actions targeting such schemes, resulting in hundreds of millions in recovery to the government over the last several years, with several large cases still pending. *See, e.g., United States ex rel. Osinek v. Permanente Med. Grp.*, 640 F. Supp. 3d 885 (N.D. Cal. 2022).

Likewise, HHS OIG has completed a series of plan-specific audits, as well as industry-wide reviews that shed light on the massive scale of the problem.

Inflated diagnoses, however, is not the only theory of FCA liability in the Medicare Advantage program, and the government is now turning its eyes towards other alleged schemes.

The New Frontier of Enforcement in the Medicare Advantage Space – Kickbacks

A new front has emerged in False Claims Act Medicare Advantage cases: kickbacks. In September 2024, Oak Street Health (a wholly-owned subsidiary of CVS Health) agreed to pay $60 million to resolve kickback allegations in connection with the Medicare Advantage program. In that matter, Oak Street Health allegedly paid insurance agents to contact seniors eligible for or enrolled in Medicare Advantage in order to refer those individuals to Oak Street Health. In exchange, Oak Street paid the insurance agents approximately $200 per beneficiary recommended or referred. The government alleged that Oak Street's subsequent (tainted) claims for payment for these beneficiaries' care were false.

The Oak Street Health matter is not alone. For example, in *United States ex rel. Butler et al v. Shikara et al.*, the relators allege that "an insurance company owned and operated by [the Defendant physician], would mobilize its agents at [the Defendant physician's] request to enroll patients with specific Medicare Advantage plans sold by particular [Medicare Advantage Organizations]."[5] As alleged, the decision of which insurer to send a given patient to was not driven by that individual patient's needs, but rather by whichever insurer "provided the sweetest financial deal for the Defendant physician." In denying defendants' motions to dismiss, the district court emphasized that a Medicare Advantage insurer is "prohibited by law to directly pay [physicians or physician groups'] to enroll . . . patients in their respective Medicare Advantage plan." Attempting to "backdoor those same patients to their plans by paying [the Defendant physician's] own insurance agency" is, "[a]s a matter of common sense," not a way to avoid liability under the FCA.

Additional Avenues of Enforcement

With enrollment only increasing, it is unlikely that the DOJ will shift its enforcement priorities away from Medicare Advantage fraud any time soon. HHS-OIG's Strategic Plan can give relators and companies an idea of the types of Medicare Advantage fraud – in addition

to diagnosis code inflation and kickbacks – that could be the next area of focus:

- **Fraud in connection with plan establishment and contracting:** Medicare and Medicaid have operational requirements for Medicare Advantage Organizations, such as financial solvency and providing an adequate network of physicians to beneficiaries. If Medicare Advantage Organizations misrepresent their compliance with those requirements, relators and the government may argue that those organizations could be liable under the False Claims Act. This is not a new theory, but it is likely to appear with increased frequency as the government ramps up scrutiny of all Medicare Advantage Plans. *See, e.g., United States et al. ex rel. Sewell v. Freedom Health, Inc., et al.*, No. 8:09-cv-1625 (M.D. Fla. 2009) (alleging, among other things, that Freedom Health made material misrepresentations to CMS regarding the scope and content of its network of providers in its applications to CMS).[6]
- **Fraud in connection with enrollment:** To attract more members, Medicare Advantage Organizations may be tempted to violate marketing guidelines, which could result in a claim that there is False Claims Act liability. The Eighth Circuit recently rejected the notion that marketing violations could be material to an FCA claim, *see United States ex rel. Holt v. Medicare Medicaid Advs. et al.*, 115 F.4th 908, 920 (8th Cir. 2024), but other jurisdictions have allowed this theory to proceed, *see Butler*, 2024 WL 4354807, at *14-16. Given the wide array of marketing regulations – and the increased focus on the relationships between Medicare Advantage Organizations and on-the-ground insurance agents and providers – it is possible that violations of at least some marketing rules or regulations may ultimately be held material to payment in certain cases. At the heart of these enrollment-focused FCA allegations is the notion that a Medicare Advantage Plans' submission of claims for a beneficiary that was enrolled on false pretenses (e.g., via a kickback) is a false claim subject to liability under the FCA. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 312 (3d Cir. 2011); *see also Butler*, 2024 WL 4354807, at *14-16 (adopting reasoning in *Wilkins* and extending it).

  In addition to marketing violations, Medicare Advantage Organizations could submit false eligibility information for enrollees to the government which could result in unwarranted payments.
- **Fraud in connection with services to people:** Per HHS-OIG, Medicare Advantage plans have different incentives based on the capitation payment. Therefore, plans may be tempted to prevent enrollees from accessing certain services to reduce medical costs and increase revenue, via pre-authorization processes or other onerous administrative hurdles. These practices too could lead to arguments about liability under the FCA.

Can These Cases Fit Within the False Claims Act Framework?

By its nature, Medicare Advantage poses various issues when it comes to False Claims Act cases. Defense counsel will want to consider various potential defenses in these matters, including but not limited to whether there is a claim, whether the materiality standard is satisfied, and whether the government has been damaged by the purported fraud. For example, in the *Holt* case, the district court found that the role of the insurance carriers undermined the relator's argument that the government was receiving a false claim for payment. The Eighth Circuit did not delve into this issue on appeal, focusing instead on materiality, which, as noted above, it found to be lacking.

Finally, due to the capitated per-member-per-month payment model, it can be challenging to determine the amount of damage (if any) the government sustained as a result of an alleged fraudulent claim. If the government is making capitated payments regardless of the services provided, it can be difficult to prove that the government would not have made those payments. This question has largely been resolved in the risk-adjustment cases (though disputes continue) but will remain an area of dispute and inquiry as a wider variety of fraud schemes are addressed in FCA cases. Relators may argue that the FCA penalties provision could be an avenue for recoveries in cases where damages are difficult to measure.

Conclusion

Potential relators and compliance departments should be on alert for these types of issues, and, if warranted by the circumstances, bring the issues to the DOJ's attention (either via a qui tam action or a voluntary self-disclosure). Defense counsel should be on the lookout for this to be a growing area of litigation and should be aware of the various defenses and how courts will view those defenses.

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tleblowers at all stages of litigation—from filing a qui tam complaint under seal all the way through trying the case to a jury. Through her representation of whistleblowers, Allison has developed specialized knowledge in many types of False Claims Act cases, including cases involving healthcare fraud, defense procurement fraud, and cybersecurity fraud.

Endnotes

[1]See https://oig.hhs.gov/reports/all/2024/medicare-advantage-questionable-use-of-health-risk-assessments-continues-to-drive-up-payments-to-plans-by-billions/
[2]See, e.g., https://www.thenation.com/article/society/medicare-advantage-privatization-inequity-fraud/
[3]See https://oig.hhs.gov/reports-and-publications/featured-topics/managed-care/Strategic_Plan_Managed_Care.pdf?oig-pub-tracking=ma-cigna-impact-brief
[4]See https://www.justice.gov/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks#:~:text=Boynton%2C%20head%20of%20the%20Justice,and%20the%20patients%20they%20serve.%E2%80%9D
[5]*United States ex rel. Butler et al v. Shikara et al.*, Case No. 20-80483, 2024 WL 4354807 (S.D. Fla. Sept. 6, 2024).
[6]See https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle