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The Health Law Section ("HLS") website has been updated with articles on significant developments in health law that may be of interest to you in your practice.

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FEDERAL CASE LAW

Eleventh Circuit Clarifies Public Disclosure Bar for Defense of FCA Qui Tams

A recent Eleventh Circuit ruling further expands what qualifies as news media when applying the public disclosure bar to whistleblower False Claims Act (FCA) claims.

The "**public disclosure bar**" is a key defense to FCA qui tam suits filed by whistleblowers, also called relators. While the FCA encourages individuals to report government-related fraud by filing a qui tam, the public disclosure bar prevents what the Eleventh Circuit described as "opportunistic relators with nothing new to contribute [from] exploit[ing] the False Claims Act's qui tam provisions for their potential benefit." Specifically, it prevents a relator from bringing an FCA qui tam suit based on "substantially the same information" that has been previously disclosed in the "news media."

In ***United States ex rel. Jacobs v. JP Morgan Chase Bank, N.A.***, the Eleventh Circuit further clarified the public disclosure bar's application. The court addressed what types of internet websites qualify as news media, the extent to which disclosed content must be substantially the same as the allegations of the qui tam and confirmed that the "quick trigger" determination continues to apply after the 2010 amendment.

In *United States ex rel. Jacobs,* the relator alleged that JP Morgan Chase acquired mortgage promissory notes from Washington Mutual after its collapse in 2008 and that "millions" of notes for mortgage loans were not properly executed. The relator claimed that JP Morgan Chase forged endorsements for these loans using signature stamps of former Washington Mutual employees. He accused the bank of submitting false claims for loan servicing costs to Fannie Mae and Freddie Mac.

The Eleventh Circuit upheld the district court's dismissal of the relator's complaint on the grounds that the FCA's public disclosure bar applied. The court found that the allegations had already been disclosed in three blog posts prior to the qui tam suit, and as a result, the relator was not an original source of the information in his qui tam.

The Eleventh Circuit's opinion addressed the following key areas:

1. News media include online blogs written for the purpose of publicly disseminating information.

The court expanded on its analysis in *United States ex rel. Osheroff v. Humana, Inc* as to what constitutes news media. The court reaffirmed that the public disclosure bar's reference to news media was to be given a "broad sweep" and include "publicly available websites intended to disseminate information to the public."

In *Jacobs,* the defendant sought dismissal on the grounds that three blog articles published online prior to the relator's suit constituted news media and that the content of those blogs publicly disclosed the fraud subsequently alleged in the qui tam. The court agreed and rejected the relator's attempt to characterize the online blogs as "merely individual-run accounts that

broadcast the personal views of their authors." Blogs, the court found, can be a source for the dissemination of public information under the FCA if they are intended to disseminate information to the public. The court left for another day the issue of whether private or personal social media pages could qualify as news media.

2. "Substantially the same" allegations do not mean identical allegations:

The public disclosure bar prohibits qui tams based on substantially the same allegations previously disclosed in news media. The court clarified that "substantially the same" does not mean the allegations must be identical. Rather, the court reaffirmed *Osheroff*, finding that publicly disclosed allegations need only "significant[ly] overlap" with the qui tam complaint.

Significant overlap does not require that the publicly disclosed information allege a violation of the FCA. While Rule 9(b) requires an FCA complaint to plead fraud with particularity, including details about the submission of fraudulent claims, this level of detail is not necessary for the public disclosure bar.

In *Jacobs*, the court found it sufficient that the blogs disclosed the "core fraud" hypothesis concerning Washington Mutual's original alleged fraud. The blog articles provided a sufficient inference of fraud, and the court rejected the relator's claim that the additional details he provided made him an original source, exempt from the public disclosure bar. The court observed that the relator's allegations "merely supplement[ed] and contextualize[d] the core fraud hypothesis in the blog articles."

3. District courts are to make a "quick trigger" determination as to whether the allegations in the qui tam complaint are substantially the same as allegations or transactions contained in public disclosures.

Prior to the 2010 amendments to the FCA's public disclosure bar, the Eleventh Circuit prescribed a three-prong "*Cooper*" test for determining whether the public disclosure bar applied:

1. Have the allegations made by the plaintiff been publicly disclosed?
2. If so, is the disclosed information the basis of the plaintiff's suit?
3. If yes, is the plaintiff an "original source" of that information?

The second prong was meant to act as a "**quick trigger**" to get to the "more exacting original source inquiry." The 2010 FCA amendments eliminated the "based upon" language of prong two. *Osheroff* clarified that "substantially the same" was to be substituted for "based upon" in the three-prong test. At least one district court, however, in *United States ex rel. Rubin v. Sterling Knight Pharms.*, questioned whether, in evaluating prong two, courts should still make a "quick trigger determination" when comparing publicly disclosed allegations with the qui tam complaint.

Jacobs makes explicitly clear that the quick trigger determination still applies and that the more exacting determination still resides with whether the relator is an original source of the information he provided as defined by the FCA.

In sum, *Jacobs* further expands what qualifies as news media for the FCA and how such sources can be marshalled to support defendants seeking dismissal of FCA claims based on the prior public disclosure of substantially the same allegations against a defendant online.

Submitted and authored by: A. Brian Albritton, Esq., and Raquel Ramirez Jefferson, Esq., Phelps Dunbar LLP

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Zafirov Decision Sets Stage for Appellate Showdown Over Constitutionality of FCA's Qui Tam Provision

For the first time ever, a judge has ruled that the *qui tam* provision of the False Claims Act (FCA), which whistleblowers have used to recover $52 billion on behalf of the government since 1986, is unconstitutional.

In *U.S. ex. rel. Zafirov v. Florida Medical Associates LLC* (*Zafirov*),[1] a whistleblower physician brought an FCA case against providers and a Medicare Advantage Plan for allegedly submitting false risk adjustment data to the Centers for Medicare and Medicaid Services. The relator posited that this was a scheme that yielded higher government reimbursement for services than was otherwise medically warranted. After five years of litigation, U.S. District Court Judge Kathryn Kimball Mizelle for the Middle District of Florida dismissed the whistleblower's suit because the FCA's "idiosyncratic" *qui tam* provision violates the Appointments Clause of Article II of the U.S. Constitution (the Appointments Clause). Article II, wrote Judge Mizelle, requires that the president, a court, or the head of a federal department appoint "Officers of the United States."[2] The test to determine whether a person is such an officer is whether the position (1) exercises significant authority pursuant to federal law and (2) is a continuing position established by law.[3]

Judge Mizelle found that relators in FCA cases exercise significant authority pursuant to federal law by bringing civil enforcement cases on behalf of the federal government to vindicate a public right, litigating such cases to final judgment and beyond, binding the government by setting precedent, and recovering treble "punitive" damages for the public fisc. The court noted that the Department of Justice (DOJ) only intervenes in about 20 percent of *qui tam* cases, and even then the government has "limited control" over the suits because it must obtain judicial approval for voluntary dismissal. Conversely, relators remain parties after government intervention; have "unchecked" power and "unfettered freedom" to initiate, litigate, and appeal these actions; and are not limited by DOJ policy or the Justice Manual. The court's order describes relators as having "greater independence than a Senate-confirmed United States attorney or assistant attorney general."

Judge Mizelle also found that relators hold a "continuing position established by law" because, among other things, the relator's position is not limited in duration and is non-personal in nature, akin to a self-appointed special prosecutor. Ultimately the court concluded that relators are officers of the United States who must be appointed to their positions pursuant to the Appointments Clause and granted the defendants' motion for judgment on the pleadings because the relator was "unconstitutionally appointed" when she brought the lawsuit.

The *Polansky* Effect

Zafirov will most likely be appealed to the United States Court of Appeals for the 11th Circuit. On appeal, the District Court's conclusion that FCA relators exercise significant authority pursuant to federal law (and are therefore federal officers who require appointment) will have to be reconciled against the Supreme Court's recent holding in *U.S. ex rel. Polansky v. Executive*

[1] *U.S. ex. rel. Zafirov v. Fla. Med. Assocs. LLC, et al.*, No. 8:19-cv-01236-KKM-SPF (M.D. Fla. Sept. 30, 2024) (granting Defendant's motion for judgment on the pleadings).
[2] Art. II. Sec. 2, Clause 2.
[3] *Buckley v. Valeo*, 424 U.S. 1, 126 n.162 (1976).

Health Resources Inc., where SCOTUS described the relator's control of a *qui tam* suit as being significantly more limited.

The *Polansky* Court reviewed the FCA's multiple restrictions on a relator's prosecution of a *qui tam* suit. For example, if the DOJ declines to intervene, the Government remains the "real party in interest," retains the right to stay discovery, and receives most of the lawsuit's ultimate financial recovery. If the DOJ intervenes, then the Government becomes a party, proceeds with the action alongside the relator, and acquires the right to dismiss the FCA suit despite the whistleblower's objections as long as the relator is provided notice and a hearing.

Importantly, the majority in *Polansky* held that pursuant to Section 3730(c)(3) of the FCA, the DOJ may intervene in a whistleblower's suit ***at any point in the litigation***, independent of the seal period, by showing "good cause." The DOJ can then dismiss a *qui tam* case over the relator's objections "whenever it has intervened" by meeting Federal Rule of Civil Procedure 41(a)'s lenient voluntary dismissal standard, which merely requires "a court order, on terms that the court considers proper." SCOTUS noted that Rule 41's dismissal standard "will be readily satisfied" by the DOJ's motion "in all but the most exceptional cases."

By applying Rule 41's lenient standard to the DOJ's dismissal motion in *Polansky*, SCOTUS adopted the Third Circuit's "Goldilocks" position. It rejected both a liberal standard advocated by the DOJ, which would have given the Government virtually unfettered discretion to dismiss pending FCA actions, and a more onerous dismissal standard advocated by the defendants. Although the DOJ's dismissal discretion is not absolute, the Government will meet the Rule 41 standard in FCA dismissal cases "[a]bsent some extraordinary circumstance." Accordingly, a relator's power is ultimately always limited by the DOJ's discretion to intervene and dismiss at any point in the relator's litigation of an FCA case.

Nonetheless, the *Zafirov* order relied heavily on Justice Thomas' dissent in *Polansky* without acknowledging the lenient dismissal standard the majority opinion adopted. For further analysis of the *Polansky* decision, please see our previous blog.

Should the *Zafirov* defendants win on appeal and create a circuit split, SCOTUS will be called upon to resolve the constitutionality of the FCA's *qui tam* provision, which could fundamentally alter the landscape of fraud enforcement nationwide. For now, at least one court has ruled that *qui tam* whistleblowers should be out of business. We will continue to monitor developments in this space.

Submitted and authored by: Jeremy Burnette, Esq. and Noam Fischman, Esq., Akerman LLP

ADMINISTRATIVE AGENCIES AND FEDERAL REGULATIONS

Artificial Intelligence in Healthcare: HHS Issues Final Rule on Nondiscrimination

Introduction

On May 6, 2024, the US Department of Health and Human Services Office for Civil Rights ("OCR") published a final rule (the "Rule") under Section 1557 of the Affordable Care Act ("Section 1557") advancing protections against discrimination in healthcare.[1] Section 1557 prohibits recipients of federal funding from discriminating in health programs and activities based on race, color, national origin, sex, age, or disability. Regulated entities include health care organizations, health insurers, and clinicians that participate in Medicare, Medicaid, or other programs (collectively, "Covered Entities"). The Rule gives additional protections to the categories of sexual orientation, gender identity, pregnancy, or related conditions along with disability and limited English proficiency (LEP).[2] The Rule also specifies that health insurers cannot deny, cancel, limit, or refuse to issue or renew health insurance coverage based on a protected characteristic. Overall, the Rule aims to reduce language access barriers, expands physical and digital accessibility, and address bias in health technology.

Artificial Intelligence and Technology

One of the chief reasons for the drafting of the Rule was to address the increasing use of artificial intelligence ("AI") in healthcare. The Rule states that nondiscrimination in health programs and activities continues to apply to the use of AI, clinical algorithms, predictive analytics, and other tools. The Rule applies the nondiscrimination principles under Section 1557 to the use of Patient Care Decision Support Tools in clinical care. Patient Care Decision Support Tools (hereinafter "Patient Care Tools") is defined as "any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities."[3] The Rule requires Covered Entities to: (1) make reasonable efforts to identify uses of Patient Care Tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability on an ongoing basis; and (2) for each Patient Care Tool, make reasonable efforts to mitigate the risk of discrimination resulting from the Patient Care Tool's use in its health programs or activities.[4] In practice, these Patient Care Tools are used for numerous purposes that impact patient care, including assessing patient health status, determining eligibility for certain care, analyzing medical necessity, and making recommendations related to care and disease management. Furthermore, these Patient Care Tools can perform screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, healthcare operations, and allocation of resources. The Rule applies to telehealth as well, which has seen a significant uptick after COVID-19.

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[1] Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024), https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities.

[2] Press Release, U.S. Department of Health and Human Services, *HHS Issues New Rule to Strengthen Nondiscrimination Protections and Advance Civil Rights in Health Care* (Apr. 26, 2024), https://www.hhs.gov/about/news/2024/04/26/hhs-issues-new-rule-strengthen-nondiscrimination-protections-advance-civil-rights-health-care.html.

[3] 89 FR 37522, 37695 (revising 42 C.F.R. § 92.4).

[4] *Id.* at 37701 (revising 42 C.F.R. § 92.210).

Compliance with the Rule

Notably, for practical purposes, the Rule applies *only* to the organizations and individuals who use AI tools, not to the entities that develop them. OCR notes that *if* the Covered Entity has reason to believe that Patient Care Tools use variables that measure race, color, national origin, sex, or disability, or otherwise is aware or reasonably should be aware, that the Patient Care Tool could potentially result in discrimination, the Covered Entity should consult publicly available sources (scientific articles, professional organizations, government agencies, and nonprofit organizations) or contact the developer of the tool.[5] OCR does not require Covered Entities to take specific risk mitigation efforts under Section 92.210(c) of the Rule. Rather, OCR notes that the "reasonable efforts" standard appropriately balances the need for Covered Entities to protect against discrimination versus the burden of doing so, while still allowing Covered Entities to implement greater protections against discrimination at their discretion.[6] In order to appropriately comply with these new identification and mitigation requirements under the Rule, within 300 days of the Final Rule's effective date (July 5, 2024), Covered Entities must establish and implement policies and procedures to assess their use of Patient Care Tools and their potential for discriminatory impact on patient care. Importantly, the Rule does not actually prohibit the use of protected characteristics as inputs to algorithms. Rather, citing age as an example, the OCR explains that such use is acceptable if considering the characteristic is clinically indicated or otherwise conforms to best practices.[7]

Enforcement

Starting in May 2025, the OCR will address potential violations of the Rule through complaint-driven investigations and compliance reviews. Individuals can seek to enforce Section 1557 through private lawsuits under certain circumstances as well. In terms of enforcement, OCR will assess each allegation of a violation of Section 92.210 on a case-by-case basis and may consider factors such as the Covered Entity's size and resources, whether the Covered Entity used tools in a manner intended by the developer and approved by regulators, whether the covered entity received product information from the tool's developer regarding variables that may lead to discrimination, and whether the covered entity has a process in place for evaluating patient care decision support tools.[8] If OCR receives a complaint of algorithmic discrimination, OCR will assess whether the Covered Entity reasonably attempted to identify algorithms that use characteristics like race, age, and gender to provide recommendations. Secondly, OCR's enforcement assesses whether the end user reasonably attempted to mitigate discrimination by the algorithm.

Conclusion

The likely consequences of violating Section 1557 are less harsh than one might think. Although penalties can include termination from Medicare or fines, the OCR typically enforces Section 1557 through corrective action plans. However, it is important for Covered Entities to demonstrate compliance with the Rule and take proactive and preventative measures to detect

[5] *Id.* at 37646–47.
[6] *Id.* at 37649.
[7] *Id.*
[8] *Id.* at 37648.

and respond to potential discrimination in Patient Care Tools. As OCR has issued manageable standards for the obligations of Covered Entities under the "reasonableness" standard, Covered Entities can be optimistic that AI innovation will not be stymied and should view the Rule as an important regulatory tool as healthcare enters its new technological frontier.

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Hospital and MA Plan Considerations for CMS Final Rule to Remedy 340B Drug Payment Policy

In November 2023, the Centers for Medicare & Medicaid Services (CMS) published a final rule, "Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022" (the "340B Payment Policy Final Rule").[1]

The rule, which goes into effect on January 8, 2024, describes CMS's plan to remedy its prior adjustments of Medicare Part B payment rates for drugs purchased by certain hospitals under the 340B Program for calendar years (CYs) 2018-2022. This remedy arises from the U.S. Supreme Court's June 2022 decision in *American Hospital Association v. Becerra*, which invalidated those earlier adjustments.[2]

While the 340B Payment Policy Final Rule addresses repayment of Medicare Part B reimbursement, this *Insight* discusses the potential secondary effects of the Supreme Court decision and the 340B Payment Policy Final Rule on hospital reimbursement by Medicare Advantage (MA) plans under Medicare Part C.

CMS guidance on how the 340B Payment Policy Final Rule will impact MA plans is limited. For contracted (i.e., in-network) hospitals, CMS here, as with other Medicare reimbursement issues,[3] takes a hands-off approach and lets the MA plans' contracts dictate the plans' repayment obligations, if any. For non-contracted (i.e., out-of-network) hospitals, CMS's guidance regarding what the MA plans must pay the non-contracted hospitals has the potential for varying interpretations, and repayment for 340B reimbursement may also end up pursuant to negotiations between the parties.

Background

In December 2017, CMS issued a final rule (effective January 1, 2018) (the "2018 Final Rule") to reduce Medicare Part B reimbursement for 340B drugs.[4] The reimbursement rate was significantly reduced for specific 340B hospitals from the average sales prices (ASP) plus 6 percent to ASP minus 22.5 percent for each drug. Rural sole community hospitals, children's hospitals, and prospective payment system (PPS)-exempt cancer hospitals were exempt from the payment adjustment due to their receiving special payment adjustments under the outpatient PPS (or "OPPS"). This significant change led to affected hospitals, "which generally serve low-income or rural communities," receiving less for 340B drugs provided to Medicare patients.

The Supreme Court in *American Hospital Association v. Becerra* invalidated CMS's 2018 Final Rule—holding that because CMS had not conducted a survey of the hospitals' acquisition costs,

[1] 88 Fed. Reg. 77,150 (Nov. 8, 2023).
[2] 596 U.S. 724 (2022).
[3] CMS has taken the same "hands-off" approach with regard to MA plans passing down or withholding sequestration cuts. *See* April 17, 2014, letter from CMS to the American Hospital Association where CMS stated, "We are prohibited from interfering in the payment arrangements between MAOs and contracted providers."
[4] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59,216 (Dec. 14, 2017). The 340B Drug Pricing program is a federal program that allows certain hospitals and other providers to purchase covered outpatient drugs from manufacturers at a discounted price. See 42 C.F.R. Part 10.

the agency could only set reimbursement rates based on the average price charged by manufacturers for the drug and could not vary reimbursement rates solely for 340B hospitals.[5] The decision reversed an earlier decision of the U.S. Court of Appeals for the District of Columbia Circuit, which had previously upheld the reduced reimbursement rates.[6]

In order to maintain budget neutrality and offset the additional spending required pursuant to the Supreme Court's decision, the 340B Payment Policy Final Rule establishes a 0.5 percent conversion rate with respect to all other Medicare Part B services (i.e., reducing these payments by 0.5 percent each year until the offset is reached, after approximately 16 years).

Key Takeaways from CMS's "Lump Sum Payments"

After the Supreme Court's decision in *American Hospital Association v. Becerra*, CMS reversed its policy setting reimbursement back to ASP minus 22.5 percent, provided that hospitals acquiring drugs under the 340B Program would be paid at the default rate of ASP plus 6 percent for CY 2023—with a reduction of 3.09 percent to the 2023 OPPS conversion factor to ensure "budget neutrality" and to offset the now-invalid former policy.

To remedy hospitals' $10.5 billion dollar loss in 340B drug payments from CY 2018-2022, CMS determined that the best option "would be to make one-time lump sum payments to affected 340B covered entity hospitals calculated as the difference between what they were paid for 340B drugs . . . and what they would have paid had the 340B Payment Policy not applied."[7]

The 340B Payment Policy Final Rule further instructs 340B hospital Medicare Administrative Contractors to issue the one-time lump-sum payments within 60 calendar days of receiving CMS instructions to pay. Hospitals will be paid at the end of CY 2023 or the beginning of CY 2024 and interest is not included in the remedy payments because CMS determined that it lacks the authority to do so.[8]

Considerations for Medicare Advantage Plans

Regarding MA, the 340B Payment Policy Final Rule reiterated the agency's position from its memorandum to MA plans in December 2022 (the "2022 memorandum"). The 340B Payment Policy Final Rule restated that MA plans must pay non-contract hospitals at least the amount such hospitals receive under Original Medicare payment rules, according to the Social Security Act.[9] However, with respect to contracted hospitals, the 2022 memorandum and the 340B Payment Policy Final Rule provide that CMS may not require an MA plan to use a particular

[5] 596 U.S. 724, 734 (2022).
[6] American Hospital Assn. v. Azar, 967 F.3d 818, 828 (2020).
[7] 88 FR 77156.
[8] 88 FR 77169 (citing *Libr. of Cong. v. Shaw*, 478 U.S. 310, 316 (1986) ("For well over a century, this Court, executive agencies, and Congress itself consistently have recognized that federal statutes cannot be read to permit interest to run on a recovery against the United States unless Congress affirmatively mandates that result.")).
[9] 88 FR 77184 (citing 42 U.S.C. § 1395w–22); *see also* 42 U.S.C. § 1395w-22(a)(2)(A) (2024) ("A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least (ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).").

pricing structure. Therefore, MA plans are free to negotiate payment rates, and the modification of such rates, with their contracted 340B entities.[10]

As a threshold matter, the increased Part B reimbursement to 340B hospitals may not be relevant to contracted hospitals unless the MA plan contract sets reimbursement at a percentage of the Medicare Part B fee schedule. Otherwise, the MA plan may have an argument that its reimbursement methodology is not impacted by any changes to CMS's reimbursement methodology under Medicare Part B.

For MA plan contracts that base hospital reimbursement on the Medicare fee schedule, the plans' obligation to reimburse such hospitals the difference in 340B drug costs may depend on other provisions in the contract. One such provision could be that which governs a hospital's right to recover additional funds from a plan that has underpaid a claim. An underpayment recovery provision is helpful to a hospital in that it gives the hospital a right to demand correction of inaccurate claims. However, oftentimes, participating provider agreements have language that places a time-based limit on the right to assert an underpayment recovery requested (e.g., within one year of the claim's payment date). In such a case, the MA plan may argue that it does not need to repay if the period for recovery of underpayment under the contract has lapsed.

In such negotiations, the parties may also want to consider that CMS has imposed cuts to other Part B services. Depending upon the individual facts and circumstances of the relationship between an MA plan and a hospital, the parties may wish to similarly seek "budget neutrality" in how they institute the repayments to 340B hospitals and corresponding decreases for all other Part B services.

The 2022 memorandum reminds MA plans that they "must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules."[11] Non-contracted hospitals may try to raise an argument to request repayment that does not exist for contracted hospitals. However, two factors may lead to difficulties for the MA plans and hospitals alike in seamlessly reconciling repayment issues related to the 340B payment adjustment.

First, neither the 340B Payment Policy Final Rule nor the 2022 memorandum lays out a reconciliation schedule for the MA plans and their non-contracted hospitals.

Second, non-contracted hospitals typically do not execute any sort of contract with the payor that could otherwise govern this type of reimbursement change.

In this case, while the repayment amount may be required under CMS guidance, the timing and other logistics of the repayment will likely be subject to a negotiation between the parties or, if the parties are unable to agree, determined by a court of law.

[10] Centers for Medicare & Medicaid Services, Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program—Informational for MAOs (Dec. 20, 2022) [hereinafter 2022 CMS Memo], https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf; 88 FR 77150, 77184.

[11] 2022 CMS Memo ("As a reminder, MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with section 1852(a) of the Act.").

Looking Ahead

MA plans and 340B hospitals subject to repayment under the 340B Payment Policy Final Rule will have to review the terms of any relevant contracts and their respective rights and responsibilities in light of the 340B Payment Policy Final Rule to repay affected 340B hospitals.

These rights and obligations will likely differ for contracted and non-contracted hospitals, given the guidance in CMS's 2022 memorandum and the 340B Payment Policy Final Rule. For contracted hospitals, the right to repayment will depend on the extent to which the contract both bases reimbursement on the Medicare fee schedule and sets forth an affirmative obligation to repay the 340B cuts. For non-contracted hospitals, the main challenge will be strongly negotiating a reconciliation process for the timely repayment of the 340B cuts.

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Health Care Providers: Revisit Trade Secret and Confidentiality Protections Post-Noncompete Ruling

A federal court in Texas struck down the Federal Trade Commission's ("FTC") rule banning noncompetes on August 20, stating that the FTC exceeded its authority and that the rule was arbitrary and capricious.[1] This decision means that employers across the nation, including health care providers, can continue to use state-compliant noncompetes to protect their business interests, pending any appeals. But with the future of noncompetes under discussion at federal and state levels, health care providers should review their current confidentiality protections.

The FTC's noncompete rule, first adopted on April 23, 2024, barred employers from entering into noncompetes with workers and required them to rescind existing noncompetes before September 4, 2024.[2] The FTC argued that noncompete clauses are "unfair methods of competition" under Section 5 of the FTC Act and that it had the power to issue the rule pursuant to Section 6(g) of the same act. In further support of its rule, the FTC pointed to studies which concluded that noncompetes stifle innovation and worker mobility. The FTC rejected requests to exempt the health care industry from its noncompete rule.

The FTC rule faced immediate legal challenges after its adoption. Ryan LLC, a tax services and software firm in Dallas, along with the United States Chamber of Commerce and other business groups, filed emergency motions to preliminarily enjoin the FTC from enforcing the rule. These plaintiffs argued that the agency acted beyond the scope of its statutory authority and that the rule was arbitrary and capricious. On July 3, 2024, the court granted these motions and temporarily blocked the rule until it could hear more arguments on the matter.[3] Thereafter, the plaintiffs filed motions to strike down the rule permanently. The FTC filed a counter motion to declare the rule as valid.

Court Finds FTC Exceeded Authority With Noncompete Ban

The court ultimately sided with the plaintiffs, confirming that the FTC overstepped its authority and that the rule was arbitrary and capricious. The court explained that Section 6(g) of the FTC Act did not expressly grant the agency the authority to promulgate substantive rules regarding unfair methods of competition. The court further noted that agencies must operate within the bounds of authority explicitly granted by Congress. It ruled that the FTC's expansive interpretation of its own rulemaking power was overly broad and unsupported by the statutory text.[4]

The court also held that the FTC's rule lacked a reasonable explanation for its sweeping bans, was arbitrary and capricious, and unlawful under the Administrative Procedure Act ("APA"). The court determined the FTC relied on inconsistent and flawed empirical evidence to support the rule and failed to consider less onerous and targeted alternatives to the national ban without adequate justification. "The rule imposes a one-size-fits-all approach with no end date, which

[1] *Ryan, LLC v. Fed. Trade Comm'n*, No. 3:24-CV-00986-E, 2024 WL 3879954, at *1 (N.D. Tex. Aug. 20, 2024).
[2] Non-Compete Clause Rule, 89 Fed. Reg. 38,342, 38,502–03 (May 7, 2024).
[3] *Ryan LLC v. Fed. Trade Comm'n*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *5 (N.D. Tex. July 3, 2024).
[4] *Ryan, LLC v. Fed. Trade Comm'n*, No. 3:24-CV-00986-E, 2024 WL 3879954, at *12 (N.D. Tex. Aug. 20, 2024).

fails to establish a 'rational connection between the facts found and the choice made,'" the court stated in its ruling.[5] The court also noted that the FTC had not considered the benefits of noncompetes, such as protecting trade secrets and encouraging investment into employee training.

The Future of Noncompetes and Action Steps for Health Care Providers

Because the court invalidated the ban under the APA, the ruling applies nationally to all American companies. The ruling removes one roadblock for businesses' continued use of state-compliant noncompetes to safeguard valuable business interests. However, the enforceability of such restrictive covenants can vary based on the applicable law in each state.

This may not be the final word on noncompete bans, so it's important to stay informed. The FTC may appeal, and other challenges to noncompetes may arise. For example, last year, the National Labor Relations Board General Counsel took the position that noncompetes violate workers' rights to engage in concerted activities under Section 7 of the National Labor Relations Act.[6] Several states have also passed laws curbing the use of noncompetes. Without question, noncompete law is rapidly evolving and requires vigilant monitoring to ensure compliance with all applicable laws.

Health care providers should take this opportunity to revisit and strengthen the nonsolicitation and nondisclosure provisions in their agreements, as well as to reinforce trade secret and confidentiality protections. Given the importance of relationships and the sensitive nature of patient information and proprietary medical processes, ensuring robust confidentiality clauses and trade secret protections is crucial. These provisions can serve as a valuable safeguard for health care organizations, especially in light of the uncertain future of noncompete agreements. Health care providers should review their current agreements to ensure that they adequately protect proprietary information, patient data and other confidential materials. This review should include assessing the scope and enforceability of existing confidentiality and nondisclosure agreements and making necessary updates to align with current best practices and legal standards.

By focusing on these areas, health care providers can better protect their critical business interests and stay competitive, regardless of changes in noncompete laws.

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[5] *Ryan, LLC v. Fed. Trade Comm'n*, No. 3:24-CV-00986-E, 2024 WL 3879954, at *13 (N.D. Tex. Aug. 20, 2024) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[6] Jennifer A. Abruzzo, General Counsel, National Labor Relations Board, Non-Compete Agreements that Violate the National Labor Relations Act—Memorandum GC 23-08 (May 30, 2023), https://www.nlrb.gov/news-outreach/news-story/nlrb-general-counsel-issues-memo-on-non-competes-violating-the-national.

Antitrust Battle Against Certificate of Public Advantage (COPA) Laws

In an effort to prevent anticompetitive behavior in the American healthcare marketplace, the Federal Trade Commission (FTC) has recently turned its attention to the rise in hospital mergers facilitated through the use of Certificate of Public Advantage (COPA) laws.

COPAs allow state agencies to approve proposed mergers among healthcare facilities following a satisfactory determination that the advantages of the merger outweigh the anticompetitive effects of consolidation in the healthcare marketplace.[1] Typically, the state departments of health are charged with supervising and regulating mergers exercised under COPAs.[2]

The FTC asserts that COPAs function as a mechanism to shield hospital mergers from scrutiny under state and federal antitrust laws subject to state action doctrine.[3] The FTC argues that hospital mergers granted pursuant to COPAs are destined to cause adverse effects in the marketplace, such as higher prices for patients seeking medical care, a decline in the quality of care rendered, and a reduced level of access to various medical services.[4]

It appears that the FTC is concerned that these mergers will eventually result in a heavily consolidated hospital market under the control of a single health system. Studies on the effects of these mergers released by the FTC shows a general increase in commercial inpatient prices by a minimum of 20%.[5] The FTC is also concerned that these mergers pursued under the gloss of COPAs fail to boost wages for hospital employees due to a reduced supply in employment opportunities.[6]

Hospital executives that advocate for mergers through use of COPAs often cite cost savings and efficiencies that could improve patient outcomes following consolidation.[7] Hospital systems nationwide have faced significant financial pressures stemming from rising costs for labor, drugs, and medical supplies in the years following the disturbance caused by the COVID-19 pandemic.[8]

Recently, on September 5, 2024, the FTC has challenged Indiana's first proposed merger under the state's COPA, enacted in 2021, referencing the same arguments mentioned above.[9] The FTC has urged the Indiana Department of Health and state lawmakers to oppose the consolidation of Union Hospital and Terre Haute Regional Hospital.[10]

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[1] Federal Trade Commission, *COPA Policy Paper*, (August 15, 2022) [hereinafter COPA Policy Paper], https://www.ftc.gov/system/files/ftc_gov/pdf/COPA_Policy_Paper.pdf.
[2] *Id.*
[3] Federal Trade Commission, *Certificates of Public Advantage (COPAS)*, https://www.ftc.gov/news-events/features/certificates-public-advantage-copas (last accessed September 13, 2024).
[4] *Id.*
[5] COPA Policy Paper, at 3.
[6] *Id.*
[7] *Id.*
[8] American Hospital Association, *New AHA Report Finds Financial Challenges Mount for Hospitals & Health Systems Putting Access to Care at Risk*, (April 20, 2023), https://www.aha.org/press-releases/2023-04-20-new-aha-report-finds-financial-challenges-mount-hospitals-health-systems-putting-access-care-risk.
[9] Rebecca Pifer, *FTC Opposes Indiana's First Hospital Merger Under Controversial COPA Law,* Healthcare Dive, (September 6, 2024), https://www.healthcaredive.com/news/ftc-opposes-indiana-hospital-copa-union-terre-haute-merger/726253/.
[10] *Id.*

Both hospitals are in Vigo County, located near Indiana's western border. According to the Indiana Department of Health's county health scorecard, Vigo County experiences serious public health challenges, particularly ranking in the bottom third among Indiana counties for life expectancy and bottom half for adult obesity.[11] To solve these challenges, Union Health and Terre Haute believe this partnership will enhance patients' access to quality medical care, create synergies of medical expertise between healthcare providers at both hospitals, and lower costs.[12] The FTC has submitted a comment to the Indiana Department of Health generally objecting to the proposed merger in an effort to dissuade the agency from approving the same.[13]

COPAs exist in Florida but are commonly invoked for rural hospital system mergers and related cooperative agreements. Specifically, section 381.04065, Florida Statutes, states the consolidation of hospital networks or technologies between members of rural health networks do not violate state or federal antitrust laws when such arrangements improve the quality of health care and moderate cost increases.[14] The Florida Department of Health is charged with the duty of approving and supervising rural hospital networks that seek to merge under this statute.[15] The state legislature views this policy as a proper means "to facilitate the provision of quality, cost-efficient medical care to rural patients."[16]

Conclusion

Hospital mergers will continue to be a prevalent option for providers seeking to deliver care more efficiently and maintain healthy operating margins. Indeed, such mergers will see an uptick as financial challenges continue to mount for hospitals. As such, the FTC will be keen on limiting the scope of these proposed mergers under COPAs to achieve its mission of protecting American consumers from anticompetitive business practices that disrupt the healthcare industry.

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[11] Health First Indiana, *County Health Scorecard*, https://www.in.gov/healthfirstindiana/county-health-scorecard/ (last updated June 4, 2024).
[12] Union Health, *Union Health and Terre Haute Regional Hospital Merger*, https://union.health/upload/docs/UnionHealth/merger/UnionHealthTerreHauteRegionalMergerFAQ.pdf (last accessed September 13, 2024).
[13] Federal Trade Commission, *Federal Trade Commission Staff Submission to Indiana Health Department Regarding the Certificate of Public Advantage Application of Union Health and Terre Haute Regional Hospital*, (September 5, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/in_copa_comment_9-5-24_public_redacted.pdf.
[14] Fla. Stat. § 381.04065.
[15] *Id.*
[16] *Id.*

STATE LAWS AND REGULATIONS

AHCA's Latest Interpretation of Florida's Health Care Clinic Statute

Florida does not generally prohibit the corporate practice of medicine. However, Florida Statutes Chapter 400 Part X requires that any health care entity which meets the definition of a "Clinic" under the Statute must obtain a Health Care Clinic license. For the purposes of the Statute, "Clinic" is defined as "an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider." The Statute does provide for exemptions, which are listed in subsections (a) through (q).

One of the most commonly utilized exemptions is subsection (g). This subsection states:

A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, and that is wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner if one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) which provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

Furthermore, this subsection is oft times relied upon by Advanced Practice Providers (APP), such as Physician Assistants and Advanced Practice Registered Nurses, so that these individuals may own a practice without the need to have a Clinic license.

The Florida Agency for Health Care Administration (AHCA) has authority over this Statute from a regulatory perspective. In the case of *The Obstetric Physical Therapy Center, LLC v. The Agency for Health Care Administration*, case number 22-006PH, an AHCA Informal Hearing Officer was asked to determine whether a licensed physical therapist assistant who owned 100 percent of a health care entity satisfied the requirements of subsection (g). The Informal Hearing Officer found that because the owner was a physical therapy assistant (PTA), and PTAs are required by law to be supervised by a licensed physical therapist, the owner could not qualify for the exemption. In *Obstetric Physical Therapy Center*, the Informal Hearing Officer found that a physical therapist would need to be in a supervisory capacity as to this physical therapy practice and that the PTA was not capable of being in any position of authority over a physical therapist.

Therefore, the Informal Hearing Officer declared that the PTA failed to meet the components of the exemption related to the ability to "either obtain or maintain the responsibility for the entity's compliance with all federal and state laws . . . ," and the Informal Hearing Officer opined that the

owner in this case violated the requirement that the practitioner-owner not supervise services beyond the scope of the practitioner-owner's license. Based on these findings, the Informal Hearing Officer denied the requested exemption.

In light of this decision by the AHCA, practitioner-owners who rely on an exemption under subsection (g) should immediately consult experienced health care counsel. Reliance on an exemption that the AHCA may determine is not valid could place prior collections and billings at risk.

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