

# **Health Law Developments**

The Newsletter of the Health Law Section
State Bar of Georgia
Fall 2024

# From the Chair

Aaron M. Danzig



Welcome to the first Health Law Section newsletter of the year! In this issue, we have three excellent and timely articles. Sean Sullivan, Keevana Glossin, and Carolyn Bergkvist of

Alston & Bird write about the future of telehealth and remote care; Kana Caplan of Krevolin & Horst, Jennifer Whitton of Health Law Strategists and Georgia State College of Law student Aditya Krishnaswamy discuss non-compete agreements and how they may affect physician recruiting and retention; and Kara Silverman, Jerad Rissler and Kelsey O'Neill explain a recent federal district court ruling in Florida finding, for the first time, that the relator provisions of the False Claims Act are unconstitutional.

Additionally, we invite you to attend the Advanced Health Law Seminar on November 1 at the Loew's hotel. This promises to be a great event and learning experience with panels such as AI & Healthcare, False Claims Act Trials, and the No Surprises Act. Also, we are delighted to have the Honorable Keith R. Blackwell and Raj Shah provide Perspectives on Professionalism along with a legislative update on what to expect in the 2025 Georgia legislative session. A special thanks to our sponsors Alston & Bird, Arnall Golden Gregory LLP, Chilivis Grubman LLP, and Parker Hudson Rainer and Dobbs LLP.

Hope to see you there!

# Inside This Issue

Advanced Health Law Seminar2
Telehealth and Remote Care in 2024 and Beyond3
Thank You to Our Sponsors: Alston & Bird and Parker Hudson7
Non-Compete Agreements are Safe for Now from the FTC8
Thank You to Our Sponsors: Arnall Golden Gregory and Chilivis Grubman13
An Uncertain Future for the False Claims Act An Uncertain Future for the False Claims Act14





# ADVANCED HEALTH LAW



Nov. 1



9 a.m. - 4:40 p.m.



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6 CLE Credit Hours
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1 Professionalism Credit Hour
1 Trial Practice Credit Hour



Special thanks to the Health Law Section for its financial support of registration costs

# **Agenda**

AI AND HEALTHCARE: LEGAL PERSPECTIVES ON INNOVATION,
RISK MANAGEMENT, AND COMPLIANCE

**FALSE CLAIMS ACT TRIALS AND ENFORCEMENT UPDATE** 

PERSPECTIVES ON PROFESSIONALISM

SUPREME COURT'S ADMINISTRATIVE STATE RULINGS
AND IMPACT ON HEALTHCARE

**COMMERCIAL PAYOR DISPUTES AND THE NO SURPRISES ACT** 

**LEGISLATIVE UPDATE: WHAT TO EXPECT IN THE 2025 SESSION** 

# Telehealth and Remote Care in 2024 and Beyond

Sean Sullivan, Keevana Glossin, and Carolyn Bergkvist

Telehealth has changed a lot in the last five years. While physicians and other practitioners struggled to provide care remotely during the initial months of the COVID-19 pandemic, states and the federal government issued dozens of waivers, promulgated regulatory changes, and even passed new laws, both temporary and permanent, to enable remote care and allow patients to see their doctors via telehealth. Now, nearly five years later, the dust still has not settled. Many of these flexibilities have become permanent, while others have been extended repeatedly on a temporary basis, with lawmakers cautious to enact permanent changes without having long term data on the cost and efficacy of telehealth outside of a global pandemic. But at the same time, practitioners and patients have grown accustomed to these flexibilities, and in many ways have permanently incorporated telehealth into their practices and into their lives. Advising providers on when and how telehealth may be used is more complex than ever, but this article attempts to shed some light on the current state of telehealth coverage and reimbursement in Georgia and at a federal level.

The COVID-19 public health emergency (PHE) was first declared by the Secretary of Health and Human Services (HHS) on January 31, 2020. The PHE officially ended on May 11, 2023; however, many of the regulatory flexibilities that derived from the PHE remain in place today. As 2024 winds down it appears some flexibilities will expire at the end of the year, while others may be extended by Congress or in the Centers for Medicare and Medicaid Services (CMS) 2025 Medicare Physician Fee Schedule (2024 MPFS). Attorneys advising telehealth companies should take inventory of any flexibilities currently used by their clients, develop a plan to bring operations into full compliance if and when they expire, and continue to monitor regulatory and legislative activity to ensure compliance in 2025 and beyond. This article does not address every relevant post-PHE telehealth flexibility but summarizes key changes to existing federal telehealth and remote care flexibilities.<sup>2</sup>

### MEDICARE TELEHEALTH COVERAGE

Originating Site Requirements: Telehealth services can be rendered regardless of the patient's or provider's geographic location (i.e., telehealth is not limited to rural areas and the patient can be at home) through December 31, 2024, pursuant to the Consolidated Appropriations Act of 2023 (CAA).<sup>3</sup> Absent additional legislative action, after December 31, 2024, Medicare-covered telehealth services cannot be provided in a patient's home or other non-traditional originating sites (with certain exceptions for treatment of substance abuse, mental health, end stage renal disease, and acute stroke), and the eligible originating sites will be

limited to those listed at 42 C.F.R. § 410.78(b)(3). While we believe it is likely Congress will once again extend this flexibility before the end of 2024 (at least on a temporary basis), as of the date of this article, no such extension has been enacted. CMS does not have regulatory authority to extend this flexibility, and so the statutory requirement that Medicare telehealth services be furnished to a patient at an eligible originating site will once again go into effect on January 1, 2025, unless Congress acts.<sup>4</sup>

Expanded List of Eligible Practitioners: The list of health care professionals that can furnish distant-site telehealth services (including physical therapists, occupational therapists, speech-language pathologists, and audiologists) remains expanded through December 31, 2024, under the CAA.<sup>5</sup> However, like the originating site requirements, unless Congress takes additional action, the list of distant site practitioners eligible to furnish Medicare telehealth services will revert on January 1, 2025, to only those practitioners listed at 42 C.F.R. § 410.78(b)(2), which do not include physical therapists, occupational therapists, speech-language pathologists, or audiologists.<sup>6</sup>

Payment Parity in Non-Facility Settings: CMS extended payment parity for telehealth provided in non-facility distant site settings through 2023 by allowing providers to use non-facility place of service codes when telehealth services are not provided to patients in hospitals, clinics, or other facility-based settings. However, CMS did not extend this flexibility, and starting in 2024, now requires providers to report a Place of Service (POS) code of "02" for telehealth provided other than in a patient's home, or "10" for telehealth provided to the patient in their home. POS 02 results in reimbursement at the facility rate, which is consistent with lower, pre-PHE reimbursement for these telehealth services. However, POS 10 for telehealth provided to patients in their homes results in reimbursement at a higher facility rate, consistent with PHE era funding for telehealth services.<sup>7</sup> Note also that when the distant site practitioner is in a hospital and the patient is in the home, CMS has instructed providers to use modifier "95" and the applicable hospital POS code.8

Audio-Only Telehealth: Reimbursement is available for eligible audio-only telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, if the distant site practitioner is technically capable of using an interactive audio-video telecommunications system, but the patient is not capable of, or does not consent to the use of video technology.<sup>9</sup>

While non-behavioral/mental health audio-only telehealth services for certain CPT codes will continue to be reimbursed through December 31, 2024 under the CAA, 10 CMS has proposed to permanently allow audio-only telehealth for non-behavioral/mental health services to a patient in their home if the distant site practitioner is technically capable of using an interactive audio-video telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology. 11 However, practitioners would be required to use the modifier "93" (or for rural health clinics and federally qualified health centers, modifier "FQ"), in order to verify that these conditions were met.<sup>12</sup> Note there are additional flexibilities for audio-only telehealth for opioid use disorder treatment services furnished by opioid treatment programs (OTPs), and CMS has proposed to make audio-only telehealth permanently available for periodic assessments.13

# GEORGIA MEDICAID TELEHEALTH COVERAGE

The flexibilities that were in place during the COVID-19 PHE, such as the ability to use audio-only modalities in certain circumstances, and to conduct an initial patient assessment via telehealth have ended as a result of the expiration of the federal PHE.<sup>14</sup>

Approved Locations: During the PHE, Georgia Medicaid permitted providers to render telehealth services to all members with access to video or telephone communication regardless of patient location and permitted providers to deliver medically necessary telehealth services from various settings including their homes or other settings in which the privacy and confidentiality of the member could be assured. <sup>15</sup> Georgia Medicaid providers are still permitted to deliver telehealth services to members located in their home at the time of service using POS 10, and can still deliver telehealth services from their homes. <sup>16</sup>

<u>Audio-Only Telehealth</u>: Following the end of the PHE, Georgia Medicaid requires telehealth services to be provided via real-time, interactive, audio-video telecommunication technologies as a condition of payment. Examples of non-covered services modalities include telephone conversations, e-mails, and faxes.<sup>17</sup>

In-Person Assessments: During the PHE and into this year, Georgia Medicaid permitted the initial assessment of a patient to occur via telehealth. However, starting in November of 2024, Georgia Medicaid will no longer reimburse providers for initial assessments conducted via telehealth.<sup>18</sup>

<u>Written Consent:</u> All providers are required to obtain the Medicaid member's written consent to the provision of services via telehealth prior to the initial telehealth visit, and

Georgia Medicaid offers a recommended form that contains all required elements (but providers are free to develop and use their own forms as well).<sup>19</sup>

# FACILITY-SPECIFIC TELEHEALTH FLEXIBILITIES

**Hospital Services**: Through the Acute Hospital Care at Home program, hospitals can continue to furnish inpatient services, including routine services, outside of the hospital through December 31, 2024.<sup>20</sup> Without further Congressional action, this flexibility will not be extended into 2025.

<u>Hospice Care</u>: Providers can use telehealth to recertify patients' eligibility for hospice care through December 31, 2024.<sup>21</sup> As with the Acute Hospital Care at Home program, only Congress can extend this flexibility into 2025.

### Federally Qualified Health Centers and Rural Health

<u>Clinics</u>: FQHCs and RHCs can serve as distant-site providers for telehealth services generally through December 31, 2024,<sup>22</sup> but absent Congressional action by the end of the year, will be permitted to provide only behavioral/mental telehealth services in 2025,<sup>23</sup> a flexibility that was made permanent in 2022.

# OTHER FEDERAL AGENCY TELEHEALTH FLEXIBILITIES

HIPAA: During the PHE and the subsequent transition period, the HHS Office for Civil Rights (OCR) exercised enforcement discretion for imposing penalties for violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) related to the good-faith provision of telehealth services. OCR's enforcement discretion ended effective August 9, 2023.<sup>24</sup> Currently, OCR requires all telehealth services, including audio-only telehealth services, to be provided through HIPAA-compliant platforms, including the use of Business Associate Agreements with telehealth technology vendors.<sup>25</sup>

**OIG**: The HHS Office of Inspector General's (OIG) discretion to enforce certain provisions of the Anti-Kickback Statute (AKS) or the Beneficiary Inducement Statute (BIS) that prohibit routine reductions or waivers of costs owed by federal health care program beneficiaries for services provided via telehealth or other remote care technologies terminated on May 11, 2023. OIG currently enforces the AKS and BIS and requires that physicians and other practitioners hold Federal health care program beneficiaries responsible for any applicable cost-sharing obligations related to telehealth services.<sup>26</sup> However, non-routine, unadvertised waivers of Federal health care program beneficiaries' cost-sharing amounts due to a beneficiaries' financial need based on a good-faith,

individualized assessment of need can be protected by a safe harbor to the AKS or an exception to the BIS.<sup>27</sup>

Prescribing Controlled Substances: Prior to the PHE, the Ryan Haight Act required an in-person medical evaluation prior to prescribing controlled medications. However, on May 10, 2023, the Drug Enforcement Administration (DEA), U.S. Department of Justice, and HHS issued a final rule creating exceptions to the Ryan Haight Act. Notably, under the final rule, for any practitioner-patient telehealth relationships that were established on or before November 11, 2023, the full set of telehealth flexibilities regarding prescription of controlled medications as were in place during the PHE will continue to be permitted through November 11, 2024. Accordingly, if a patient and a practitioner established a telehealth relationship on or before November 11, 2023, the same telehealth flexibilities that governed the relationship to that point are permitted until November 11, 2024.<sup>28</sup>

### OTHER REGULATORY FLEXIBILITIES

Remote Patient Monitoring and Communication
Technology-Based Services: Effective as of the end of the PHE, CMS reimburses for Remote Physiological

Monitoring and other communication technology-based services (CTBS), such as virtual check-ins and e-visits provided to *established* patients only.<sup>29</sup> In other words, providers must conduct a new patient initiating visit, which can be conducted via telehealth, prior to rendering most remote patient monitoring services to patients that have not been seen by the practitioner or another practitioner of the same specialty in the same group practice within the last three (3) years.<sup>30</sup> However, notably, CMS permits the provision of remote *therapeutic* monitoring to new, non-established patients, though this may be changed in future rulemaking.<sup>31</sup>

<u>Transitional Care Management</u>: The face-to-face visit required within fourteen (14) days of discharge (for CPT Code 99495) or within seven days of discharge (for CPT Code 99496) may be provided via telehealth.<sup>32</sup> This is a permanent regulatory flexibility that derived from the PHE.

Behavioral/Mental Health: An in-person visit within six months of an initial behavioral/mental telehealth service, and annually thereafter, will not be required through December 31, 2024, per the CAA. For services furnished on or after January 1, 2025, absent additional legislation, an in-person visit will once again be required within six months of an initial behavioral/mental telehealth service if the patient is seen in a non-rural location and/or in their home. In other words, the six month in-person visit requirement applies only when the telehealth visit does not meet the traditional Medicare telehealth requirements of a rural location and qualifying originating site.<sup>33</sup>

<u>Virtual Direct Supervision</u>: Direct supervision will continue to include audio/video real-time communications technology through December 31, 2024. <sup>34</sup> However, under the 2025 MPFS proposed rule, CMS would extend virtual direct supervision through December 31, 2025, and would extend virtual direct supervision permanently for:

- Services furnished incident to a physician's services when they are provided by auxiliary personnel employed by the physician and working under their direct supervision and for which the underlying HCPCS code has been assigned a professional component/technical component indicator of five (5).
- Office or outpatient visits for the evaluation and management of an established patient who may not require the presence of a physician or other qualified health care professional.<sup>35</sup>

### **TAKEAWAYS**

Although most temporary waivers and regulatory flexibilities enacted at the beginning of the COVID-19 pandemic have expired, telehealth is no longer the same. In many ways, remote care using technology has been embraced by both practitioners and patients, and with many of the flexibilities becoming permanent, practicing via telehealth will never be the same. However, absent Congressional action, some of the Medicare flexibilities in place since the PHE will expire at the end of 2024, so health care providers and their attorneys should closely watch federal legislative action and agency rulemaking through the end of the year to ensure compliance into 2025 and beyond.

<sup>1</sup> See proposed rule at 89 Fed. Reg. 61596 (Jul. 31, 2024), Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments, available at https://www.federalregister.gov/d/2024-14828/p-1 (the "2025 MPFS Proposed Rule").

<sup>2</sup> U.S. Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), *available at* <a href="https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx">https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx</a>.

<sup>3</sup> H.R.2617, Consolidations Appropriations Act, 2023 (Dec. 20, 2022), available at https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

<sup>4</sup> See 42 U.S.C. § 1395m(m)(4)(C)(iii).

<sup>5</sup> Id

<sup>6</sup> See 42 U.S.C. § 1395m(m)(4)(E).

<sup>7 88</sup> Fed. Reg. 78876, 78818 (Nov. 16, 2023), Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, available at https://www.federalregister.gov/d/2023-24184/p-556.

<sup>8</sup> *Id*.

<sup>9 42</sup> C.F.R. § 410.78(a)(3).

<sup>10</sup> H.R.2617, Consolidations Appropriations Act, 2023 (Dec. 20,2022), available at <a href="https://www.congress.gov/bill/117th-congress/house-bill/2617/text">https://www.congress.gov/bill/117th-congress/house-bill/2617/text</a>.

<sup>11 2025</sup> MPFS Proposed Rule at 61632.

<sup>12</sup> *Id*.

 $<sup>13\ 2025\</sup> MPFS$  Proposed Rule at 61818-61820.

<sup>14</sup> See <a href="https://medicaid.georgia.gov/covid-19">https://medicaid.georgia.gov/covid-19</a> for access to guidance documents produced by Georgia Medicaid related to the requirements for providing services

by telehealth. Georgia Department of Community Health Division of Medicaid, *Telehealth Guidance* (January 1, 2024), *available at* <a href="https://setrc.us/wp-content/uploads/2024/02/GA-2024-Telemedicine-Guidance\_12202023\_NG-revision\_Q1-2024\_Final-20231221203701.pdf">https://setrc.us/wp-content/uploads/2024/02/GA-2024-Telemedicine-Guidance\_12202023\_NG-revision\_Q1-2024\_Final-20231221203701.pdf</a> (GA DCH Telehealth Guidance).

 $15\ \underline{\text{GA DCH Telehealth Guidance}}$  at 8.

16 O.C.G.A. § 33-24-56.4(b); and GA DCH Telehealth Guidance at 12.

17 GA DCH Telehealth Guidance at 16-17.

18 GA DCH Telehealth Guidance at 18.

19 GA DCH Telehealth Guidance at 59.

20 H.R.2617, Consolidations Appropriations Act, 2023 (Dec. 20,2022), available at <a href="https://www.congress.gov/bill/117th-congress/house-bill/2617/text">https://www.congress.gov/bill/117th-congress/house-bill/2617/text</a>.

22 *Id.*; see also Health and Human Services, *Telehealth Policy Changes After the COVID-19 Public Health Emergency* (last visited Sep. 5, 2024), *available at*, <a href="https://telehealth.hhs.gov/providers/telehealth-policy/policy-changes-after-the-covid-19-public-health-emergency">https://telehealth.hhs.gov/providers/telehealth-policy/policy-changes-after-the-covid-19-public-health-emergency</a> (indicating that federally qualified health centers and rural health clinics can serve as a distant site provider for behavioral/mental telehealth services permanently).

23 42 C.F.R. § 405.2463

24 88 Fed. Reg. 22380 (Apr. 13, 2023); U.S. Department of Health and Human Services, *HIPAA and Telehealth Guidance on HIPAA and Audio-only Telehealth* (last updated Apr. 13, 2023), *available at* <a href="https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html">https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html</a>.

25 U.S. Department of Health and Human Services, *Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication technologies for Audio-only Telehealth* (last updated Jun. 13, 2022), *available at* <a href="https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html">https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html</a>.

26 U.S. Department of Health and Human Services, OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak (Mar 17, 2022), available at <a href="https://oig.hhs.gov/documents/special-advisory-bulletins/960/policy-telehealth-2020.pdf">https://oig.hhs.gov/documents/special-advisory-bulletins/960/policy-telehealth-2020.pdf</a>.

27 See generally, Health and Human Services, Office of the Inspector General, *General Questions Regarding Certain Fraud and Abuse Authorities* (Jul. 8, 2024), *available at* https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/#13-does-the-federal-anti-kickback-statute-or-the-beneficiary-inducements-cmp-prohibit-hospitals-from-waiving-their-patients-cost-sharing-amounts-pursuant-to-hospitals-financial-assistance-policies-also-known-as-charity-care-policies.

28 21 C.F.R. § 1307.41(d); see also 88 Fed. Reg. 30037, 30039.

29 Centers for Medicare & Medicaid Services, *Physicians and other Clinicians: CMS Flexibilities to Fight COVID-19* (Feb. 24, 2023) at 7, available at <a href="https://physicians.other.clinicians: CMS Flexibilities to Fight COVID-19">Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19</a>.

30 Medicare Claims Processing Manual (IOM Pub. 100-04, Chapter 12, § 30.6.7); American Medical Association, CPT 2023 Professional Edition, Evaluation and Management (E/M) Services Guidelines ("CPT Codebook") at 7.

31 88 Fed. Reg. 78818, 78883-78884 (stating "RPM, not RTM, services require an established patient relationship after the end of the PHE. While we have not specified in rulemaking whether the RTM services require an established patient relationship, we believe that similar to RPM, such services would be furnished to a patient after a treatment plan had been established.").

32 Centers for Medicare & Medicaid Services, *Medical Learning Network Booklet on Transitional Care Management Services* (MLN908628, July 2024), available at <a href="https://www.cms.gov/files/document/mln908628-transitional-care-management-services.pdf">https://www.cms.gov/files/document/mln908628-transitional-care-management-services.pdf</a>.

33 H.R.2617, Consolidations Appropriations Act, 2023 (Dec. 20,2022), available at <a href="https://www.congress.gov/bill/117th-congress/house-bill/2617/text">https://www.congress.gov/bill/117th-congress/house-bill/2617/text</a>; See also Centers for Medicare and Medicaid Services, Medicare Learning Network Booklet on Telehealth Services (MLN901705, April 2024), available at <a href="https://www.cms.gov/files/document/mln901705-telehealth-services.pdf">https://www.cms.gov/files/document/mln901705-telehealth-services.pdf</a>.

34 42 C.F.R. § 410.32(b)(3)(ii).

35 89 Fed. Reg. 61596, 61634.



Sean Sullivan is a partner at Alston & Bird, LLP, and focuses on health care regulatory matters, with a specialization in digital health and healthcare technology issues.





Keevana Glossin

Carolyn Bergkvist

Keevana Glossin and Carolyn Bergkvist are associates at Alston & Bird, LLP and focus on health care regulatory and compliance matters.



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# Non-Compete Agreements are Safe for Now from the FTC: What's Next for Physician Recruiting and Retention in Georgia?

Kana Caplan, Jennifer Whitton, and Aditya Krishnaswamy

The use of non-compete agreements ("non-competes") in the healthcare industry, particularly in the case of physician employment agreements, is pervasive. The market in Georgia for physician and other skilled medical professional recruitment is extremely competitive, and it is both expensive and time consuming to recruit medical professionals. Additionally, once hired, healthcare employers expend tremendous resources training and integrating hired physicians and medical professionals.

Healthcare employers routinely use non-competes to protect their investment by limiting the ability of their physician employees from moving to a competing hospital or practice, encouraging stability among providers, and limiting provider interference with patient relationships and goodwill. But many public policy advocates argue that these agreements in the healthcare space impede patient choice, inappropriately restrict patient access to care, and stifle competition. The Federal Trade Commission ("FTC") estimates that banning non-competes will, among other benefits, reduce healthcare costs by \$74 - \$194 billion in reduced spending on physician services over the next decade.<sup>1</sup>

Laws on non-compete agreements vary widely from state to state. For example, California has banned non-compete agreements since 1941.<sup>2</sup> Historically, non-competes were difficult to enforce in Georgia; <sup>3</sup> however, in 2011, the Georgia Legislature passed the Georgia Restrictive Covenants Act ("GRCA"), O.C.G.A. § 13-8-50 et. seq., essentially blessing the use of non-competes "to protect legitimate business interest."<sup>4</sup>

At the national level, in 2022, the Biden administration began to signal that it would move to regulate noncompete agreements through the FTC. In January 2023, the FTC issued a long-awaited "Proposed Rule" that, if enacted, would have banned non-competes and effectively upended Georgia's GCRA and the ability of healthcare employers in Georgia to utilize noncompetes.<sup>5</sup>

After the period of public comment, on May 7, 2024, the FTC issued a final rule (the "Final Rule") that was set to take effect on September 4, 2024. The Final Rule would have eliminated the use of non-competes between employers and employees (with very narrow exceptions) and invalidated the majority of existing agreements.<sup>6</sup> Nearly immediately, business interest groups and employers sued to enjoin the enactment of the Final Rule in Texas, Florida, and Pennsylvania.<sup>7</sup>

On July 23, 2024, the U.S. District Court for the Eastern District of Pennsylvania declined to grant the plaintiff an injunction barring enforcement of the Final Rule, finding that the plaintiff was not likely to succeed on the merits because the FTC had constitutional and statutory authority to promulgate the rule.<sup>8</sup> Just a few days before the Final Rule was set to take effect, the U.S. District Court for the Middle District of Florida entered a limited injunction on August 15, 2024, banning enforcement of the Final Rule but only with respect to the particular plaintiff in that case.<sup>9</sup> The U.S. District Court for the Northern District of Texas in *Ryan*, *LLC v. FTC* enjoined the enforcement of the Final Rule nationwide on August 20, 2024, ruling that the FTC had exceeded its authority and that the rule was arbitrary

<sup>1</sup> See Federal Trade Commission, Non-Competes: What You Should Know, (last accessed Sept. 23, 2024), available <a href="https://www.ftc.gov/news-events/features/noncompetes">https://www.ftc.gov/news-events/features/noncompetes</a>.

<sup>2</sup> California Business and Professions Code sections 16600-16607.

<sup>3</sup> The use of non-competes among physicians dates back to at least 1898 when the Supreme Court of Georgia opined on a partnership contract between two doctors that provided that if the partnership was dissolved, one of the partners "will not locate or engage in the practice of medicine, surgery, or obstetrics at said town of Oliver, or at any place within fifteen miles radius from the drug store of said Lanier, unless he shall first have obtained the written consent of said Lanier." Rakestraw v. Lanier, 104 Ga. 188 (1898). In that instance, the Supreme Court examined the language of the restriction and the circumstances of the contracting parties and refused to enforce the contract.

<sup>4</sup> Becham v. Synthes USA, 482 F. App'x 387, 389 (11th Cir. 2012).

<sup>5</sup> Non-Compete Clause Rule, NPRM, 88 FR 3482 (Jan. 19, 2023) (the "Proposed Rule").

<sup>6</sup> The Federal Trade Commission, FTC Announces Rule Banning Non-competes (Apr. 23, 2024), <a href="https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-non-competes">https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-non-competes</a> (the "Final Rule").

<sup>7</sup> ATS Tree Services, LLC v. Federal Trade Commission, No. 24-cv-1743 (E.D. Pa. 2024); Properties of the Villages, Inc. v. Federal Trade Commission, No. 5:24-cv-00316, (M.D. Fla. 2024); Ryan, LLC v. FTC, Case No. 3:24-cv-00986-E (N.D. Tex. Apr. 23, 2024).

<sup>8</sup> ATS Tree Services, LLC v. Federal Trade Commission, No. 24-cv-1743 (E.D. Pa. 2024).

and capricious due to its overbroad nature. <sup>10</sup> The Ryan decision aligns with a post-Chevron <sup>11</sup> legal landscape where the Supreme Court is increasingly skeptical of broad and deferential federal agency decisions that pose "major questions" on which Congress did not explicitly authorize action. This article explores current Georgia law governing non-competes and the impact the FTC's Final Rule to ban non-competes has on physicians and healthcare workers if Ryan is overturned.

### I. Current Georgia Law Governing Non-Competes

After the enactment of the GRCA, the use of non-compete agreements, and other restrictive covenants are permitted in Georgia in order to protect "legitimate business interests." Non-competes are permitted under partnership agreements or pursuant to a sale of business "so long as such restrictions are reasonable in time, geographic area, and scope of prohibited activities." The GCRA also permits the use of non-competition agreements with employees post-employment, but only where the employee in question meets the definition of "employee" and one of the four following requirements:

- (1) Customarily and regularly solicit for the employer customers or prospective customers;
- (2) Customarily and regularly engage in making sales or obtaining orders or contracts for products or services to be performed by others;

Such term shall not include any employee who lacks selective or specialized skills, learning, or abilities or customer contacts, customer information, or confidential information.

- (3) Perform the following duties:
  - (A) Have a primary duty of managing the enterprise in which the employee is employed or of a customarily recognized department or subdivision thereof;
  - (B) Customarily and regularly direct the work of two or more other employees; and
  - (C) Have the authority to hire or fire other employees or have particular weight given to suggestions and recommendations as to the hiring, firing, advancement, promotion, or any other change of status of other employees; or
  - (4) Perform the duties of a key employee or of a professional.

Physicians or other medical providers undoubtedly perform the services of a "professional," defined to be "an employee who has as a primary duty the performance of work requiring knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction[.]"<sup>15</sup> In order to be enforceable, non-competition agreements must meet three main requirements under the GRCA:

- First, they must be reasonable as to time. Two years or less is per se reasonable for employees, and five years (or the period of time payments are made to the owner or seller) is per se reasonable for sellers of a "material part" of a business. <sup>16</sup> Any longer period of time is presumed unreasonable.
- Second, the geographic limitation must be reasonable. The GRCA permits a reference to "the areas in which the employer does business at any time during the parties' relationship, even if not known at the time of entry into the restrictive covenant" so long as the total distance is reasonable or the restriction contains a list of particular prohibited employers. <sup>17</sup>

<sup>9</sup> Properties of the Villages, Inc. v. Federal Trade Commission, No. 5:24-cv-00316, (M.D. Fla. 2024).

<sup>10</sup> Ryan, LLC v. FTC, Case No. 3:24-cv-00986-E (N.D. Tex. Apr. 23, 2024).

<sup>11</sup> U.S. Supreme Court struck down the "Chevron doctrine" on June 28, 2024 in the case Loper Bright v. Raimondo and Relentless, Inc. v. Department of Commerce. The Chevron doctrine was a precedent that had been in place since the 1980s, and it directed courts to defer to the interpretation of federal agencies when a law was ambiguous or silent. The Supreme Court's decision overturns this precedent and now requires courts to reach their own conclusions about the meaning of a statute. 12 Becham v. Synthes USA, 482 F. App'x 387, 389 (11th Cir. 2012).

<sup>13</sup> O.C.G.A. § 13-8-53(a).

<sup>14</sup> Under O.C.G.A. § 13-8-51(5), "employee" means:

<sup>(</sup>A) An executive employee;

<sup>(</sup>B) Research and development personnel or other persons or entities of an employer, including, without limitation, independent contractors, in possession of confidential information that is important to the business of the employer;

<sup>(</sup>C) Any other person or entity, including an independent contractor, in possession of selective or specialized skills, learning, or abilities or customer contacts, customer information, or confidential information who or that has obtained such skills, learning, abilities, contacts, or information by reason of having worked for an employer; or

<sup>(</sup>D) A franchisee, distributor, lessee, licensee, or party to a partnership agreement or a sales agent, broker, or representative in connection with franchise, distributorship, lease, license, or partnership agreements.

<sup>15</sup> O.C.G.A. § 13-8-51(14).

<sup>16</sup> O.C.G.A. § 13-8-57.

<sup>17</sup> O.C.G.A. § 13-8-56.

• Third, the scope of the activity prohibited must be reasonable. A reference to the business of the employer is considered sufficiently reasonable even if it is determined to include activities the former employee did not engage in post-termination.<sup>18</sup>

Most importantly, the GRCA instructs courts to "blue pencil" or modify restrictive covenants to make them enforceable to "protect such [legitimate business] interest or interests and to achieve the original intent of the contracting parties to the extent possible." Thus, even where a restriction is poorly drafted, Georgia courts should modify it to make it enforceable.

# II. Overview of Final Rule by Federal Trade Commission

The Final Rule takes an extremely hard-handed approach, reflecting the FTC's position that non-competes are anti-competitive and a restriction on individual liberty. If not enjoined in August by the U.S. District Court for the Northern District of Texas, the Final Rule would have effectively banned all non-competes between employers and "workers" as an unfair method of competition. Key provisions of the Final Rule include:

- It would have made non-compete agreements illegal regardless of what type of employee is at issue and regardless of what level of company information the employee has accessed (see exception below).
- It would have expanded the definition of a noncompete clause to include clauses that "effectively preclude" a worker from working in the same field after conclusion of employment or a term that requires repayment of training expenses (if not reasonably tied to actual costs).
- It would have required recission of existing noncompete clauses within 180 days of taking effect and notification of former employees who have entered into such agreements.
- As part of the Final Rule, employers would have been required to provide current and former employees subject to a noncompete agreement—other than "senior executives"—notice that they will not enforce any noncompete agreement against them. The FTC has provided model notice language for businesses to use

when communicating to current and former employees that their noncompete agreements will not be enforced.

- It would have allowed existing non-competes with certain "senior executives" (workers in policy-making positions making over \$151,164 annually) to continue to be in effect. It would not have allowed new non-competes with senior executives.
- It would have permitted the use of non-competes for franchisor/franchisees and sales of businesses (assuming the seller sells at least 25% of the business sold).

Despite the Ryan ruling, the FTC has indicated it will continue to pursue individual enforcement actions and is considering an appeal. <sup>20</sup> The FTC has until October 19, 2024, to do so. However, it will almost certainly face continued enforcement challenges in the Fifth Circuit and potentially in the Supreme Court.

# III. The Final Rule's Potential Impact on the Healthcare Industry

If the Ryan decision is over-turned and the Final Rule takes effect, importantly for the healthcare industry, non-profit hospitals and other 501(c)(3) organizations may be exempt from the reach of the Final Rule.<sup>21</sup>

Under Section 5 of the Federal Trade Commission Act, 15 U.S.C. §§ 41-58 (the "FTC Act"), FTC rulemaking can only be enforced against "persons, partnerships, or corporations."<sup>22</sup> The FTC Act defines the term "corporation" as an entity "organized to carry on business for its own profit or that of its members," which means that the Final Rule arguably does not apply to non-profit organizations.<sup>23</sup> However, the FTC has indicated that even non-profit entities with tax-exempt status could fall under the FTC's jurisdiction if they engage in activities that generate private benefit or private inurement and these organizations are not granted blanket exemption. <sup>24</sup>

<sup>18</sup> O.C.G.A. § 13-8-56(3).

<sup>19</sup> O.C.G.A. § 13-8-54(a).

<sup>20</sup> The Federal Trade Commission, FTC Announces Rule Banning Non-competes (Apr. 23, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-non-competes (the "Final Rule").

<sup>21</sup> Federal Register, Final Rule § 910.4. Non-Compete Clause Rule (May 7, 2024), https://www.federalregister.gov/d/2024-09171.

<sup>22 15</sup> U.S.C. § 45(a).

<sup>23 15</sup> U.S.C. 45(a)(2).

<sup>24</sup> Federal Register, Final Rule § 910.4. Non-Compete Clause Rule (May 7, 2024), https://www.federalregister.gov/d/2024-09171.

The FTC will utilize a two-part test to determine whether a non-profit is organized for profit—essentially structured in a way that it may be considered by the FTC to be organized to carry on business for its own profit or the profit of its members, and subject to Section 5 of the FTC Act:<sup>25</sup>

- (1) Source of Income: How is the corporation organized and does it only engage in business for charitable purposes?
- (2) Destination of Income: Who derives a profit from the corporation?

To understand how the FTC will enforce the Final Rule over tax-exempt healthcare organizations, if the Final Rule ever goes into effect, four examples are provided by the FTC of organizations that would be subject to the reach of the FTC Act:

- A tax-exempt physician hospital that engages in business on behalf of for-profit physician members.
- An independent physician association that contracts with payers on behalf of for-profit physician members. The physician services are provided for a fee.
- A non-profit that has ceded effective control to a forprofit partner.
- A non-profit that pays excessive compensation to board members.

### IV. Steps Employers Can Take Amid Uncertainty

As litigation stemming from the Ryan decision evolves to determine whether the Final Rule will take effect, and as employers wait to see how the FTC pursues individual enforcement actions, healthcare employers in Georgia should evaluate their employment and other agreements that contain non-competition covenants to ensure their business is protected. First and foremost, until the Final Rule goes into effect and survives appellate challenges, employers may continue to utilize non-competition agreements consistent with past practice. Additionally, healthcare employers can take prophylactic steps to protect their arrangements with physicians and other medical professionals, including:

(1) Review existing form employment contracts to ensure that they contain a "severability" clause. "Severability" clauses make clear that if a certain clause in a contract is determined to be unenforceable, the remaining clauses of the contract remain enforceable.

(2) Review existing contracts to ensure they contain other types of restrictive covenants that prohibit departing employees from

harming the company. Those restrictions are not impacted by the language of the Final Rule (if and when it takes effect) and, in Georgia, would continue to be governed by the GRCA. For example:

- Non-solicitation agreements can prohibit departing employees from soliciting customers, employees, or referral sources of the employer.
- Garden leave agreements can prohibit competition so long as an employee continues to be paid.
- Robust non-disclosure agreements and confidentiality covenants can prohibit departing employees from retaining company trade secrets or other confidential information. Under certain circumstances, Georgia courts have viewed customer lists as trade secrets. Employers should be sure to include a Defend Trade Secrets Act notice provision in their employment agreements, which will provide employers additional remedies under the Defend Trade Secrets Act.
  - (3) Ensure that employment agreements contain clear provisions with respect to the employer's ownership of any intellectual property created or accessed by the employee during the course of employment. This provides an additional layer of protection with respect to the use of an employer's sensitive information. These provisions should include an automatic assignment of any rights to such intellectual property from the employee to the employer.

In addition to the contractual clauses suggested above, it's a good time to take stock of how important company information is stored and shared with employees. In the post-pandemic age where employees frequently store and reference high value company information in their homes or on personal devices, theft of trade secrets has become increasingly easy for employees and may go undetected. Often, when a key employee leaves, employers only possess a suspicion that a theft of information has occurred. Tying the key employee to a non-compete allows the employer to ensure that its information is not being taken directly to a competitor for the period of time when the information is fresh

<sup>25</sup> Cmty. Blood Bank of Kansas City Area, Inc. v. FTC, 405 F.2d 1011, 1016 (8th Cir. 1969).

(and therefore valuable). Employers should consider how their most valuable company information is stored, who can access it, what access records are logged and maintained, and what steps the employer has put in place to protect the information. Typical protections include: limiting access to only employees that need to know, limiting access to only via companyowned devices, setting up password protections for key documents, using non-disclosure agreements, and utilizing other restrictive covenants (such as non-solicits) that limit a departing employee's ability to use any retained confidential information.

### V. Conclusion

Further judicial proceedings are anticipated with possible Supreme Court review given the likelihood of a circuit split on the issue if the various district court decisions are appealed (which is likely) and the Fifth Circuit, Eleventh Circuit, and Third Circuit uphold the district court decisions.

Although the future of the Final Rule and non-competes are unclear, employers in Georgia are currently free to utilize non-competes in employment agreements within the bounds of the GCRA outlined in this article.



Kana Caplan is a partner at Krevolin & Horst, and practices complex business litigation, with a focus on trade secrets, restrictive covenants, and business divorce.



Jennifer Whitton is a founding partner of Health Law Strategists, LLC, and focuses her practice exclusively on healthcare law, specializing in acquisitions and other healthcare transactions, as well as healthcare regulatory matters.



Aditya Krishnaswamy is a 3L at Georgia State University College of Law.



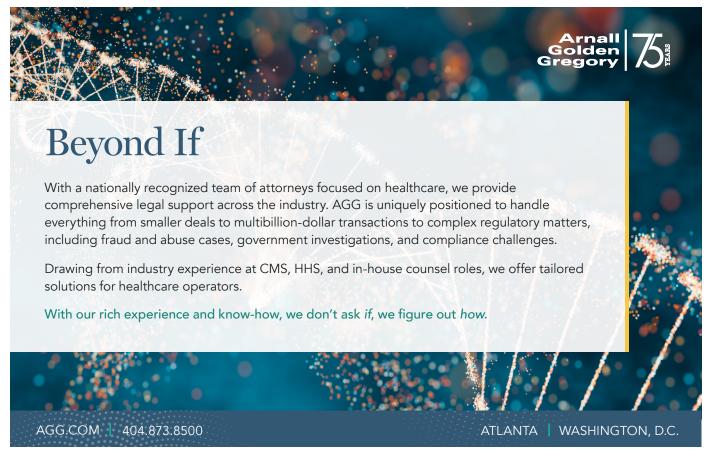
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## An Uncertain Future for the False Claims Act

Kara Silverman, Jerad Rissler and Kelsey O'Neill

On September 30, 2024, the United States District Court for the Middle District of Florida terminated a relator's five-year-long pursuit of qui tam litigation under the federal False Claims Act (FCA), ruling that her self-appointment to the office of relator under the FCA's whistleblower provision was not a valid appointment under Article II of the United States Constitution.1 The constitutionality of the FCA's qui tam provision has been questioned in prior cases, but the district court's order is the first to find that the qui tam provision of the FCA violates the Appointments Clause of the U.S. Constitution.<sup>2</sup> Prior courts have found that Congress's delegation of law enforcement power to private citizens to enforce federal law was permissible because Congress may shift executive power to third parties to achieve important public policy goals, and the Department of Justice (DOJ) maintains residual power to petition courts to limit the private party's authority to enforce the law.<sup>3</sup> More recently, however, Justice Kavanaugh's concurring opinion (joined by Justice Barrett) and Justice Thomas's dissent in United States ex rel. Polansky v. Executive Health Resources, Inc. called upon the Court to consider in an appropriate case the "substantial arguments" that the qui tam provision of the FCA is inconsistent with Article II.<sup>4</sup> Justice Thomas's dissent again questioned whether qui tam actions are constitutional under Article II because they allow private individuals to represent the interests of the United States in litigation.5 Heeding this call to consider the constitutionality of the FCA's appointment of relators to prosecute the United States' interests in complex litigation, the district court concluded that the FCA's qui tam provision "directly defies the Appointments Clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public."6

### FALSE CLAIMS ACT OVERVIEW

The False Claims Act is the federal government's primary tool to address and deter fraud against the United States and was originally enacted in response to defense contractor fraud during the American Civil War.<sup>7</sup>

1 See U.S. ex rel. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19 cv-01236-KMM-SPF (M.D. Fla. May 20, 2019).

The FCA imposes substantial damages and penalties for its violation, providing that any person who knowingly presents, or causes to be presented, false claims to the government is liable for three times the government's damages plus a penalty of up to about \$28,000 per claim.8

In addition to permitting the United States to pursue the government's interests against violators of the FCA, the FCA also allows any person (a relator) to represent the government's interests in connection with the FCA by filing a *qui tam action* in the name of the United States against those who have allegedly defrauded the government.<sup>9</sup> The DOJ may intervene in a *qui tam* action or decline to pursue it.<sup>10</sup> If the DOJ intervenes, the relator is permitted to participate as a party prosecuting the action.<sup>11</sup> If the DOJ declines to intervene, the relator may pursue the lawsuit on the government's behalf.<sup>12</sup> Successful *qui tam* suits can result in a substantial bounty for the private citizen.<sup>13</sup>

At its inception, the FCA's *qui tam* provisions were rarely invoked. That changed in 1986 with a package of amendments aimed at enticing whistleblower participation in FCA litigation, which have since "triggered an explosion of qui tam lawsuits."<sup>14</sup>

In the fiscal year ending September 30, 2023, DOJ obtained more than \$2.68 billion in settlements and judgments from civil cases involving fraud and false claims against the government.<sup>15</sup> Of those settlements and judgments, over \$2.3 billion stemmed from lawsuits filed under the *qui tam* provision of the FCA.<sup>16</sup> During that same fiscal year, the government paid out over \$349 million to relators.<sup>17</sup> Additionally, of the more than \$2.68 billion in settlements and judgments, over \$1.8 billion related to matters involving the healthcare industry, including managed care providers, hospitals, pharmacies, laboratories, long-term acute care facilities, and physicians.<sup>18</sup>

Common targets of FCA litigation include participants in complex and highly regulated industries, such as healthcare, defense spending, and government contracting.

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8 31 U.S.C. § 3729(a)(1); Federal Civil Penalties Inflation Adjustment Act of 1990.
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15 Press Release, U.S. Dep't of Just. Off. of Pub. Affs., False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023 (Feb. 22, 2024) *available at* https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.

<sup>2</sup> Order, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>3</sup> Id.; see also Morrison v. Olson, 487 U.S. 654 (1988).

<sup>4 599</sup> U.S. 419, 442 (2023) (Kavanaugh, J., concurring); see also id. at 447–50 (Thomas, J., dissenting).

<sup>5</sup> Id. at 447-50 (Thomas, J., dissenting).

<sup>6</sup> Order at 51, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>7 31</sup> U.S.C. §§ 3729–3733; *The False Claims Act*, U.S. DEP'T OF JUST. CIV. DIV., *available at* https://justice.gov/civil/false-claims-act (last updated Feb 23, 2024); Act of March 2, 1863, Ch. 67, 12 Stat. 696.

<sup>9 31</sup> U.S.C. § 3730(b)(1).

<sup>10 31</sup> U.S.C. § 3730(b)(4).

<sup>11</sup> Id. at § 3730(c)(2)(C).

<sup>12</sup> Id. at § 3730(c)(3).

<sup>13</sup> Id. at § 3730(d).

<sup>14</sup> Order at 7, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>16</sup> *Id*.

<sup>17</sup> Id.

<sup>18</sup> *Id*.

FCA suits in these industries often depend on interpretation of complex, vague, and ambiguous rules or regulations governing payment. Thus, FCA suits and decisions entered on them—including decisions on motions to dismiss or for summary judgment—may shape the way an entire industry views its obligations. When the interpretations that shape those views are proffered by the United States directly, there is some assurance that the litigation reflects the views of the United States and the pertinent agencies. A relator who is not appointed and whose reward for pursuing the case is determined primarily on the amount of recovery, on the other hand, may shape the way critical services such as healthcare are delivered without the same accountability and without consultation or approval of the relevant governing agencies.

### **THE ARGUMENTS**

In 2019, Clarissa Zafirov, a Florida-based physician, brought a qui tam action against several healthcare companies alleging the companies acted in concert to falsely adjust diagnosis codes submitted to the Centers for Medicare and Medicaid Services (CMS) for tens of thousands of Medicare Advantage beneficiaries in violation of the FCA.<sup>19</sup> The alleged false claims inflated CMS's reimbursements to the defendants by hundreds of millions of dollars according to the relator.<sup>20</sup> Medicare Advantage risk adjustment is a system through which CMS pays plans more for patients who have more health needs than other patients, based on data submitted by providers.<sup>21</sup> Here, the relator alleged the defendants manipulated risk adjustment data by submitting "hundreds of thousands of false and unsubstantiated diagnosis codes" resulting in the defendants receiving larger payments from CMS than permitted.<sup>22</sup>

Zafirov did not assert the defendants' actions harmed her personally. Rather, she pursued claims exclusively on behalf of the "real party in interest," the United States.<sup>23</sup> The government declined to intervene in Zafirov's *qui tam* action, and Zafirov pursued the action in the United States' name on her own for the next five years, with no participation in the litigation by the government other than the occasional "statements of interest" and the defense of the statutory *qui tam* provision allowing Zafirov to pursue the litigation.<sup>24</sup>

19 Complaint Alleging Violations of the Federal False Claims Act at 17, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. May 20, 2019).

20 *Id*.

The defendants, a group of Medicare Advantage organizations and provider organizations backed by the United States Chamber of Commerce, argued that the whistleblower authority provided under the FCA violates Article II of the U.S. Constitution by shifting the power to execute the nation's laws from the executive branch to private third parties.<sup>25</sup> Specifically, the defendants argued that the FCA's qui tam provision (1) violates the Appointments Clause because it permits relators to exercise an executive function (conducting civil litigation on behalf of the U.S. government to enforce public rights) despite not being properly appointed officers of the United States, and (2) violates the Vesting and Take Care Clauses because the FCA delegates executive authority, without sufficient executive control to take care that the laws are faithfully executed, to private persons outside the executive branch.<sup>26</sup> The defendants further relied on Justice Thomas's dissent in Polansky expressing doubts that the qui tam provision would pass muster under Article II.<sup>27</sup> In response, Zafirov relied on the history of qui tam suits, as well as prior case law in support 4860-0268-4651.v5 of her contention "that she is subject to sufficient control by the President and is not an officer of the United States."28

### THE RULING

The district court reached three conclusions regarding the Appointments Clause argument.<sup>29</sup> First, it determined that an FCA relator is an officer of the United States because relators exercise significant authority on behalf of the United States and occupy a continuing position.<sup>30</sup> Second, the historical examples of *qui tam* provisions highlighted by Zafirov "do not exempt an FCA relator from the Appointments Clause."<sup>31</sup> Third, the only permissible remedy for Zafirov's unconstitutional appointment was dismissal.<sup>32</sup> Given these conclusions based on the Appointments Clause, the court declined to address the defendants' additional arguments under the Take Care and Vesting Clauses of Article II.<sup>33</sup>

In conclusion, the court noted that the FCA *qui tam* provision has been described as "unusual" and "unique" and asserted this description was "no surprise" given that "[a]n FCA relator's authority markedly deviates from the constitutional norm" by "permit[ting] anyone—wherever situated, however, motivated, and however financed—

26 Id. at 9, 13–26.

<sup>21</sup> Risk Adjustment, CTRS. FOR MEDICARE & MEDICAID SERVS., available at https://www.cms.gov/priorities/innovation/key-concepts/risk-adjustment (last visited Sept. 24, 2024).

<sup>22</sup> Complaint Alleging Violations of the Federal False Claims Act at 18, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. May 20, 2019).

<sup>23</sup> Order at 50 n.9, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>24</sup> Order at 9, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>25</sup> Defendants' Joint Motion for Judgment on the Pleadings or to Dismiss for Lack of Subject-Matter Jurisdiction, U.S. *ex rel.* Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Feb. 16, 2024).

<sup>27</sup> Id. at 9, 20-21.

<sup>28</sup> Relator's Memorandum in Opposition to Defendants' Motion for Judgment on the Pleadings or to Dismiss for Lack of Subject Matter Jurisdiction, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Mar. 29, 2024).

<sup>29</sup> Order at 11, U.S. *ex rel*. Zafirov v. Fla. Med. Assocs., LLC, No. 8:19-cv-01236-KMM-SPF (M.D. Fla. Sept. 30, 2024).

<sup>30</sup> Id. at 16-17.

<sup>31</sup> Id. at 11, 39.

<sup>32</sup> *Id.* at 11, 49–51.

<sup>33</sup> Id. at 11.

to perform a 'traditional, exclusive [state] function' by appointing themselves as the federal government's 'avatar in litigation.'"<sup>34</sup> It further asserted "[t]hat arrangement directly defies the Appointments Clause by permitting unaccountable, unsworn, private actors to exercise core executive power with substantial consequences to members of the public."<sup>35</sup> Citing several sources calling into question the constitutionality of the *qui tam* provision, the court stated the "conclusion that an FCA relator is an officer of the United States is neither novel nor surprising."<sup>36</sup>

### An FCA Relator Is an Officer of the United States

"[A]s the head of the Executive Branch," the President "has the power and the duty to enforce federal law." That power may be shared, but "[t]o maintain the Executive Branch's unitary structure and prevent the abuse of power, '[t]hese lesser officers must remain accountable to the President, whose authority they wield." The Appointments Clause serves to retain this accountability by requiring the appointment of principal and inferior officers. "If an individual satisfies [two] conditions"—that she "exercises significant authority pursuant to the laws of the United States" and "occupies a 'continuing' position established by law"—then she is an "Officer[] of the United States" and "the Constitution requires that she be appointed consistent with the Appointments Clause."

An FCA Relator Exercises Significant Authority Pursuant to the Laws of the United States

"[A]n FCA relator wields significant authority because she 'conduct[s] civil litigation in the courts of the United States for vindicating public rights." This significant, if not unfettered, control over litigation conducted in the name of the United States "is textbook 'significant authority." Rejecting Zafirov's arguments to the contrary, the court noted that, "[o]f the four courts of appeals opinions that [Zafirov] cites, only two—both from the early 1990s—addressed the significant authority element." And, according to the district court, "[n]one of those circuits examined, much less reconciled, the long line of Supreme Court precedents explaining that enforcement authority and charging discretion are core executive power, especially when coupled with the authority to impose a punitivesanction." The court further rejected Zafirov and the United States'

efforts to distinguish "between a relator's power and the exercise of significant authority in *Buckley*." It noted that "[t]he Supreme Court has long rejected a constitutional distinction between civil and criminal cases when evaluating whether an individual exercises core executive power" and that FCA actions are at least partially punitive. It further observed that, while rulemaking or other administrative powers belong to officers, such powers were not necessary to be an officer; "[t]he Supreme Court held that the FEC's enforcement power—*by itself*—constituted significant authority." As to Zafirov's argument that a relator typically only pursues a single enforcement action, the court noted that "[t]he officer distinction . . . turns on the power bestowed to the official, namely the power to litigate civil cases

'in the courts of the United States for vindicating public rights"; it does not turn "on the number of enforcement actions brought by one official."48 Moreover, considering "relators collectively," as a group, they "prosecute most FCA actions, so they indeed hold the 'primary responsibility' in this field."49 As for "the government's ability to pursue a parallel action and to exert limited control after intervening," the court determined that this "does not lessen a relator's unchecked civil enforcement authority to initiate an enforcement action."50 In the court's view, "backend executive supervision—exercised by the government in only a fifth of cases—does not diminish the significance of an FCA relator's front-end power to bring an enforcement action against a private party in federal court on behalf of the United States."51 Finally, the court noted the lack of authority for the proposition "an individual who prosecutes matters on behalf of the United States must receive federal resources for her pre-suit investigations to be deemed an officer of the United States."52

The court also rejected attempts by the United States and an *amicus* to equate relators to "ordinary private plaintiffs, who do not exercise significant authority when they seek relief under other federal statutes." The court observed that there is a distinction between parties who sue in their own names and on their own behalf to redress private harms and suits by individuals in the name of the United States solely to redress alleged harms to the public.<sup>54</sup>

An FCA Relator Occupies a Continuing Position Established by Law

<sup>34</sup> *Id.* at 51. 35 *Id.* 36 *Id.* at 51–52. 37 *Id.* at 13. 38 *Id.* at 14. 39 *Id.* at 15. 40 *Id.* at 16. 41 *Id.* at 17. 42 *Id.* at 20. 43 *Id.* at 22.

<sup>45</sup> *Id.* at 24. 46 *Id.* 47 *Id.* at 25. 48 *Id.* at 26. 49 *Id.* 50 *Id.* at 26–27. 51 *Id.* at 27. 52 *Id.* 53 *Id.* at 28.

The court also determined that a relator satisfies the second condition to be deemed an "Officer of the United States"-"occupy[ing] a 'continuing' position established by law."55 This "inquiry focuses on an individual's statutory duties, powers, and emoluments," which in the case of the FCA, are defined by the statute.<sup>56</sup> "The existence of statutorily defined duties, powers, and emoluments confirms that a relator holds a continuing office," which the court referred to as "the office of an FCA relator," which "is continuous even if it is not continually filled."57 In the court's view, this "office of relator exists whether a person is appointed to that office or not, making that office 'continuous and permanent."58 That "[r]elators self-appoint as special prosecutors to recover punitive damages against private parties on behalf of the federal government" makes them "analogous to . . . Independent Counsel."59 Further, the role of relator is not dissimilar to that of bank receivers whose "duties were tied to a specific bank and discharged on completion of the project" and who were uniformly considered "officers of the United States."60 "Terms that endure for only a single action—such as bank receivers, special prosecutors, and relators—can qualify as continuing positions."61

### Article II Contains No "Qui Tam" Exception

Rejecting Zafirov's argument "that the FCA's qui tam structure survives constitutional scrutiny because early Congresses enacted some analogous statutes", the court observed that, "no Supreme Court or Eleventh Circuit precedent blesses Zafirov's theory of historical exceptionalism when the enactments directly contradict the Constitution."62 Thus, "the Constitution prevails over practice, especially when the text is clear and the practice is neither continuous nor challenged."63 In that regard, the court noted that although the FCA was enacted in 1863, use of the qui tam provisions did not become common until after the 1986 amendments.64 That brief history does not "require[] a departure from the Supreme Court's well-settled Article II jurisprudence" because "[w]hen the Constitution is clear, no amount of countervailing history overcomes what the States ratified."65

Having concluded that Zafirov, in her role as a relator, is an officer, the court conclude "there is no question that she is improperly appointed" because "[a]t its most permissive, the Appointments Clause allows Congress to 'by law' vest the

55 Id. at 30.

56 Id.

57 Id. at 31.

58 Id.

59 Id. at 32.

60 Id. at 33.

61 Id. at 34. 62 Id. at 39.

64 Id. at 6-7, 47.

65 Id. at 47-48.

appointment of inferior officers 'in the President alone, the head of an executive department, or a court."66 And, "rather than vest the appointment of a relator in the Executive Branch or in a court" as required by Article II, "the qui tam provision permits any 'person' to self-appoint."67

### The Remedy Is Dismissal

Absent a future congressional amendment, the court made it clear that no avenue exists under the qui tam provision for the plaintiff to obtain authority to prosecute on behalf of the United States.68

### POSSIBLE RAMIFICATIONS IF THE FALSE **CLAIMS ACT IS DEEMED UNCONSTITUTIONAL**

How other courts—or the Eleventh Circuit on appeal may react to Zafirov is unknown. However, if the decision portends widespread invalidation of the qui tam provision of the FCA, that may potentially reduce the reporting and enforcement of alleged fraud. Whistleblowers often bring allegations of fraud to the government's attention. Sometimes the Government intervenes and takes over the litigation, but more often, the government declines to intervene, leaving the whistleblower the option to continue to pursue the action in the name of the United States. And often whistleblowers have taken non-intervened cases forward (as Zafirov did for five years before dismissal). But if the holding of Zafirov gains traction, how will that affect whistleblowers' willingness to come forward? And, if they do, will the inability of the whistleblower to pursue the case alter the government's intervention decision?

Assuming that relators can still access the bounties available to them in intervened cases, invalidation of the qui tam provision may not materially affect whistleblowers' willingness to come forward. The bigger question is what will invalidation of the qui tam provision mean for the government's intervention decision? Will there be a legislative fix to appoint relators in a manner that comports with the Constitution? Barring that, will the government intervene in cases that, in the past, it might have declined? And how many more cases can it take? The elimination of the qui tam provision would increase the burden on federal resources and the DOJ to bring the action on their own accord. This point was emphasized in a 1986 Senate Judiciary Committee Report stating, "available Department of Justice records show most fraud referrals remain unprosecuted and lost public funds, therefore, remain uncollected," and that a "resource mismatch" exists between federal government and large companies.<sup>69</sup> Following this report, Congress expanded the authority of relators to direct litigation when

66 Id. at 48.

67 Id. at 48-49.

69 S. REP. NO. 345, 99th Cong., 2d Sess. 4-8 (July 28, 1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5269, 5273.

the DOJ intervenes. Without the *qui tam* provision, we are likely to see a substantial decline in the number of claims prosecuted under the FCA.

No doubt this case will face appeal before the Eleventh Circuit and perhaps the Supreme Court in due time. And other courts have reached the opposite conclusion on the constitutionality of the *qui tam* provision.<sup>70</sup> Given the vast sums recovered through the FCA, it would not be surprising to see bipartisan efforts at a legislative fix. What that would look like remains to be seen. For now, however, historical pedigree may no longer be sufficient, and the landscape of FCA claims may look drastically different in the near future.

70 See e.g., United States ex rel. Butler v. Shikara, et al., Case No. 20-80483-CV-MIDDLEBROOKS (SD Fl. Sept. 6, 2024) (discussing and rejecting same Article II argument at length and denying motion to dismiss on all grounds).





Kara Silverman and Jerad Rissler are partners at Arnall Golden Gregory LLP. Both focus their practices on government investigations and litigation, particularly in healthcare law.



Kelsey O'Neill is a litigation law clerk at Arnall Golden Gregory LLP.

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### CONTACT

Kyle Gause, Atlanta | kyleg@gabar.org Kindall Harville, Savannah | kindallh@gabar.org LaCara Reddick, Tifton | lacarar@gabar.org

