FOLEY

FOLEY & LARDNER LLP

PYA

SESSION 1

# Refreshing Compliance Programs to Respond to OIG's New Health Care Compliance Guidance and Recent Enforcement Actions

January 18, 2024


FOLEY.COM

# Contacts

**Judith A. Waltz**
Foley & Lardner LLP
Partner | San Francisco

**T: 414.434.6412**
**E: jwaltz@foley.com**

**Shannon Sumner**
PYA, P.C.
Principal | Nashville

**T: 800.270.9629**
**E: ssumner@pyapc.com**

**Jana Kolarik**
Foley & Lardner LLP.
Partner | Jacksonville

**T: 904.633.8915**
**E: jkolarik@foley.com**

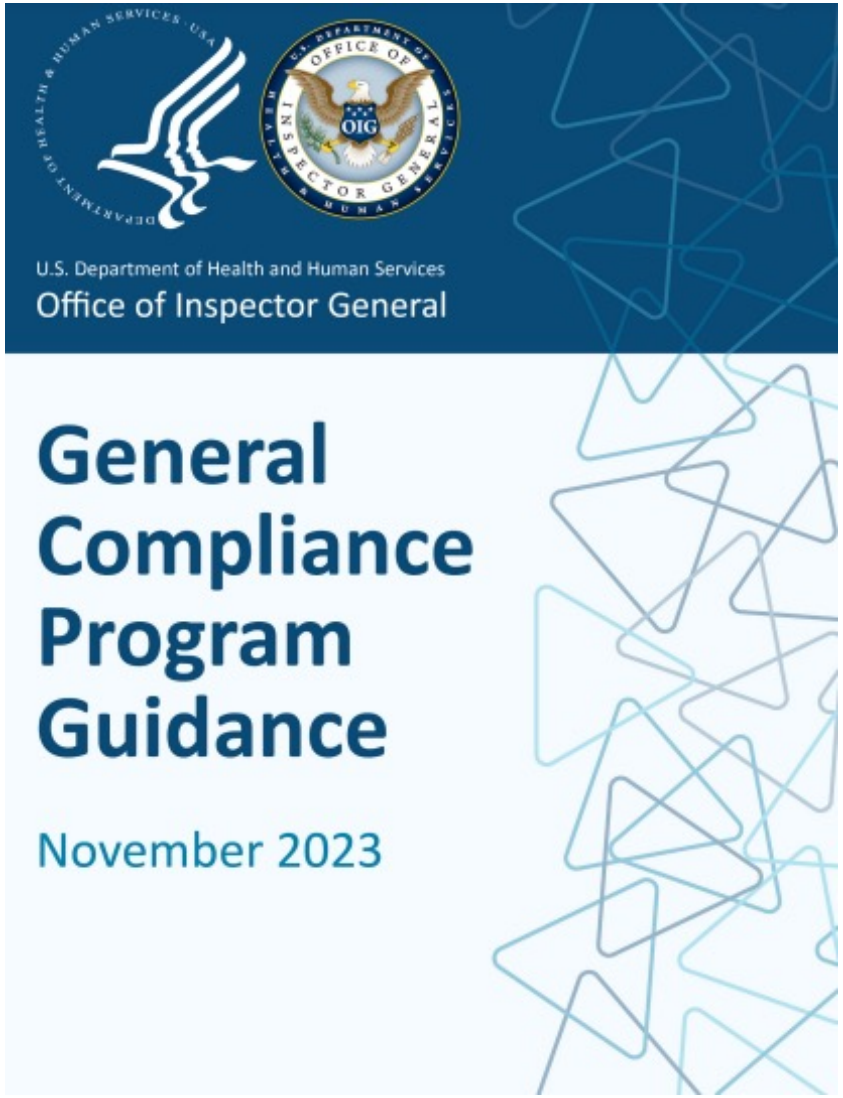
**Angie Caldwell**
PYA, P.C.
Office Managing Principal | Tampa

**T: 800.270.9629**
**E: acaldwell@pyapc.com**

# Presentation Overview

- In this session we will provide the following information:
  - A general overview of the November 2023 release of the OIG's General Compliance Program Guidance (GCPG) including focus on risk assessments
  - Action steps that may be taken in light of the GCPG
  - A summary of recent enforcement actions for consideration by compliance officers when developing their 2024 compliance work plan

# OIG's General Compliance Program Guidance (11/23)



# Background for the GCPG

https://oig.hhs.gov/compliance/general-compliance-program-guidance/

- Compliance with the GCPG is voluntary, non-binding.
- A desktop reference: 91 pages of general compliance guidance, tools and references addressed to all varieties of federal health care program providers and suppliers. Includes discussions of the key laws in health care fraud enforcement and includes frameworks and questions for an analysis of situations under those laws.
  - Discussions of the key laws in health care fraud enforcement and frameworks and questions for an analysis under those laws.
  - Helpful citing references (with links) to various resources for compliance professionals.
  - Recaps from prior guidance (Adv. Ops.), CIAs, and various other OIG issuances.

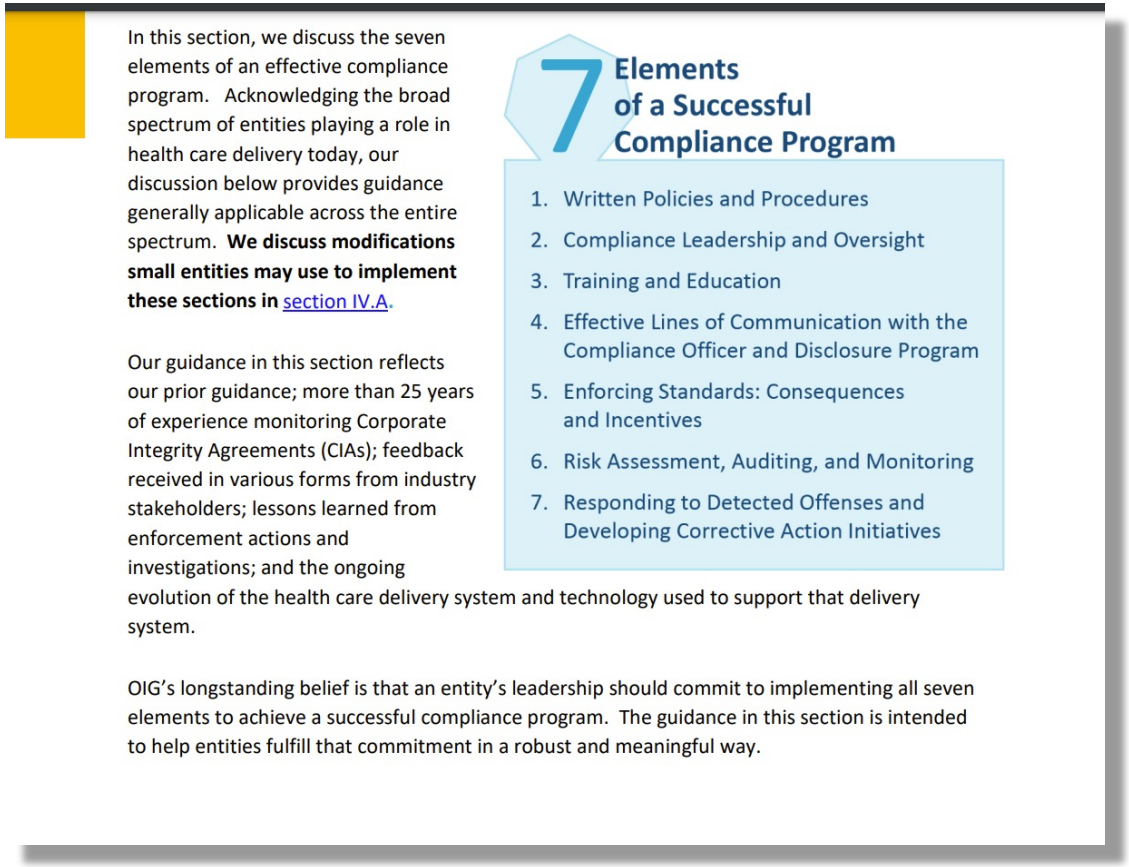
# Background for the GCPG (cont.)

https://oig.hhs.gov/compliance/general-compliance-program-guidance/

- The GCPG will be followed by compliance guidance addressed to multiple health care industry subsectors (i.e., specifically targeted categories of providers/suppliers) that will replace the existing compliance guidance which have been issued over the course of the last three decades, starting with the 1998 Compliance Program Guidance for Hospitals.

# The Seven Elements

- The GCPG sticks with the seven elements of compliance identified in the U.S. Sentencing Guidelines, Ch. 8,  as the framework for its compliance program recommendations. https://www.ussc.gov/guidelines/2023-guidelines-manual/annotated-2023-chapter-8#8b21



In this section, we discuss the seven elements of an effective compliance program. Acknowledging the broad spectrum of entities playing a role in health care delivery today, our discussion below provides guidance generally applicable across the entire spectrum. **We discuss modifications small entities may use to implement these sections in** section IV.A.

Our guidance in this section reflects our prior guidance; more than 25 years of experience monitoring Corporate Integrity Agreements (CIAs); feedback received in various forms from industry stakeholders; lessons learned from enforcement actions and investigations; and the ongoing evolution of the health care delivery system and technology used to support that delivery system.

OIG's longstanding belief is that an entity's leadership should commit to implementing all seven elements to achieve a successful compliance program. The guidance in this section is intended to help entities fulfill that commitment in a robust and meaningful way.

**7 Elements of a Successful Compliance Program**

1. Written Policies and Procedures
2. Compliance Leadership and Oversight
3. Training and Education
4. Effective Lines of Communication with the Compliance Officer and Disclosure Program
5. Enforcing Standards: Consequences and Incentives
6. Risk Assessment, Auditing, and Monitoring
7. Responding to Detected Offenses and Developing Corrective Action Initiatives

# GCPG “Themes”

- Focus on operational effectiveness of the compliance program, not just the structure.
- Focus on the fluidity of compliance risks – compliance challenges change and so should the issues reviewed as part of the risk assessment. (Cf. recent CIA IRO designs.)
- Focus on the compliance committee (rather than the compliance officer) – e.g., risk assessments managed by the CC rather than CO; attendance included in evaluation of CC members. CC engagement reflects commitment of the organization.
- Focus on high level accountability – CC, board, owners (P/E)

# Key Insights Noted in the GCPG

- Quality – Intersection with compliance noted throughout.
- Reporting Relationship – CCO should not be GC nor report to the GC (in bold).
- Compliance Committee – member attendance and participation included in each member's performance and compensation evaluation.
- Board - should meet with the CCO no less than quarterly and reserve time each meeting for executive session, absent management.
- Board – evaluate the Compliance Committee's risk assessment process.
- Board – receive annual reports on the entity's effectiveness in addressing and resolving compliance committee identified risks.
- Training – ensure a mechanism for participants to ask questions about the content.
- Training – participation a condition of continued employment or engagement.

# Key Insights Noted in the GCPG (cont.)

- Training – Compliance Committee members should deliver compliance training to help normalize compliance as part of the entity's culture.
- Investigations – The compliance officer should stay involved in all health care compliance investigations in which counsel takes the lead.
- Incentives for compliance – additional compensation, significant recognition or other similar forms of encouragement.
  - Compliance Committee and Compliance Officer should devote time, thought and creativity to the compliance activities they would like to incentivize.
  - Assess whether other incentive plans can be achieved while operating in an ethical and compliance manner (e.g., sales goals, admission goals).

# Key Insights Noted in the GCPG – Risk Assessment

- Action Item. Annual Risk Assessment – Responsibility of the Compliance Committee with coordination with audit, quality, and risk management functions.
  - References the COSO ERM Framework and other non-traditional references (e.g., Green Book, US GAO).
  - Use of data analytics and metrics.
  - OIG Toolkits: Measuring Compliance Program Effectiveness https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf
  - GCPG notes some common compliance risk areas (p. 34):
    - Billing, Coding, Sales, Marketing, Quality of care, Patient incentives, Arrangements with physicians, other health care providers, vendors, and other potential sources or recipients of health care business
  - OIG indicated that specific compliance guidance for subsectors (e.g., lab, SNF) will be rolled out starting 2024, but until then the identified risk areas in existing OIG Compliance Guidance should be considered for inclusion in the risk assessment

# Key Insights Noted in the GCPG (p. 35) – Exclusion

- **Action Item**: All organizations should have a policy and procedure on the screening of employees, contractors, and other individuals and entities that furnish items and services for or on behalf of the organization against the LEIE and any **applicable State Medicaid program exclusion lists.**
  - State by state check – and different terms, e.g.: Medicaid Sanction List (Alabama); Suspended and Ineligible Provider List (California); Quality Assurance Administrative Actions List Medicaid (Connecticut); Agency for Health Care Administration Public Record Search (Florida); State Adverse Actions List (Louisiana); Medicheck Precluded Providers List (Pennsylvania).
- Collateral terminations (from Affordable Care Act) - ACA Section 6501 amended section 1902(a)(39):
  "[T]he State agency shall…terminate the participation of any individual or entity in such program if …participation of such individual or entity is terminated under title XVIII [Medicare] or any other State plan[Medicaid]…and provide that no payment may be made under the plan with respect to any item or service furnished by such individual or entity during such period…."; *See also*: 42 C.F.R. § 445.416: "Must deny enrollment or terminate the enrollment."

# Key Insights Noted in the GCPG (p. 35) – Exclusion (cont.)

- Note that there is federal CMP authority (in addition to state penalties) that may apply: 42 C.F.R. § 1003.200(b)(4): Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program. Penalty $24,164.

# Compliance Program Adaptations for Large and Small Entities

- Small Entities – individual and small group practices or other entities with a small number of employees.
  - Compliance Contact (in lieu of dedicated compliance officer) - Person should not have any responsibility for the performance or supervision of legal services and *whenever possible* should not be involved in the billing, coding or submission of claims.
  - If no Board, the compliance contact should provide at least an annual report to the owner or CEO.
  - OIG Resources on-line for training and policies/procedures for customization.
  - Policies for good-faith reporting of compliance issues and prohibit retaliation, including posting information about the OIG Hotline.
  - Risk Assessments – Doesn't have to be complicated/at least an annual audit.

# Compliance Program Adaptations for Large and Small Entities (cont.)

- Large Entities
  - Department of compliance personnel.
  - Consider Deputy Compliance Officers responsible for specific areas (audits, investigations, training, policies).
  - Regional compliance officers.
  - Blend of various skill sets (auditors, clinicians, data analysts) and utilize consultants where necessary.
  - Compliance subcommittees with responsibilities for policies and procedures, training, risk assessments, etc.
  - Separate Board Compliance Committee (vs. combined with Audit Committee).
  - International organizations should ensure the parent board is well versed in US Federal healthcare program requirements.

# Other Compliance Considerations

- Forthcoming ICPGs will address industry subsector specific risks for different types of providers.
- Entities should incorporate quality and patient safety oversight into their compliance programs.
- The Board should require regular reports from senior leadership with oversight for quality, patient safety in conjunction with compliance officer reports.
- Compliance Committee should include members responsible for quality assurance and patient safety and adequacy of patient care.
- Quality audits and reviews should be included in the compliance work plan.
- Compliance committees should also assess staffing for nursing, therapy and other clinical services.
- Compliance officers should develop productive working relationships with clinical and quality leadership, collaborating on compliance matters and be informed regarding internal audits.

# Other Compliance Considerations (cont.)

- Risk Assessment – ensure medical necessity, patient safety and other quality compliance issues are included in the risk universe.
- New entrants into the health care industry, including new models of care require an understanding of the FWA laws applicable.
- “Follow the Money” – Private equity and other private investors – governing bodies should carefully scrutinize the operations and incentive structures, especially investors who provide management services.
- Payment Incentives - Obtain a clear understanding of the various payment incentives within your entities.  Fee for service (overutilization), capitation (stinting on care) and quality of care (gaming of data).
- Financial Arrangements – Ongoing monitoring of financial arrangements with referral sources (IRO work plans).

# Recent Settlements Worth Exploring

**Community Health Network $345 million**

- The U.S. alleged that, in 2008 and 2009, Community leadership began recruiting physicians — many of them specialists — to get their "downstream referrals." Community paid those physicians far above market value and included incentives based on referral targets, according to the U.S. complaint. Then, it allegedly submitted those inflated claims to Medicare.
  - Understand your entity's internal review guidelines for physician compensation arrangements including involvement of counsel, independent valuation firms, management and governance.
  - Understand whether your entity has separation (and policy) between those who determine physician compensation and those who have access to referral information.
  - Understand your entity's processes for determining commercial reasonableness for a particular arrangement (e.g., medical director).
  - Understand your entity's incentive compensation programs as they relate to service line margin/provider profitability.

# Compliance Officer Files Whistleblower Complaint

HHS-OIG General Compliance | District of Delaware | Christiana

justice.gov/usao-de/pr/christianacare-pays-425-million-resolve-health-care-fraud-allegations-0

An official website of the United States government Here's how you know

DOJ Menu

United States Attorney's Office District of Delaware

About DE | Find Help | Contact Us

Search

About | News | Meet the U.S. Attorney | Divisions | Resources | Careers | Contact

Justice.gov > U.S. Attorneys > District of Delaware > Press Releases > ChristianaCare Pays $42.5 Million To Resolve Health Care Fraud Allegations

PRESS RELEASE

## ChristianaCare Pays $42.5 Million To Resolve Health Care Fraud Allegations

Thursday, January 4, 2024

Share

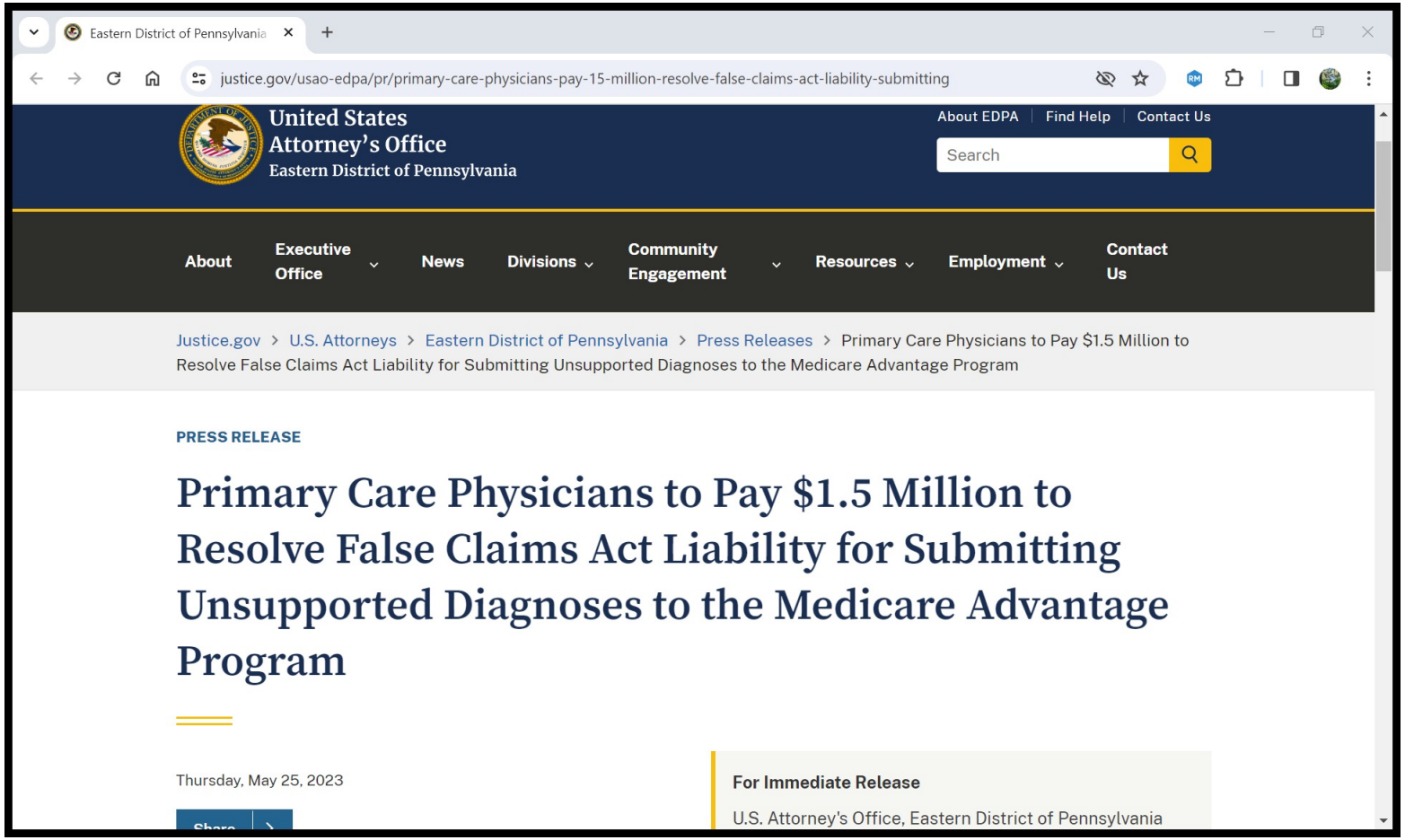
**For Immediate Release**

U.S. Attorney's Office, District of Delaware

WILMINGTON, Del. – U.S. Attorney David C. Weiss announced today that ChristianaCare has paid $42.5 million to resolve allegations of health care fraud arising under the federal False Claims Act and the Delaware False Claims and Reporting Act. ChristianaCare operates three hospitals and numerous other healthcare facilities in northern Delaware and the surrounding area. The settlement amount has been allocated between the United States and the State of Delaware based on the value of the underlying healthcare claims.

In a complaint filed under the whistleblower provisions of the False Claims Act in 2017, ChristianaCare's former chief compliance officer alleged that ChristianaCare had provided illegal remuneration to non-employee neonatologists and surgeons in the form of services from ancillary support providers (including nurse practitioners, hospitalists, and physician assistants) to inpatients at ChristianaCare hospitals. The lawsuit alleged that the services of the ancillary support providers impermissibly sought to induce

# Improper Claims Submitted to MA Plans; E/M Codes Without Sufficient Documentation: “Incident to”





FOLEY & LARDNER LLP
PYA

# District of Massachusetts | Reading Owner to Telemedicine Companies Charged with $44 Million Medicare Fraud Scheme

**(telemarketing, physician/patient relationship)**

According to the charging documents, between January 2018 and August 2021, Santana, through his companies Conclave and Nationwide, entered into business relationships with telemarketing companies that generated leads by targeting Medicare beneficiaries. The telemarketers then allegedly paid Conclave and Nationwide on a per-order basis to generate orders for DME and genetic testing for these beneficiaries. To arrange for these orders to be signed, Santana allegedly worked with medical staffing companies to find doctors and nurses who were willing to review and sign prepopulated orders, typically without any contact with the beneficiaries. It is alleged that the records falsely portrayed the medical providers as having performed a legitimate examination of the beneficiary. Santana then allegedly provided the signed orders to the telemarketing companies which sold the orders to DME suppliers and laboratories. It is alleged that Santana knew these DME suppliers and laboratories would use the signed orders to submit claims to Medicare for DME and genetic testing that were medically unnecessary, based on false documentation and tainted by kickbacks.

https://www.justice.gov/usao-ma/pr/reading-owner-telemedicine-companies-charged-44-million-medicare-fraud-scheme 2/5

# Billed for MD, Service Performed by NPP; Upcoded Office Visits Including for COVID-19 Testing Services

Eastern District of Missouri | Un

justice.gov/usao-edmo/pr/united-states-reaches-91-million-civil-settlement-total-access-urgent-care-over-false

United States Attorney's Office
Eastern District of Missouri

About EDMO | Find Help | Contact Us

Search

About | News | Meet the U.S. Attorney | Divisions | Programs | Careers | Contact Us

Justice.gov > U.S. Attorneys > Eastern District of Missouri > Press Releases > United States Reaches $9.1 Million Civil Settlement with Total Access Urgent Care Over False Claims Allegations

PRESS RELEASE

## United States Reaches $9.1 Million Civil Settlement with Total Access Urgent Care Over False Claims Allegations

Thursday, December 21, 2023

Share

**For Immediate Release**

U.S. Attorney's Office, Eastern District of Missouri

ST. LOUIS – The U.S. Attorney's Office for the Eastern District of Missouri announced today that Total Access Urgent Care (TAUC) has agreed to pay $9,150,794 to settle allegations that TAUC submitted false claims for medical services, including COVID-19 testing.

"This settlement will fully repay three federal health care programs for TAUC's overbilling for COVID tests and office visits," said U.S. Attorney Sayler A. Fleming.

According to the United States' allegations, from April of 2017 through November of 2021, TAUC submitted claims for payment to Medicare and TRICARE indicating that a physician performed office visits when a non-physician practitioner had actually done so, thereby receiving reimbursement at a higher rate. From November of 2015 through November of 2021, TAUC submitted claims to Medicare and TRICARE for office visits that were upcoded. During the latter portion of that period, it also submitted upcoded office visit claims to a program that reimbursed for the testing or treatment of, and vaccination against, COVID-19 for people who

# About Foley

Foley & Lardner LLP is a preeminent law firm that stands at the nexus of the Energy, Health Care & Life Sciences, Innovative Technology, and Manufacturing Sectors. We look beyond the law to focus on the constantly evolving demands facing our clients and act as trusted business advisors to deliver creative, practical, and effective solutions. Our 1,100 lawyers across 25 offices worldwide partner on the full range of engagements from corporate counsel to intellectual property work and litigation support, providing our clients with a one-team solution to all their needs. For nearly two centuries, Foley has maintained its commitment to the highest level of innovative legal services and to the stewardship of our people, firm, clients, and the communities we serve.

**FOLEY.COM**



# About PYA

For 40 years, PYA, a national professional services firm providing healthcare management consulting and accounting, has helped its clients navigate regulatory compliance. PYA's suite of compliance services includes developing and evaluating compliance programs and performing risk assessments, serving as an Independent Review Organization, supporting providers undergoing investigations/payer audits, advising on reimbursement and revenue management, and providing fair market value compensation opinions. Serving clients in all 50 states from offices in seven cities, PYA is consistently ranked by Modern Healthcare as one of the Top 20 healthcare consulting firms in the U.S. and by INSIDE Public Accounting as one of the nation's “Top 100” Largest Accounting Firms.

**PYAPC.COM**

FOLEY
FOLEY & LARDNER LLP

PYA