HEALTHCARE REGULATORY ROUNDUP – EPISODE #67

2024 GCPG - Updates, Key Insights, & Recommendations

March 20, 2024

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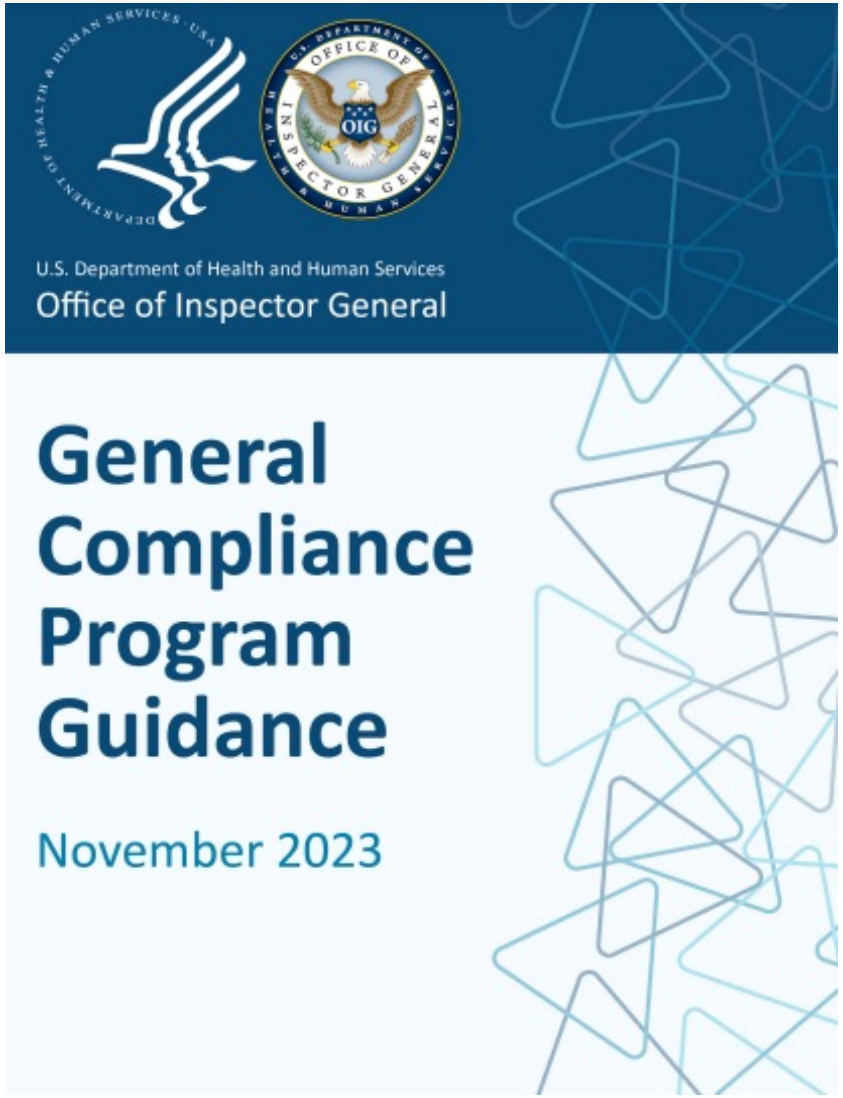
Presentation Overview

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


U.S. Department of Health and Human Services
Office of Inspector General
General Compliance Program Guidance
November 2023

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.
  1. Hospitals
  2. Home health agencies
  3. Clinical laboratories
  4. Third-party medical billing companies
  5. DME, prosthetics, orthotics and supply industry
  6. Hospices
  7. Medicare Advantage organizations
  8. Nursing facilities
  9. Physicians
  10. Ambulance suppliers
  11. Pharmaceutical manufacturer

Background for the GCPG (cont.)

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

- “Improve and update existing CPGs and to deliver new CPGs…”
- No longer going to publish updated or new CPGs in the *Federal Register*
- Current, updated, new CPGs available via OIG website
- “GCPG applies to all individuals and entities involved in the health care industry”
- 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.

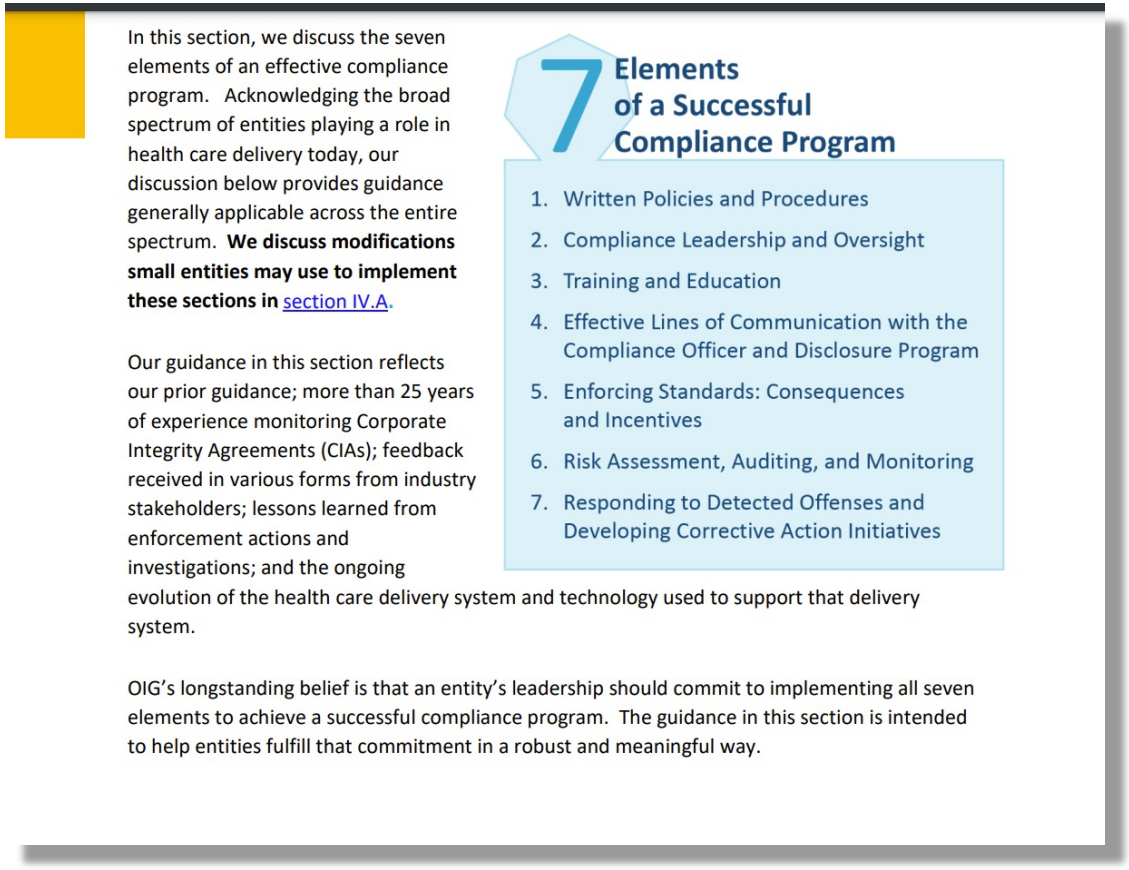
What's to Come?

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

- In 2024, OIG will publish industry segment-specific CPGs or ICPGs for different types of providers, suppliers and other participants
  - Tailored to fraud and abuse risks for each industry subsector
  - Detail compliance measures that can be taken to reduce risk
  - Will replace the existing compliance guidance which has been issued over the course of the last three decades, starting with the 1998 Compliance Program Guidance for Hospitals.
- February 21, 2024, OIG announced the first two industry segment-specific CPGs:
  - Medicare Advantage
  - Nursing Facilities
  - Anticipate to be followed by Hospitals and Clinical laboratories
- OIG "welcomes feedback from the healthcare community…"
  - Compliance@oig.hhs.gov – designated email inbox for feedback

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.

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

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.

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 – Regulatory

- Specific to the AKS
  - Nature of the relationship between the parties
  - Manner in which participants were selected
  - Manner in which remuneration is determined
  - Value of remuneration
    - FMV in an arm's-length transaction for legitimate, reasonable, and necessary services that are actually rendered
    - Is the determination of fair market value based upon a reasonable methodology that is uniformly applied and property documented?
  - Nature of items or services provided
    - Actually, needed and rendered, commercially reasonable and necessary to achieve a legitimate business purpose

Key Insights Noted in the GCPG – Regulatory (cont.)

- Specific to the AKS (cont.)
  - Federal program impact
  - Clinical decision making
  - Steering
  - Potential conflicts of interest
  - Manner in which the arrangement is documented

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 is 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 compliant 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

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).
- Regular reviews to keep billing and coding practices up-to-date
- Regular internal billing and coding audits

Other Compliance Considerations (cont.)

D. Financial Arrangements Tracking

Entities involved in Federal health care program business may manage a significant volume of financial arrangements and transactional agreements, including those between referral sources and referral recipients, which can implicate the Federal anti-kickback statute and the PSL, among other Federal fraud and abuse laws. While legal counsel may be involved in the initial structuring and drafting of these agreements, ongoing monitoring of compliance with the terms and conditions set forth in the agreements remains equally important from a fraud and abuse perspective. Entities should consider what type of centralized arrangements tracking system to establish, depending on the size of their organization, to ensure that proper supporting documentation is maintained, regular legal reviews are conducted, and fair market value assessments are performed and updated routinely as appropriate. As applicable, tracking systems should also account for service and activity logs and use of lease space and equipment to ensure consistency with contract terms. The business need or rationale for arrangements should also be documented. An effective and robust arrangements tracking system—that is audited regularly—is a compliance measure that can be taken to prevent violations and mitigate potential liability under the Federal fraud and abuse laws.

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

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PRESS RELEASE

ChristianaCare Pays $42.5 Million To Resolve Health Care Fraud Allegations

Thursday, January 4, 2024

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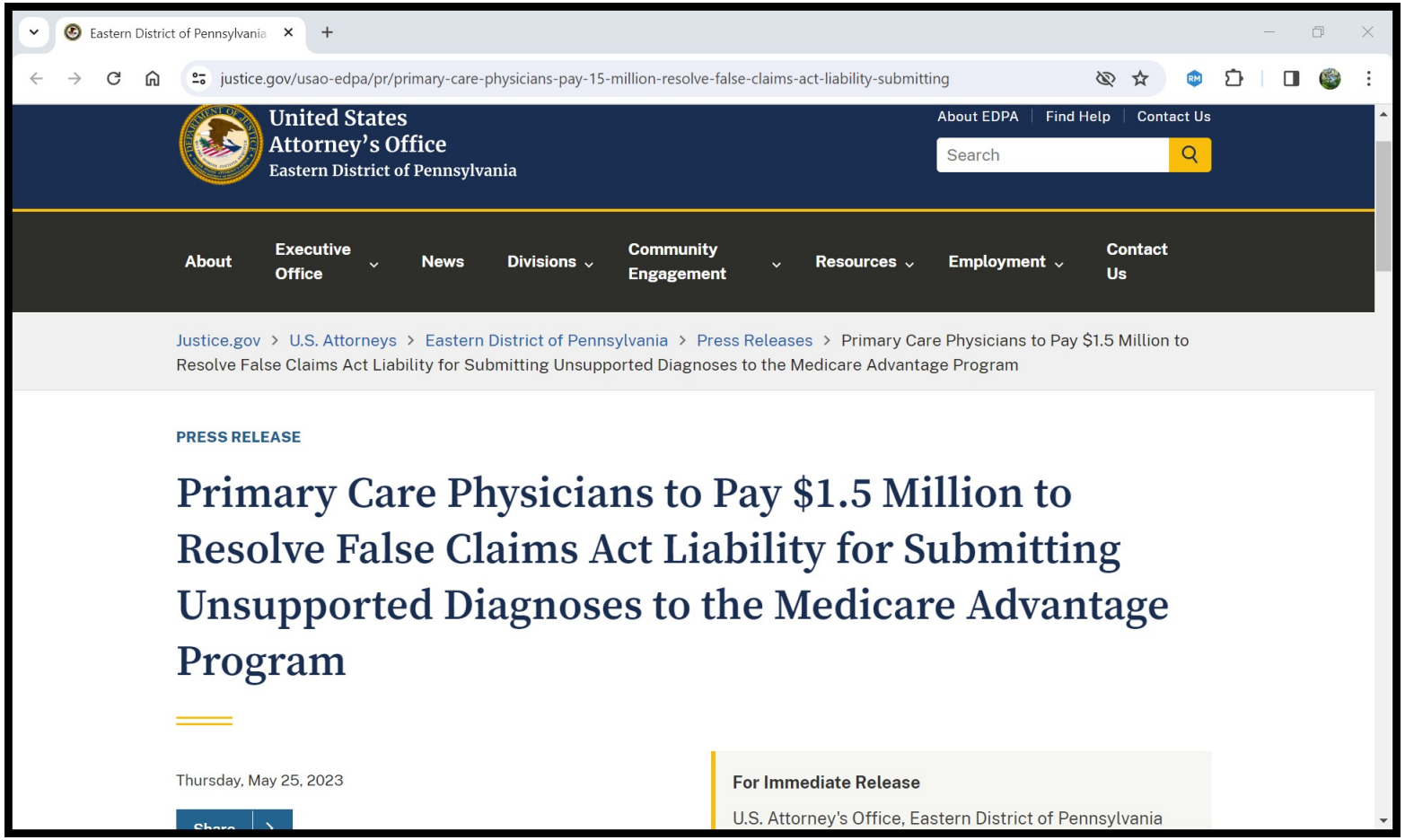
For Immediate Release

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”



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

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PRESS RELEASE

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

Thursday, December 21, 2023

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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

How can we HELP?