Corporate Integrity Agreement Trends and Considerations for Compliance

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Presenter Bios

Elizabeth Haley

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Elizabeth A. Haley is Vice President, Compliance, Culture & Ethics for CVS Health. In this role, she is responsible for developing the strategic direction and delivery of the Corporate Compliance Program, including enterprise training, policy management, and program alignment with legal and regulatory requirements. Further, in her role Elizabeth is responsible for negotiating and implementing government settlement agreements, establishing relationships with government regulators, and oversight of the Company's compliance with anti-money laundering regulations. Elizabeth is also responsible for operations, investigations, and reporting for the Ethics Line disclosure program. Elizabeth has 15 years of legal experience representing clients in the healthcare sector. Elizabeth joined CVS Health as part of the acquisition of Omnicare, Inc., where she was Associate General Counsel in the Legal Department for over four years. Elizabeth began her legal career as a litigation attorney at an international law firm headquartered in New York City, specializing in antitrust and health care litigation. Elizabeth received a Bachelor of Arts from the College of the Holy Cross and a Juris Doctor from Notre Dame Law School.

Jane Yoon

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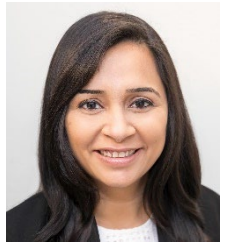
Jane H. Yoon is a partner in the Litigation practice of Paul Hastings and is based in the firm's New York office. Ms. Yoon represents corporate entities and their executives in connection with government and internal investigations into allegations of potential violations of the federal Anti-Kickback Statute, health care fraud, the Food Drug & Cosmetic Act, and the False Claims Act. These matters range from conduct surrounding patient support/assistance programs, specialty pharmacy arrangements, clinical trials and investigator-initiated studies, promotional activities, and the full range of interactions between manufacturers, providers, patients, payers, and third-party vendors. Ms. Yoon also handles compliance and investigations matters relating to Medicare Advantage, including Medicare risk adjustment, kickback and billing fraud allegations.

Prior to joining Paul Hastings, Ms. Yoon was a federal prosecutor for approximately seven years in the Health Care & Government Fraud Unit in the Criminal Division of the U.S. Attorney's Office for the District of New Jersey, where she routinely partnered with HHS-OIG, FDA-OCI, FBI, IRS, and other federal agencies in the investigation and prosecution of health care fraud, government fraud and complex tax matters.



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Dhara Satija is the Director of Healthcare Consulting in the Life Sciences Consulting Group of Paul Hastings. Dhara has nearly 15 years of consulting experience serving healthcare and life sciences clients across an array of issues, including projects ranging from strategy and operations to regulatory and corporate compliance, risk management, and investigation and litigation support. In particular, Dhara has led projects related to: development and implementation of compliance programs (i.e., written standards, training, and monitoring/auditing); design and delivery of internal compliance audits, investigations, and corrective action plans; support for provider self-disclosures/voluntary refunds; government-initiated audits; litigation support services; and Corporate Integrity Agreement (CIA) requirements.

Today's Objectives:

During this presentation, we will cover:

1. Overview of recent enforcement activities/trends

2. Discuss key considerations and leading practices to help strengthen and sustain an effective compliance program and culture within an organization

3. Learn from practical examples with key takeaways

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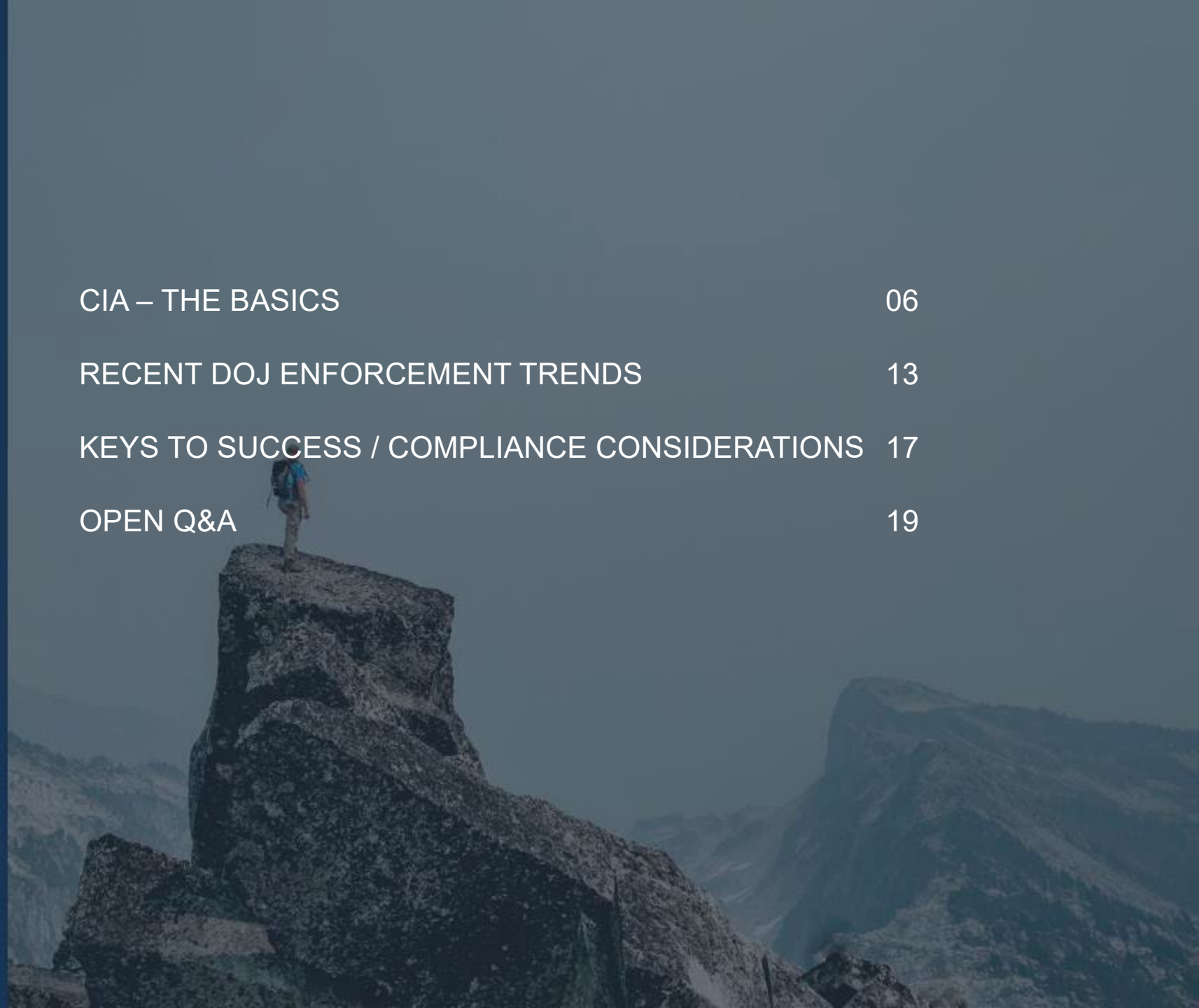

Polling Question

Are you currently or have you ever been involved with the CIA?

A. Yes
B. No

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CORPORATE INTEGRITY AGREEMENTS (CIAS) – THE BASICS

CIAs – The Basics

How is CIA negotiated?

Office of Inspector General (“OIG”) negotiates corporate integrity agreements (“CIAs”) with health care providers and other entities as part of a settlement of Federal health care program investigations arising under a variety of civil false claims statutes (e.g., certain federal or state investigations or litigations).

What is CIA?

A document that outlines the obligations to which an entity agrees as part of a civil settlement. CIAs are negotiated **agreements** – not court orders. Organizations negotiate the terms of the agreement and **essentially promise** to abide by such terms.

What is the expectations?

Health care providers or entities agree to the obligations, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs

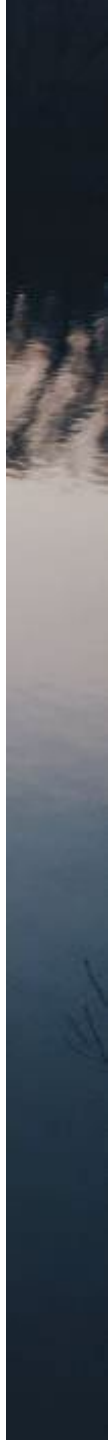
Source: https://oig.hhs.gov/compliance/corporate-integrity-agreements/

CIAs – Common Elements

CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs.

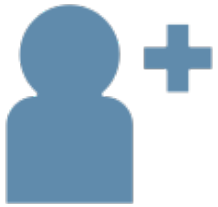
Common Elements:

- **Length of CIAs:** 5 years
- **Independent Oversight Requirements:** Either Independent Review Organization (“IRO”) and/or Monitor
- **Reporting Requirements:** Annual Reports
- **Key Compliance Program Requirements:**
    1. Hire a compliance officer/appoint a compliance committee;
    2. Develop written standards and policies;
    3. Implement a comprehensive employee training program;
    4. Retain an independent review organization to conduct annual reviews;
    5. Establish a confidential disclosure program;
    6. Restrict employment of ineligible persons;
    7. Report overpayments, reportable events, and ongoing investigations/legal proceedings; and
    8. Provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.



Quality of Care CIAs

"Quality of Care" CIAs focus on when a False Claims Act settlement resolves allegations of fraud impacting quality of patient care.



Key Elements:

- Requires that the provider retain an entity with clinical expertise to perform quality-related reviews (e.g., retain an independent quality monitor for entity's delivery of care and ability to prevent, detect, and respond to patient care problems).
- May require provider to retain a peer review consultant to evaluate peer review and medical credentialing systems OR to retain a clinical expert to review the medical necessity and appropriateness of certain admissions and medical procedures.
- Require the provider to appropriately respond to the monitor and/or consultant's recommendations for improvement to quality, peer review, and/or medical credentialing systems during the term of the CIA.

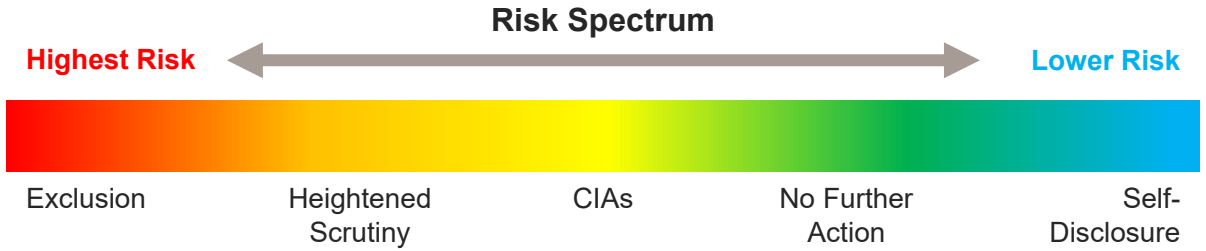
When a provider enters into a quality of care CIA as part of a settlement, it is not an admission that the provider provided substandard or worthless patient care

Source: https://oig.hhs.gov/fraud/fraud-risk-indicator/false-claims-act-settlements-on-the-risk-spectrum/

Fraud Risk Indicator

The goals of CIAs are to strengthen a person's compliance program and promote compliance so that future issues can be prevented or identified, reported, and corrected. Integrity obligations also enhance OIG's oversight of the person.

OIG evaluates health care fraud cases on a continuum: resolution of OIG's exclusion authorities is based on OIG's assessment of future risk to the Federal health care programs.



In evaluating a person's place on the risk spectrum, OIG considers and weighs the facts across four factors:

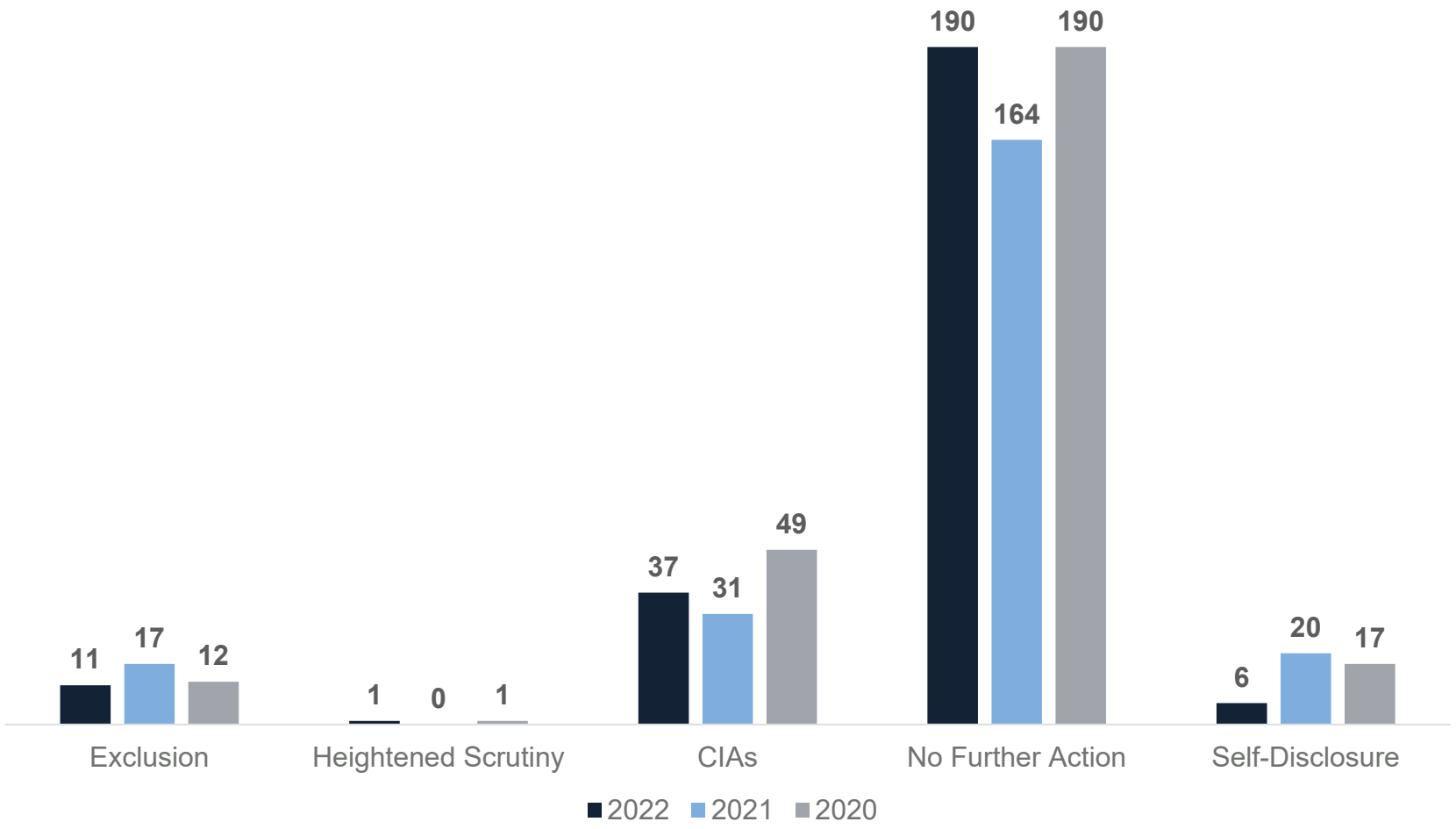
1. Nature and circumstances of conduct,
2. Conduct during the Government's investigation,
3. Significant ameliorative efforts, and
4. History of compliance.

Each factor: (1) indicates a higher risk; (2) indicates a lower risk; or (3) is neutral to the risk assessment.

Source: https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf

False Claims Act Settlements on the Risk Spectrum

OIG assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud.



Source: https://oig.hhs.gov/fraud/fraud-risk-indicator/false-claims-act-settlements-on-the-risk-spectrum/

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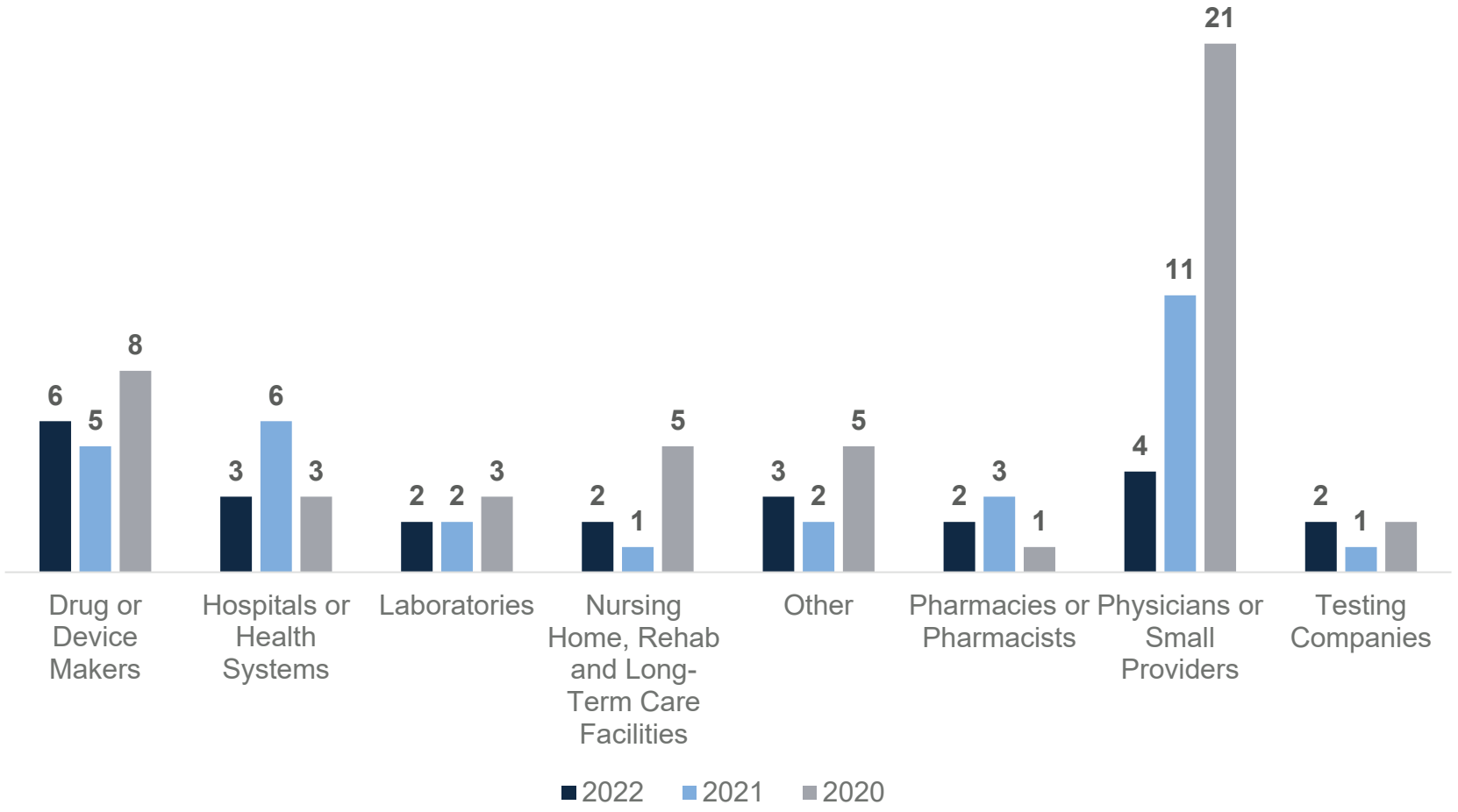
CIAs by the Numbers

2020 set a record with 45+ CIAs. This number decreased to 31 in 2021 and HHS OIG is on track for **37 in 2022*.**



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*2022 segmentation is based on 24 publically listed CIAs through 11-4-22.
Source: CIAs publically listed on 11-4-2022 https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp

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RECENT DOJ ENFORCEMENT TRENDS

Regulators Expect Compliance + Closely Scrutinize the Healthcare Industry

"Health care fraud was once again the leading source of the department's False Claims Act settlements and judgments this past year."

- Regulators continue to emphasize the **importance of an effective, dynamic compliance program** that is able to evolve with its organization. According to guidance material issued by the U.S. Department of Justice, ***"One hallmark of an effective compliance program is its capacity to improve and evolve."***
- Of the more than $2.2 billion in settlements and judgments recovered by the DOJ in 2020, **over $1.8 billion relates to matters that involved the healthcare industry**
- **The DOJ recovered more that $5.6 billion in 2021**, providing the 2nd highest False Claims Act (FCA) collection year in history
  - Healthcare cases accounted for over 80% of the total recoveries for FCA enforcement
  - This number is up significantly from the $2.2 billion recovered in 2020 (notably, a significant amount of the $5.6 billion was obtained from a settlement with a Pharmaceutical Company)

"Kickbacks in the healthcare industry are pernicious because of their potential to subvert medical decision-making and to increase healthcare costs. **In addition to pursuing improper payments by drug manufacturers, the department resolved other schemes involving the willful solicitation or payment of illegal remuneration to induce the purchase of a good or service paid for by a federal health care program**."

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The Return of DOJ Monitorships

"In recent years, some have suggested that monitors would be the exception and not the rule. To the extent that prior Justice Department guidance suggested that monitorships are disfavored or are the exception, I am rescinding that guidance. Instead, I am making clear that the department is free to require the imposition of independent monitors whenever it is appropriate to do so in order to satisfy our prosecutors that a company is living up to its compliance and disclosure obligations under the DPA or NPA."

- Deputy Attorney General Lisa Monaco (October 28, 2021)

"We prefer not to hear a 'check-the-box' presentation from outside counsel. We like to see the Chief Compliance Officer leading the compliance presentation and demonstrating knowledge and ownership of the compliance program. Not for show, but because we want to empower these teams. Other senior management should also participate, taking ownership of their role in the compliance program and demonstrating commitment to compliance. Based on what we learn about the company's compliance program, we determine whether an independent compliance monitor should be imposed. We believe that monitorships are effective tools for strengthening corporate compliance programs in companies where there were compliance weaknesses that resulted in criminal conduct. Monitors can be allies to compliance officers in making recommendations that create lasting, sustainable change in corporate culture."

- Assistant Attorney General Kenneth A. Polite Jr. (March 25, 2022)

The Return of DOJ Monitorships (cont.)

Recently, Assistant Attorney General Kenneth A. Polite Jr. stated that the DOJ is considering:

- Requiring both the Chief Executive Officer (CEO) **and the Chief Compliance Officer (CCO)** to certify at the end of the term of the agreement that the company's compliance program is reasonably designed and implemented to detect and prevent violations of the law (based on the nature of the legal violation that gave rise to the resolution, as relevant), and is functioning effectively.
  - This would mirror the certification made by independent compliance monitors in "hybrid" monitorships (i.e., where a company is required to retain an independent monitor for a specific period followed by a period of self-reporting)
- For companies with self-reporting obligations, requiring the CEO **and CCO** to certify that all compliance reports submitted during the term of the resolution are true, accurate, and complete.
  - CEOs and CCOs may find it necessary to seek assurances, such as formalized KPIs and additional internal testing, prior to self-certification. **Though not specified by Polite, it is possible this could be subject to the penalty of perjury, providing potential personal liability for CEOs and CCOs**

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KEYS TO SUCCESS / COMPLIANCE CONSIDERATIONS

CIAs – Keys to Success

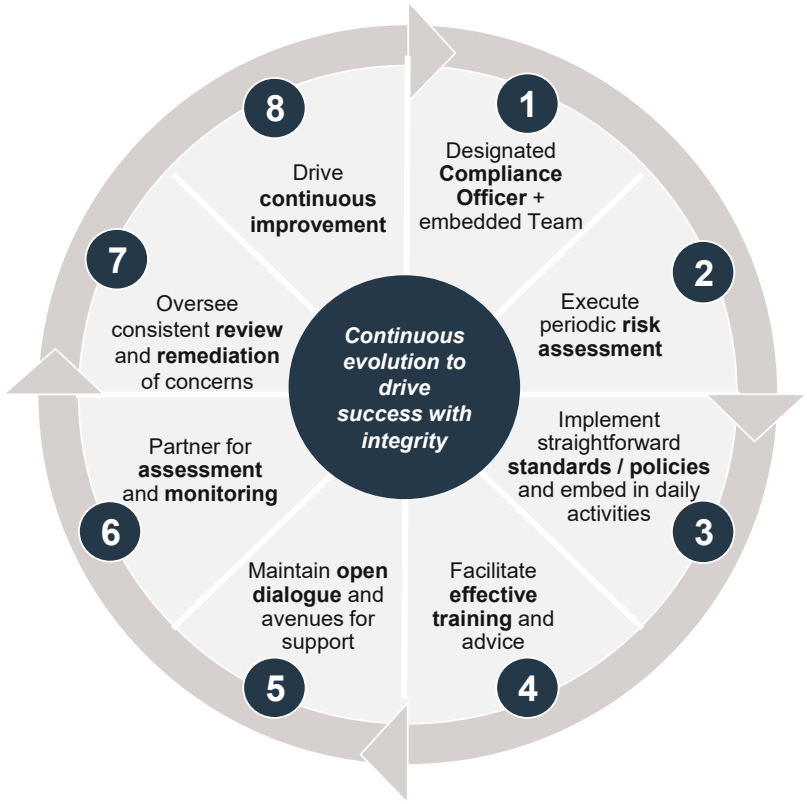
Start Early

Business leader commitment and ownership

Build Trust

Don't Have one in the First Place

Implement & sustain an effective compliance program



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Q&A

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Thank You!!!