

Presenter Biographies



Dhara Satija

Healthcare Consulting Leader
Paul Hastings, LLP

(978) 604-9939

dharasatija@paulhastings.com

Dhara Satija is director in the Paul Hastings Life Sciences Consulting Group where she leads the group's healthcare consulting practice. She 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, Ms. Satija 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; compliance and revenue cycle due diligence; support for provider self-disclosures/voluntary refunds; government-initiated audits; litigation support services; and Corporate Integrity Agreement (CIA) requirements.





Patti Ariel
Interim Chief Compliance Officer, WMC
Health Network

(914) 493-8461 patti.ariel@wmchealth.org

Prior to her retirement in 2021, Patricia (Patti) was the Senior Vice President, Chief Compliance Officer, Internal Audit & Corporate Compliance at Westchester Medical Center Health Network. Patti has recently joined WMC Health Network as the interim Chief Compliance Officer. With over 25+ years of experience in the healthcare industry in various financial and senior management roles, Patti joined Westchester Medical Center in 2007 when it was a 3 hospital system. Westchester Medical Center is now a network with 10 member hospitals that include a Children's hospital, psychiatric hospital as well as Skilled Nursing Facilities & Home Health Care. Her responsibilities cover the network Compliance Program. She also serves as the HIPAA Privacy Officer. She served as a Vice President of Billing & Collections for a National Home Health Care Company and as a Corporate Compliance & Internal Audit Officer for a National Specialty Pharmacy & Wound Care Company. Prior to coming to Westchester Medical Center, she served as the Chief Compliance Officer at Northwell Health, formally known as North Shore Long Island Jewish Health System.

Over the last 20+ years, Patti's role in compliance has encompassed all aspects of healthcare regulations, including her participation in Federal and State settlement discussions and oversight of corporate integrity agreements. She currently reports to the CEO and Board. She has a BAA in finance and taught as an adjunct professor at Long Island University in New York. She is certified in healthcare compliance (CHC), is a member of Health Care Compliance Association (HCCA) and Society of Corporate Compliance & Ethics (SCCE). She is currently a member of the Board of New England Healthcare Internal Auditors (NEHIA) and previously served as President for 3 years.



Today's Objectives:

During this presentation, we will cover:

- 1. Overview of regulatory and enforcement trends impacting healthcare due diligence activities
- 2. Imperative for enhanced compliance oversight of post-acquisition integration activities
- 3. Best practices and practical considerations for managing compliance risks and program requirements in acquisitions
- 4. How to prepare, how to respond, and what possible outcomes to expect in managing compliance investigations post-acquisition integration

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Polling Question #1 Have you ever been involved in an integration?

Polling Question #2 If yes, were you involved in any aspect of the due diligence integration processes?

Polling Question #3 If yes, do you feel that the organization conducted the appropriate amount of due diligence?

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OVERVIEW OF REGULATORY LANDSCAPE AND ENFORCEMENT TRENDS IMPACTING HEALTHCARE TRANSACTIONS



Key laws and regulations

Anti-Kickback Statute (AKS)

False Claims Act (FCA)

Stark Law

Health Insurance
Portability &
Accountability Act
(HIPAA)

Health Information
Technology for Economic
and Clinical Health
(HITECH)

Medicare and Medicaid

State and Local Laws (e.g., false claims, privacy)

Civil Monetary Penalties Law **Exclusion Provisions**



Established hallmarks of an effective compliance program

The OIG and DOJ provide particular detail on their expectations – OIG's "seven elements" and DOJ's "hallmarks" establish the program elements that must be tailored to a company's risk profile to establish an effective compliance program





Is the program well designed?

"[A] critical factor[] in evaluating any program [is] whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees" Evaluation Guidance at 2.

Design

"Is the corporation's compliance program well designed?"

2. Implementation

"Is the program being applied earnestly and in good faith?"

Practical Effectiveness

"Does the corporation's compliance program work in practice?"

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March 2023 DOJ ECCP guidance for Mergers and Acquisitions

Ensuring risk-based diligence and integration / oversight of strategic transactions – whether M&A, joint ventures, or investments – serves to mitigate risk and ensure a company's acquisitions, partnerships, and investments are aligned to the company's ethical standards.





Mergers & Acquisitions, Joint Ventures & Strategic Investments

"The extent to which a company subjects its acquisition targets to appropriate scrutiny is indicative of whether its compliance program is, as implemented, able to effectively enforce its internal controls and remediate misconduct at all levels of the organization"



Due Diligence Process – Was the company able to complete pre-acquisition due diligence and, if not, why not? Was the misconduct or the risk of misconduct identified during due diligence? Who conducted the risk review for the acquired/merged entities and how was it done? What is the M&A due diligence process generally?



Integration in the M&A Process – How has the compliance function been integrated into the merger, acquisition, and integration process?



Process Connecting Due Diligence to Implementation – What has been the company's process for tracking and remediating misconduct or misconduct risks identified during the due diligence process? What has been the company's process for implementing compliance policies and procedures, and conducting postacquisition audits, at newly acquired entities?

2023 DOJ updated guidance



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- On January 17, 2023, Assistant Attorney General Kenneth A. Polite, Jr. ("AAG Polite") announced **several key revisions** to the Department of Justice ("DOJ") **Criminal Division's Corporate Enforcement Policy** (the "CEP") governing what credit a corporation can receive with respect to **voluntary self-disclosures**, **cooperation**, and **remediation**.
- During speeches on March 2 and 3, 2023, at the American Bar Association (ABA) National Institute on White Collar Crime (the 2023 White Collar Conference), Deputy Attorney General (DAG) Lisa Monaco, Assistant Attorney General (AAG) for the Criminal Division Kenneth A. Polite, Jr. and other US government officials announced significant changes to the US Department of Justice's (DOJ) Evaluation of Corporate Compliance Programs (ECCP) and continued to emphasize the importance of effective and robust compliance policies.
- The 2023 Evaluation Guidance's most significant changes are in the section titled "Compensation Structures and Consequence Management," which underscores that corporations should develop and maintain a positive compliance culture by establishing incentives for compliance and disincentives for compliance failures.

October 2023 DOJ updated Safe Harbor guidance for Mergers and Acquisitions









- On October 4, 2023, Deputy Attorney General Lisa Monaco (the "DAG") announced a new Mergers & Acquisitions ("M&A") Safe Harbor Policy issued by the Department of Justice ("DOJ") as part of her comments detailing increased enforcement efforts of national security related corporate crime and DOJ's efforts to incentivize stronger compliance efforts. In particular, DOJ will provide safe harbor for acquiring companies that discover and disclose criminal conduct during the M&A process in order to promote increased voluntary self-disclosures.
- Specifically, in the context of M&A activities, companies must (1) "disclose misconduct discovered at the acquired entity [to DOJ] within six months from the date of closing" and (2) "fully remediate the misconduct" within one year from the date of closing to qualify for the Safe Harbor.
- DAG made clear that DOJ does not want to discourage acquisitions,
 especially if a company with an exemplary compliance program is acquiring a
 target with a troubled past. Under the new Safe Harbor Policy, acquiring
 companies will receive a presumption of a declination.

"Compliance should no longer be viewed as just a cost center for companies.

Good corporate governance and effective compliance programs can shield companies from enormous financial risks and penalties." - DAG

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INDUSTRY TRENDS



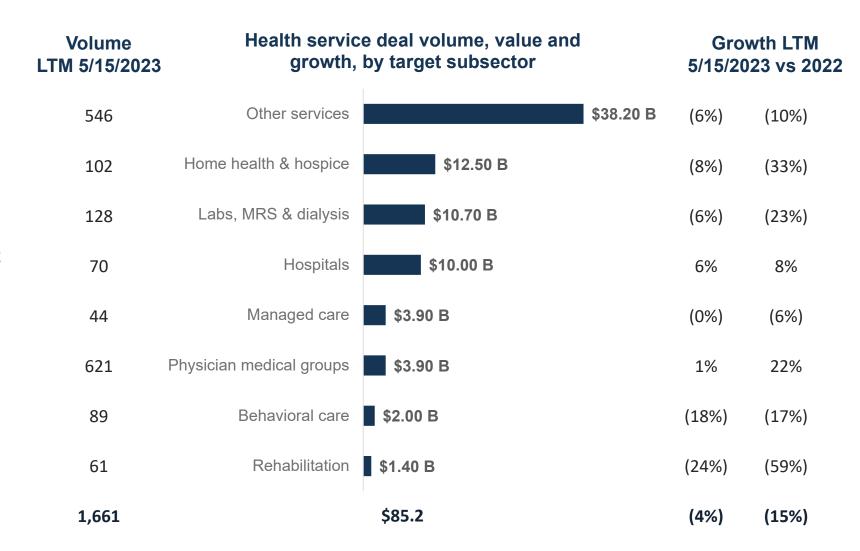
Regulatory and industry perspectives

"... healthcare has generally been seen as a "safe bet" from an investment perspective. More investors, such as private equity, have jumped in. The presence of private equity in the industry is increasing, with more than \$1 trillion dollars in 8,000 deals over the past decade. Private equity investment in nursing homes and other sectors is prompting tough questions about its impact on the quality of care that is provided, as well as the potential for profit considerations to take priority over patient care. Even traditional health systems are moving to invest in new areas of the industry, such as health plans."

Christi A. Grimm, Inspector General
 Keynote Speech
 HCCA Compliance Institute in Anaheim, CA

Mid-2023 healthcare deal outlook

Despite facing various challenges, healthcare service deal **volumes** have shown **resilience** through May 2023. However, deal **values** experienced a more significant **decline**.

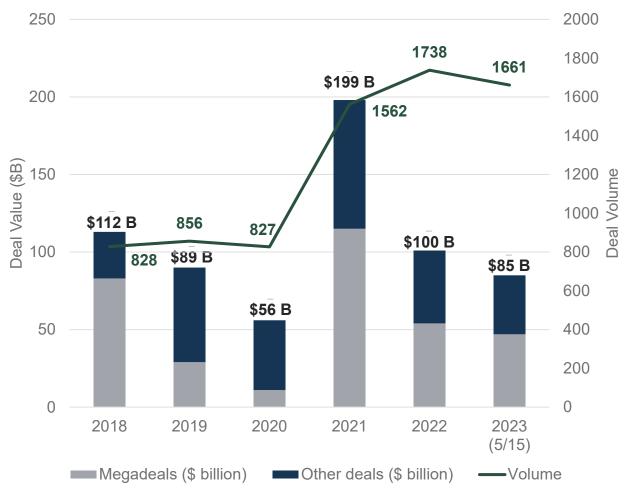


Mid-2023 healthcare deal outlook (cont.)

Health service deal **volumes** remain at nearly **twice the level** seen from 2018 to 2020. The **decline** in deal **values** is a continuation of the trend seen in 2022.

Megadeals, defined as deals valued at \$5 billion or greater, encompassed **over 50%** of the announced deal **value** in the 12 months ending May 15, 2023.

Health service deal value and volume 2018 – LTM 5/15/2023



Data from PwC, Health services: US Deals 2023 midyear outlook, https://www.pwc.com/us/en/industries/health-industries/library/health-services-deals-outlook.html

Key industry trends of HC transactions and deals in 2022 and 2023

- More than 8,000 private equity deals worth more than \$1 trillion in the past decade¹
- 450 private equity firms engaged in buyouts and acquisitions in 2022²
- Healthcare was the **2nd leading sector** for private equity investments (18%) in 2020³
- 16 states have enacted or proposed legislation to provide regulatory oversight of healthcare-related transactions⁴
- In 2021 the top five most active healthcare sectors were: life sciences, healthcare IT, physician practices, medical device, and cannabis⁵
- More than half of the total 2022 deal value stemmed from 6 megadeals, notably purchases accounting for \$26.6B⁶

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HEALTHCARE COMPLIANCE DUE DILIGENCE BASICS



A typical M&A deal structure involves the following steps:

Identify M&A opportunity and engage with potential investors

Comprehensive review, presentation, and due diligence

Valuation and purchase agreement

Confirm deal structure, financing and other related matters

Close the deal and initiate post-M&A integration activities



Benefits of due diligence

Due diligence is a vital process in M&A that helps ensure the success of the transaction. It allows potential buyers to thoroughly assess and evaluate the risks and opportunities associated with a particular business or investment. There are several key steps and questions that should be answered to effectively execute due diligence.



Define & understand company's risk profile



Discover potential areas of concern / relevant violations



Inform valuations and related negotiations



Coordinate and plan post-close integration



Reduce potential damage to brand and reputation

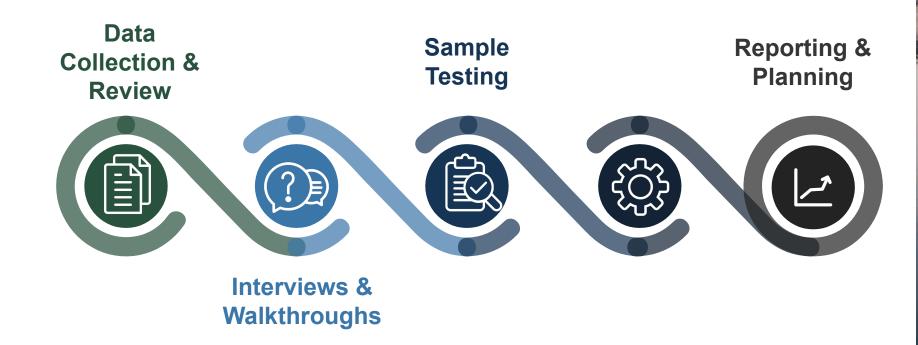


Reduce exposure to business disruption and monetary penalties



Due diligence approach

It is important to define and implement a systematic approach early in the process with the right stakeholders' commitment to achieving meaningful results and building trust within the business.





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INTEGRATION FUNDAMENTALS



Integration Fundamentals

It is important to have a structured approach to aligning different entities during and after a merger or acquisition. Incorporating the following fundamentals can help ensure a smooth integration process, maximize cooperation, and minimize disruptions.

Understanding the requirements, if same, determine how to integrate and evaluate what to streamline Establish a clear governance structure that ensures accountability Prioritize integration activities and develop integration plan **Ensure cultural alignment** Communicate early and often to alleviate concerns that may impact morale Track and monitor progress and potential risks/issues



Illustrative Integration plan

The following plan outlines the necessary actions to take prior, during, and post integration to facilitate a seamless transition and attain desired strategic goals in a timely manner.

Day 1

 Communicate strategic vision and integration timeline

Pre-day One

- Leverage learnings of due diligence to inform integration plan and priorities
- Develop strategic vision and integration timeline

Integration Phase 1, 2, etc.

- Execute in a prioritized order
- Change management
- Track to strategic vision and priorities

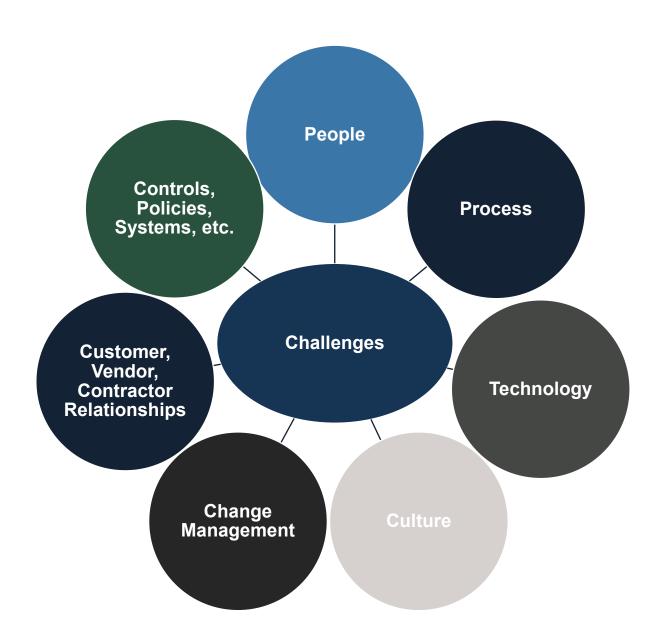


Integration Challenges and Compliance

Role of Compliance:

- Provide guidance on the interplay between risk / standards and business strategy / need
- Provide input on business and company initiatives
- Provide information to Management and the Board to enable them to carry out their duties
- Conduct monitoring, auditing, investigations and risk assessments that could help identify areas for enhancements or efficiency





Key considerations for integration

An effective integration requires the implementation and use of traditional project management activities to ensure successful implementation and integration of compliance activities across the organization.

Leading practices

- ✓ Develop robust project plan and update throughout the project
- ✓ Implement defined communication cadence to ensure prompt attention to issues and risks
- ✓ Define and implement change management needs
- Clear goals and objectives outlined to orient all stakeholders
- ✓ Understand scope of activities and dependencies with respect to needed subject matter experts; ensure needed resources are available per project plan expectations

Common pitfalls

- Unrealistic project plan, level of effort, and timeline
- Not involving the appropriate resources
- Not defining accountable parties / decision makers
- Not documenting risks and issues
- Waiting too long to pivot

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Q&A



