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NEHIA/HFMA
2023 Compliance & Internal Audit Conference

Wednesday, November 29 - Friday, December 1, 2023
Mystic Marriott Hotel, Groton, CT

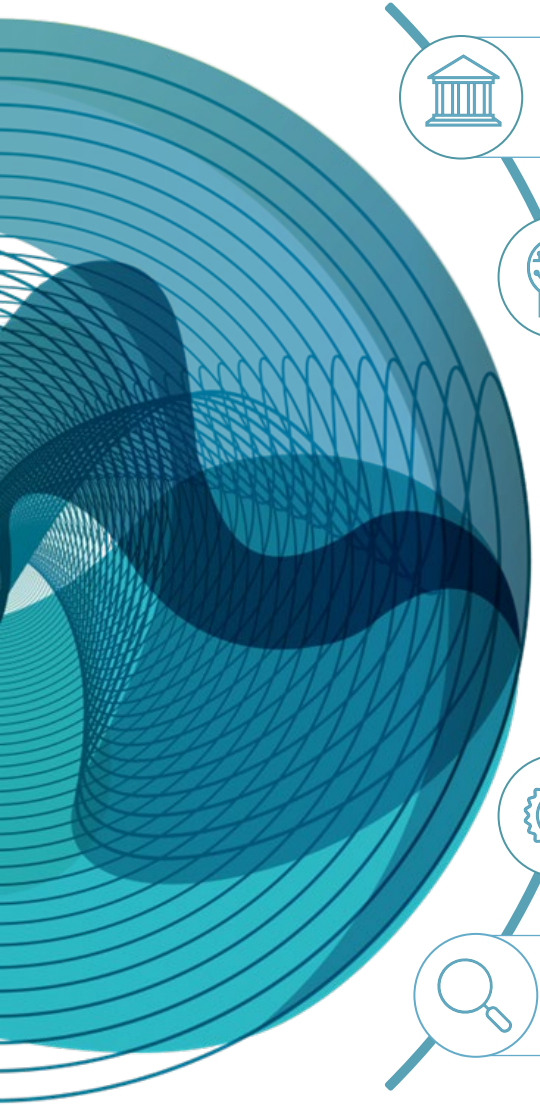
Deloitte.

HFMA and NEHIA 2023 Annual Conference

November 30, 2023

Presenters: Kelly Sauders & Heather Hagan

Discussion topics



- The current regulatory environment
- Artificial intelligence regulatory and risk considerations
- Privacy and tracking technologies
- Intersection of compliance and health equity
- Enforcement perspectives
- Compliance program effectiveness – KPIs

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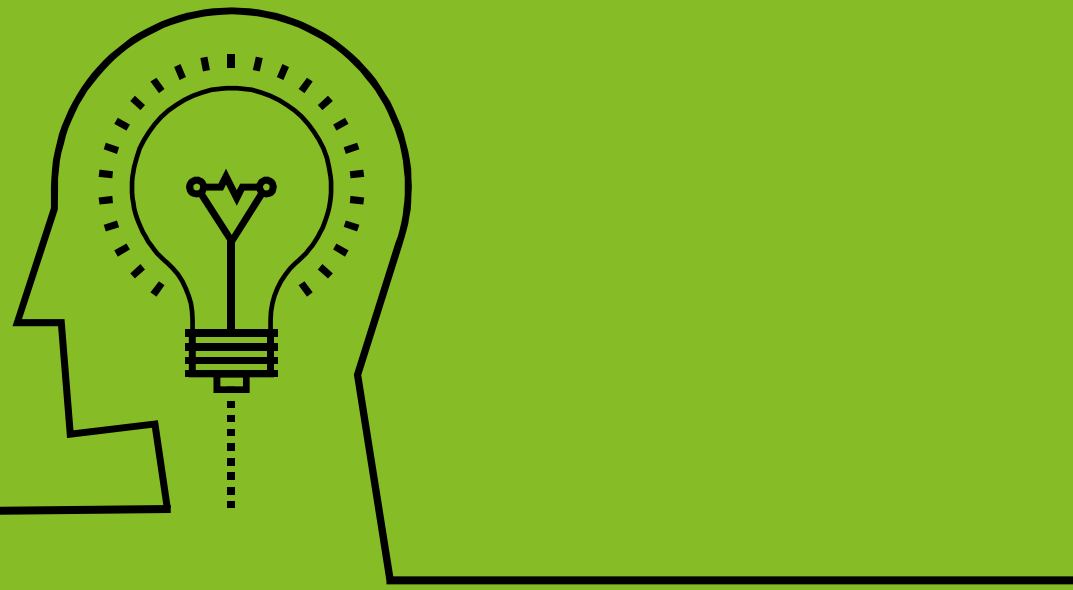
The current regulatory environment



Health care regulatory and enforcement priorities in 2023

Health care continues to be at the forefront of the Federal regulatory and legislative agenda, with activity only expected to increase. Current regulatory and legislative activity governing health care in the United States center around the following major themes.

ARTIFICIAL INTELLIGENCE (AI)

The Federal Government has signaled its intent to develop policy to regulate artificial intelligence. In Congress, lawmakers are exploring potential pathways via hearings and educational sessions. While regulators, such as Federal Trade Commission (FTC) and The Department of Health and Human Services (HHS) have begun to take action within existing authority.

SITE NEUTRAL PAYMENTS

Policymakers recently proposed bipartisan site-neutral payment legislation, meaning the payment for a service provided to a patient is the same regardless of the setting where the service is provided. Proposed provisions would implement site-neutral payments for drug administration services starting in 2025.

MEDICAID REDETERMINATIONS

The Consolidated Appropriations Act of 2023 (CAA) authorized states to begin redeterminations for Medicaid enrollees who gained eligibility due to the PHE in April 2023 with many states experiencing challenges. Millions are losing coverage and lawsuits have been filed. In August 2023, Center for Medicare and Medicaid Services (CMS) sent letters to state health officials in 50 states and D.C., warning that many are failing to meet federal requirements about determining Medicaid coverage.

COVID-19 FRAUD ENFORCEMENT ACTION

Various agencies, such as the Health Resources and Services Administration (HRSA) and the Justice Department, have begun assessing and penalizing individuals and organizations for fraud orchestrated during the COVID-19 pandemic through the Provider Relief Fund and other health care-focused relief efforts.

340B

The 340B program continues to operate without clear rules due to the lack of statutory authority for the oversight agency. Legal challenges to the program operation will likely persist due to that lack of statutory authority.

TRANSPARENCY AND TAX EXEMPTION

There has been increasing activity to advance transparency on prices and business practices for health care providers. Specifically, the No Surprises Act (NSA), which become rule in 2022, prohibits clinicians, hospitals, and other covered providers from billing patients more than in-network cost sharing amount for surprise medical bills. Bernie Sanders, who chairs the Senate Health, Education, Labor and Pensions (HELP) Committee, issued a report recently scrutinizing how tax-exempt hospitals follow through on their obligation to provide charitable care.

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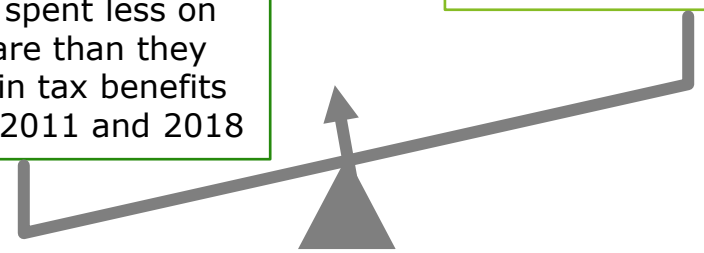
Nonprofit hospitals exploiting tax breaks over medical care

A new report released by Sen. Bernie Sanders (I-Vt.) shows that many nonprofit hospital systems across the country are failing to provide low-income Americans with the affordable medical care required by their nonprofit status – despite receiving billions in tax benefits and providing exorbitant compensation packages to their senior executives

- Most recent data from 2021 shows that 16 of the hospital chains CEOs averaged more than $8 million in compensation and collectively made over $140 million
- Another study found 86% of nonprofit hospitals spent less on charity care than they received in tax benefits between 2011 and 2018

- 12 of the 16 hospitals dedicate less than two percent of their total revenue to charity care, including 3 of the nation's 5 largest nonprofit hospital chains
- Of the 12, 6 dedicated less than 1% of their total revenue to charity care



- In 2020, 2,978 nonprofit hospitals received an estimated $28 billion in federal, state, and local tax benefits – an average of $9.4 million per hospital. Federal law requires nonprofit hospitals to operate for the public benefit, which includes charity care
- The report examines 16 of the largest nonprofit hospital systems in the U.S. each making more than $3 billion in revenue annually
- The report also shows that in recent years, the amount of charity care provided by nonprofit hospitals has declined, even when patient need, revenue, and operating profits have all increased
- Some states have already taken steps to hold nonprofit hospital systems accountable.
  - **Texas** includes a requirement that at least 5% of the hospitals' net revenues must go to community benefits, including at least four percent dedicated to free or reduced cost care
  - **Oregon** state law requires hospitals to provide reduced cost care to anyone whose income is under 400% of the federal poverty line and free care to anyone making under 200% of the poverty line. In 2023, that means individuals making less than $60,000 would not be forced to pay for the full cost of their care, while those making under $30,000 would pay nothing

Source: NEWS: Chairman Sanders Releases New Report Showing Major Nonprofit Hospital Systems Exploiting Tax Breaks and Prioritizing CEO Pay Over Helping Patients Afford Medical Care » Senator Bernie Sanders (senate.gov)

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Health Care Policy in 2023

Health care continues to be at the forefront of the Federal regulatory and legislative agenda, with activity only expected to increase. Current regulatory and legislative activity governing health care in the United States center around the following major themes.

Coverage

COVID-19 Public Health Emergency (PHE): The PHE expired May 2023; policymakers have continued to explore making certain practices increased during the pandemic permanent (e.g., telehealth in Medicare)

Medicaid Redeterminations: The CAA authorized states to begin redeterminations for Medicaid enrollees who gained eligibility due to the PHE in April 2023 with many states experience challenges. Millions are losing coverage and lawsuits have been filed.

Medicare Advantage Scrutiny: Medicare Advantage organizations have experienced increased government scrutiny, especially for marketing and utilization management practices, and several organizations saw a decrease in their Stars Ratings

Legislative Actions: *The Inflation Reduction Act of 2022* extended premium tax credits for many marketplace beneficiaries through 2025 and introduced reforms for Medicare Part D benefit design

Health Information Technology

CMS' Regulatory Action on Health IT: On December 13, 2022, CMS published the *Advancing Interoperability and Improving Prior Authorization Proposed Rule* to impose new data exchange requirements on payers and providers; The key provisions of this proposed rule include payer-to-payer data exchange, payer-built application programming interfaces (API) for providers and patients, and electronic prior authorization

Information Blocking: The Office of the Inspector General finalized its rulemaking for health IT developers or health information exchanges/networks that information block may be subject to a $1 million civil monetary penalty/violation. Proposed penalties for providers will be published before the end of 2023.

Expected Regulatory Actions: From 2023-2024, regulators are expected to go-live with the Trusted Exchange Framework and Common Agreement and issue rulemaking on algorithm transparency and electronic prior authorization.

Transparency

Price Transparency: Payers and hospitals have been required to publicly post data reflecting their standard charges with regular updates. Compliance has varied across the health care landscape; however, CMS imposed seven penalties for hospital noncompliance.

No Surprises Act (NSA): Requirements around out-of-network billing, independent dispute resolution, and Good Faith Estimates for self-pay patients are already in effect; further rulemaking to implement outstanding NSA provisions (e.g., Advanced Explanation of Benefits and Good Faith Estimates for co-providers/co-facilities) is expected in 2023.

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Health Care Policy in 2023

Continued…

Prescription drug pricing

Inflation Reduction Act of 2022 (IRA): For the first time in the history of the Medicare drug program, CMS is required to negotiate directly with pharmaceutical manufacturers to control the rising prices of certain high-cost drugs in Medicare Parts B and D. The list of 10 Part B drugs selected for negotiation in advance of PY 2026 will be released by September 1, 2023.

- Several drug manufacturers have filed lawsuits against the legislation and guidance regarding Medicare drug negotiations.
- The law's inflationary provisions on Parts B and D drugs will also "cap" drug price annual growth rates benchmarked against the Consumer Price Index for All Urban Consumers (CPI-U)
- The combined effects of drug pricing provisions is expected to affect health care stakeholders across the market

Congressional Action on Pharmacy Benefit Managers (PBM): Congress is advancing bipartisan legislation that would place stricter requirements on PBM business practices such as pricing strategies, affiliate networks, and drug formularies.

Health care's macroeconomic factors

Health care expenditures: Health care costs are projected to outpace Gross Domestic Product (GDP) growth. From 2022 to 2031, national health spending is projected to grow at an average annual rate of 5.4%, reaching $7.2 trillion by 2031.

Labor market: Health care organizations are facing unprecedented labor shortages and wage pressures, leading to significant financial implications

Federal deficit: These conditions have contributed to large Federal deficit and rising debt, which Congress is expected to take action to address in 2023. Congressional action will likely include changes to health care spending

Reimbursement trends

Hospital and physician reimbursement: The annual publication of the Medicare Prospective Payment Systems for inpatient and outpatient care did not keep up with the rate of inflation

Telehealth: CMS has made some of the telehealth flexibilities introduced during the PHE permanent (e.g., prolonged evaluation and management and chronic pain management), while the CAA extended the remaining flexibilities to end December 31, 2024

Center for Medicare and Medicaid Innovation (CMMI): CMMI continues to advance against its strategy refresh including the introduction of a new ten-year primary care model to help providers build capabilities to participate in value-based care and announced its intent to develop three new models aimed at lower prescription drug costs

Provider Relief Fund (PRF): Congress is not expected to issue new Federal COVID-19 funding; however, the Federal government has begun to audit compliance of provider recipients

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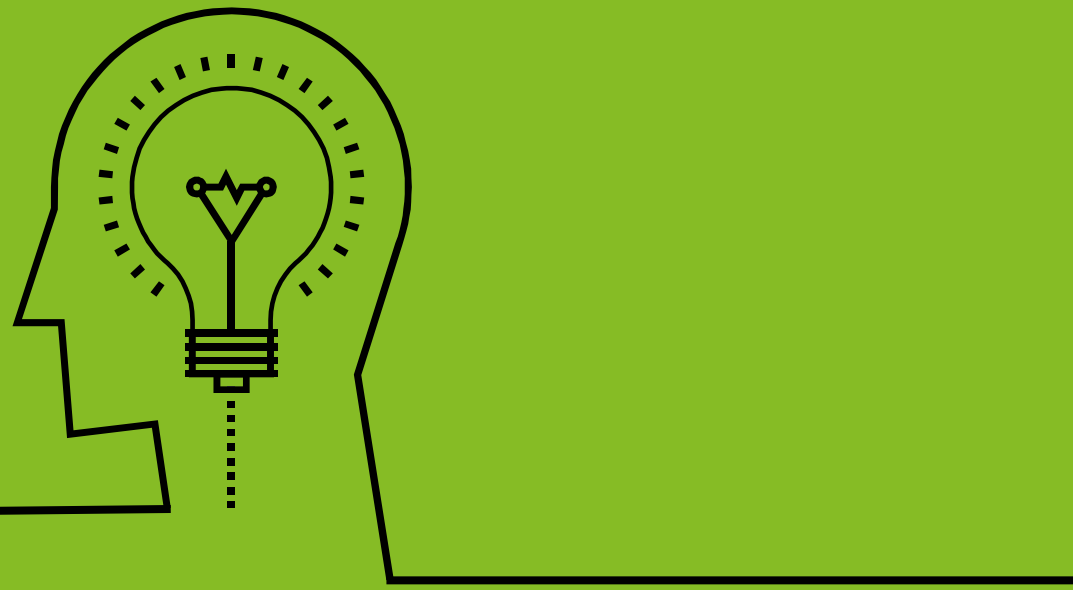
Artificial intelligence regulatory and risk considerations



Policy activity to regulate artificial intelligence is complemented by other emerging data policies governing collection, use, exchange, and security of data

ARTIFICIAL INTELLIGENCE

Policy activity has centered around protecting national security, while promoting ethical and transparent use of artificial intelligence

FEDERAL AND STATE PRIVACY PROTECTIONS

Policy activity has centered around modernizing existing privacy laws to align with current technology and putting stronger consumer protections in place

CYBERSECURITY

Policy activity has centered around improving the health care industry's cybersecurity infrastructure and setting standards following a cyberattack

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What is the pulse on AI in Washington?

The FTC has begun questioning AI companies about how they collect, source, and retain data, as well as how they train the algorithm and evaluate the accuracy of its outputs. There are also a growing number of civil class action lawsuits against AI companies for their use of algorithm.

Senator warns large technology company of AI use in hospitals

Sen. Mark Warner (D-Va.) sent a letter to leaders at a large technology, **warning the company over its testing of artificial intelligence (AI)** in hospitals.

Senator Warner inquired about consent, use of protected health information and human oversight.

The Senate's hottest hearing: AI policy

Amid a flurry of recent hearings and announcements, **Congress appears keen to pass legislation to rein in AI.** Since 2018, Congress has racked up an impressive bipartisan record of introducing AI legislation. However, Congress is not likely to pass legislation soon, and the challenge is that the technology and the industry are both moving rapidly.

Sources:

- https://thehill.com/policy/healthcare/4143447-senator-warns-google-over-ai-use-in-hospitals/
- https://thehill.com/opinion/technology/4125216-congress-must-get-ahead-on-ai-legislation-before-its-too-late/#:~:text=The%20challenge%20is%20that%20while%20technological%20change%20is,that%20maximize%20its%20benefits%20and%20reduce%20its%20harms.
- https://www.judiciary.senate.gov/committee-activity/hearings/oversight-of-ai-principles-for-regulation

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Current federal enforcement activities

The FTC has asserted its enforcement against AI tools that may be inaccurate, biased, or discriminatory by design under its current authorities (Section 5 of the FTC Act).

FTC SIGNALED EXPANDED ENFORCEMENT AREAS

FTC has not issued formal rulemaking on AI enforcement but has provided blog posts signaling their focus for potential future enforcement actions

February 2023 FTC Blog: AI advertising

Questions FTC poses to organizations using AI:

- *Are you exaggerating what your AI product can do?*
- *Are you promising that your AI product does something better than a non-AI product?*
- *Are you aware of the risks?*
- *Does the product actually use AI at all?*

July 2023 FTC Blog: Health privacy

Considerations that FTC provided on health information privacy:

- *The obligation to protect the privacy of health information is a given.*
- *Don't use behind-the-scenes tracking technologies that contradict privacy promises or otherwise harm consumers.*
- *Don't share consumers' health information improperly – and don't receive it either.*
- *An organization may be liable under the FTC Act for what they say and for what they don't say.*

Takeaways

- Under Chair Khan, the FTC has taken an active role on health care privacy and AI in 2023.
- The FTC has the dual purpose of promoting fair competition and preventing unfair or deceptive practices across all industries including health care.
- The common thread among the recent blogs is that the FTC expects companies to be truthful in their advertising and communications.
- If a company fails to meet its promises, then the FTC will be ready to enforce under unfair or deceptive practices.

Sources:

- https://www.ftc.gov/business-guidance/blog/2023/02/keep-your-ai-claims-check
- https://www.ftc.gov/business-guidance/blog/2023/07/protecting-privacy-health-information-bakers-dozen-takeaways-ftc-cases

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Regulators have begun to advance AI policy across various domains

Based on President Biden's executive orders, Executive Branch agencies have been compelled to act on AI.

HHS released AI strategy in 2021 and multiple agencies have made advancements on AI, including:

ACTIVE POLICY:

- **MEDICAL DEVICE SAFETY:** ***Food and Drug Administration*** has outlined approval guidelines for medical devices and algorithms
- **PRIVACY:** ***Office of Civil Rights*** is focused on HIPAA in the context of online tracking technologies

PROPOSED/EXPLORATORY POLICY:

- **ALGORITHM TRANSPARENCY:** ***Office of the National Coordinator for Health Information Technology*** proposes to require algorithm transparency for predictive decision support Interventions (e.g., clinical decision support)
- **HEALTH EQUITY:** ***Centers for Medicare and Medicaid Services*** is exploring how AI can be used to advance health equity, expand coverage, and improve health outcomes

Sources:
1. https://www.hhs.gov/about/agencies/asa/ocio/ai/strategy/index.html
2. https://www.hhs.gov/sites/default/files/hhs-artificial-intelligence-select-use-cases.pdf
3. https://www.ftc.gov/industry/technology/artificial-intelligence
4. https://www.ntia.gov/press-release/2023/ntia-seeks-public-input-boost-ai-accountability

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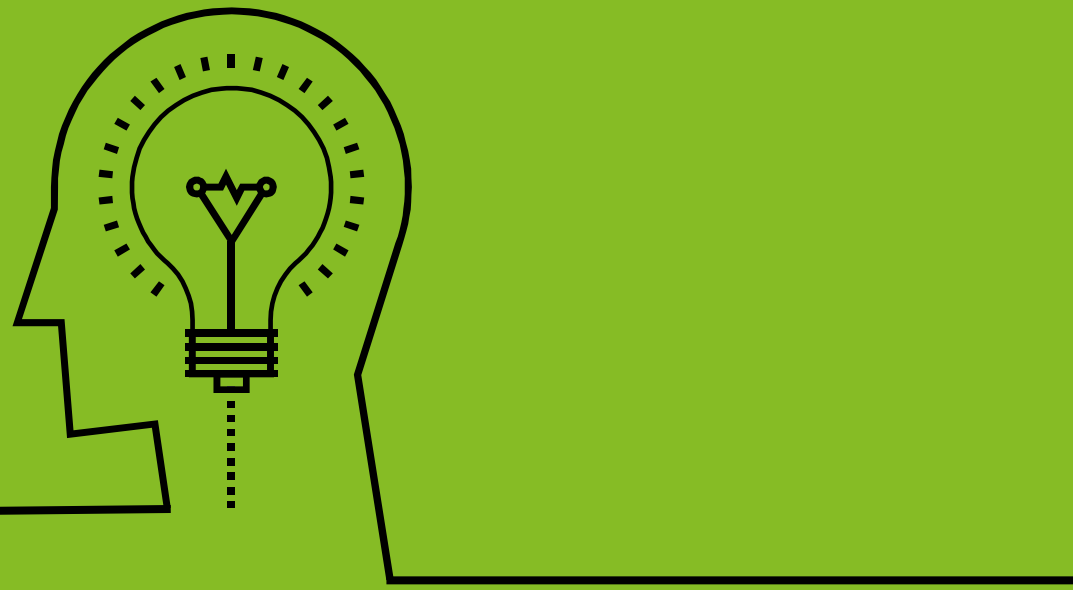
Privacy and tracking technologies



The cookie landscape has changed significantly in recent years

A series of inter-related changes across the cookie landscape has quickly encouraged organizations to solve for the future of cookies.

Technology changes

Leading **browsers are eradicating third-party cookies** and enabling Global Privacy Control (GPC), which ties directly into how cookies operate on websites and apps

- Increased pressure for tech vendors to sign BAAs with Covered Entities
- Third party cookies may need to be sunset, requiring organizations to inventory cookies/pixels and evaluate downstream impacts

Up to $10 billion in US publisher revenue is at risk because of depleting third-party data[1]

First party data

In the wake of depleting third-party data, organizations are **increasing their first- party data collection**

- Required information that historically was collected by third party cookies needs to be collected via new first party cookies

65% of respondents plan to prioritize first-party data to compensate the phasing out of third-party cookies[2]

Organizational trust

To enhance and sustain trust, organizations are **giving control to visitors** on how they'd like their cookie data processed

- Renewed focus on transparency and opt-in consent for data collection and sharing on specialty / branded / therapy area sites
- Visitors should be able to control their cookie choices on-demand

61% of consumers feel like they've lost control over how their personal information is used – up from 46% in 2019[3]

Regulatory changes

The OCR and FTC* have issued new guidance and numerous enforcement actions **signaling a renewed focus on transparency in data sharing** via cookies and tracking technologies

- Intense focus on knowing what third-party cookies are on an Organization's sites
- Increased reputational and monetary risk to the organization for gaps in cookie management

~130 health care organizations received a joint letter from the FTC and OCR highlighting risks around tracking tech

Potential impacts

*The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the U.S. Federal Trade Commission (FTC)

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The regulatory drivers are even more acute across health care and life sciences…

- In December 2022, the **Office of Civil Rights (OCR) issued new guidance* related to the use of Ad technologies** (e.g., cookies) for HIPAA-covered entities. Based on the guidance, companies may now be required to enter into business associate agreements (BAAs) with third-parties that are sent or otherwise have access to company patient information / Protected Health Information (PHI), including web tracking data.

- In July 2023, the **OCR and the FTC issued a joint letter** that went out to ~130 healthcare organizations stating that "HIPAA regulated entities are not permitted to use tracking technologies in a manner that would result in impermissible disclosures of PHI to third parties or any other violations of the HIPAA Rules."

IMPORTANT NOTES

HIPAA rules apply to tracking on user-authenticated webpages, unauthenticated webpages, and mobile apps.

An organization's online privacy policy, **terms and conditions or website banners** that ask users to accept or reject a website's use of tracking technologies/cookies **do not constitute a valid HIPAA authorization** for disclosure of PHI.

**HHS.GOV | Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates*
https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html
HIPAA: Health Insurance Portability and Accountability Act

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Cookie management considerations

Leveraging cookies or other tracking technologies on web properties requires careful consideration of applicable laws and regulatory guidance, including the December 2022 guidance issued by HHS* and the Joint FTC and OCR Letter sent to ~130 health care organizations in July**.

Considerations / Questions for evaluation

The following applies to websites that collect protected health information (PHI), including IP address, geographic locations, web URLs, or medical device ID

Third-party cookies: Does the site in question have cookies or web tracking technology that is not owned by the organization?

Business Associate Agreement (BAA): If so, does the organization have an appropriate BAA in place with the third party that provides a permissible reason for the transfer of the PHI to the third party? (***Before*** tracking and access of data by the third party begins)

Known users: Is the website authenticated or does it provide a mechanism for users to register or sign in?

Patient sites: Is the log-in to support a patient website, patient portal, or other similar site?

Condition-specific sites: Does site allow users to search for a provider, a specific condition, or symptom (e.g., congenital heart failure, pregnancy)?

Scheduling: Does the site allow users to search for doctors or schedule an appointment?

Cookie use

The permissibility of using cookies and other tracking technologies on websites should be evaluated in the context of these questions. The organization and its business associates should consider OCR's December 2022 guidance* and OCR and FTC Joint Letter** before deploying such technologies.

For more information on whether cookie use is likely to be permissible or not on a given site, we encourage you do discuss with your Legal, Privacy and Compliance teams.

*Official OCR Bulletin: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html
**Official Copy of the Joint Letter: https://www.ftc.gov/business-guidance/blog/2023/07/ftc-hhs-joint-letter-gets-heart-risks-tracking-technologies-pose-personal-health-information

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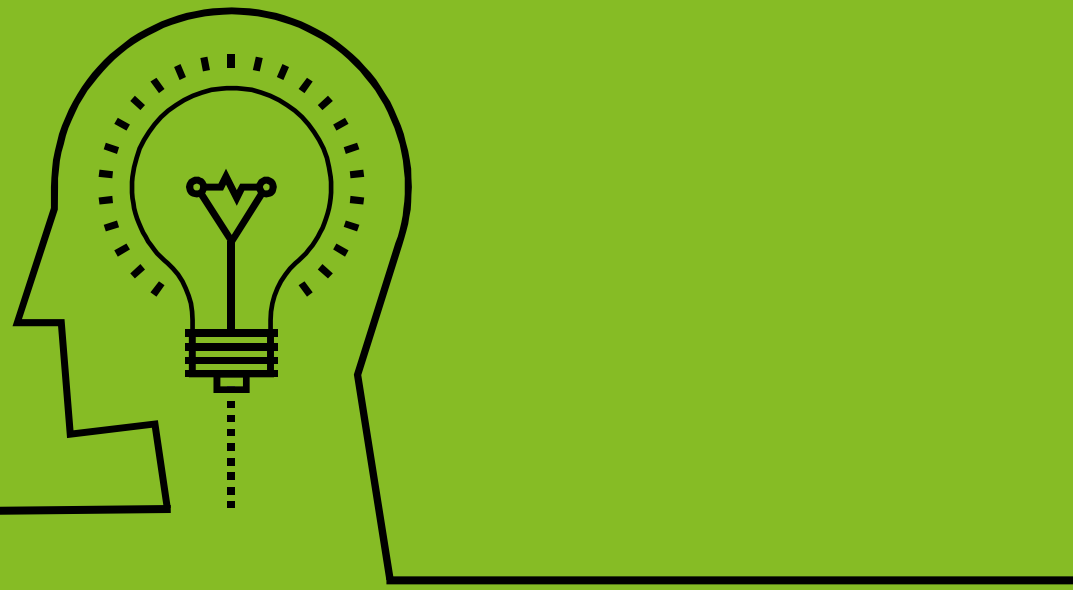
Intersection of compliance and health equity



Health equity is more than equal access to care and there is a pressing need to act today to address existing inequities

It is the **fair and just opportunity** for everyone to fulfill their human potential in many aspects of **health and well-being**

This includes a person's **mental, social, emotional, physical, financial, and spiritual health**

It means **no one is disadvantaged** based on age, gender identity, geography, income, race, social position, veteran status, and beyond

WORSENING LONGEVITY

Since 2014, the United States **average life expectancy has dropped by almost 3 years** and is overall **lower than peer countries**[1]

DISPROPORTIONATE HEALTH OUTCOMES

Black, American Indian, and Alaska Native (AI/AN) women are **2-3x more likely to die from pregnancy-related causes** than White women[2]

UNSUSTAINABLE COST OF HEALTH INEQUITY

Inequities cost approximately **$320 billion in annual health care spending** and could grow to $1 trillion or more by 2040 if unaddressed, signaling a **crisis for the industry**[3]

Sources:

[1]SSM Popul Health (2021); Johns Hopkins Bloomberg School of Public Health (2022)
[2]Centers for Disease Control and Prevention (2019)
[3]Deloitte (2022)

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Regulatory drivers of health equity

Examples[1] of current regulations involving and prioritizing health equity initiatives.

The Joint Commission	HHS	CMS	The White House	Trade Associations
Leadership Standard (LD.04.03.08) Effective January 1, 2023, ***requiring race and ethnicity information*** to be collected by accredited hospitals, health systems and organizations. The standard adds specific requirements to ***prevent discrimination*** within ambulatory and behavioral health settings.	**Section 1557 of the Affordable Care Act ("ACA")** The proposal aims to ***reinterpret and strengthen Section 1557 of the ACA*** by prohibiting discrimination based on race, ethnicity, sex, age, or disability specifically for health programs receiving federal financial assistance.	**Realizing Equity, Access, and Community Health ("REACH")** Payment model introduced by the Biden administration with ***access to enhanced care-coordination services***, telehealth visits, post-discharge home health care services and copayment assistance. ***Establishment of "Birthing-Friendly"*** hospitals to denote hospital's commitment to maternity care quality, safety, and equity (effective fall 2023).	**Advancing Racial Equity and Support for Underserved Communities Executive Order** Establishes the Biden administration's ***priority of health equality as an initiative aimed at advancing racial equity*** across federal policy making, programs, and institutions. **Blueprint for an AI Bill of Rights** Initiating continuous disparity testing in an effort to ***prevent algorithmic discrimination.***	**The American Medical Association ("AMA")** In 2019, the AMA introduced its ***Center for Health Equity*** with a three-year roadmap aimed at ***improving action and accountability*** to advance health equity; lead by their Chief Health Equity Officer.

REGULATORS PUSHING HEALTH EQUITY TO THE FOREFRONT

Source: Health Equity is Becoming a New Regulatory Reality, The Joint Commission, HHS, CMS, CMS, The White House, The White House, Trade Associations

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CMS framework for health equity

CMS's five (5) health equity pillars [1] for reducing disparities in health equity.

Data expansion and standardization

Focuses on standardized individual-level demographic and social determinants of health (SDOH).

Leveraging quality improvement to determine most individuals have access to equitable care and coverage.

Assess causes of disparities and address inequities

Measuring CMS policies' impact on health equity.

Developing sustainable insights to close gaps in health care access, quality and outcomes.

Building capacity of healthcare

Commitment to provide support to health care providers, plans and organizations.

Building capacity to meet the circumstances of the communities served.

Advancing language access and health literacy

Ensuring individuals served by CMS have equitable access to benefits and services including language access and focuses on health literacy.

Increase all forms of accessibility

Responsibility to determine individuals and families can access health care services that is responsive to their needs and preferences.

Seeking direct feedback from individuals with disabilities.

Source: CMS Framework for Health Equity

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Health equity stakeholder collaboration

Leaders across an organization are united by a moral and business imperative to advance health equity.

Chief Executive Officer

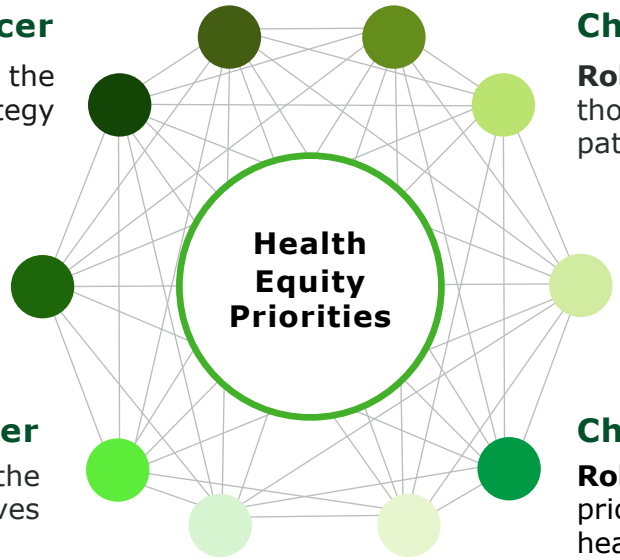
Role to play: Prioritize the organization's health equity agenda and determine the CHEO has the access, authority, and resources necessary to succeed

Chief Diversity, Equity, Inclusion Officer

Role to play: Address health equity circumstances of the organization's workforce and embed health equity priorities into the broader enterprise-wide strategy to focus DEI across workforce, marketplace and society.

Chief Health Equity Officer

Role to play: Embed health equity as a material priority within the organization and stand up an organizational health equity strategy



Chief Medical Officer

Role to play: Lead initiatives to improve health outcomes among those the organization serves and inform at-risk population and patient experience considerations in health equity strategy

Chief Operating Officer

Role to play: Set vendor and supplier diversity and strategy; create and manage contracts; set location strategy and office structure; adopt and enforce health and safety protocols; design and monitor sales strategy and analytics and supplier/vendor analytics

Chief Human Resources Officer

Role to play: Define workforce experience strategy to inform talent strategy and processes; design and deliver on financial, physical, mental, and emotional well-being; monitor pay equity; lead succession strategy and planning

Chief Strategy Officer

Role to play: Integrate the health equity agenda into the organization's shorter, moderate, and longer-term initiatives

Chief Financial Officer

Role to play: Allocate budget to operationalize heath equity priorities and measure and analyze financial return associated with health equity strategies

Chief Technology Officer

Role to play: Advance data-driven health equity efforts across the organization and identify emerging technologies to increase patient access and experience

Chief Compliance Officer

Role to play: Serve as a trusted advisor as the organization navigates their response the equity challenge

A governance model committee structure including senior leaders, nurses at the bedside, patient representatives/patient advocates

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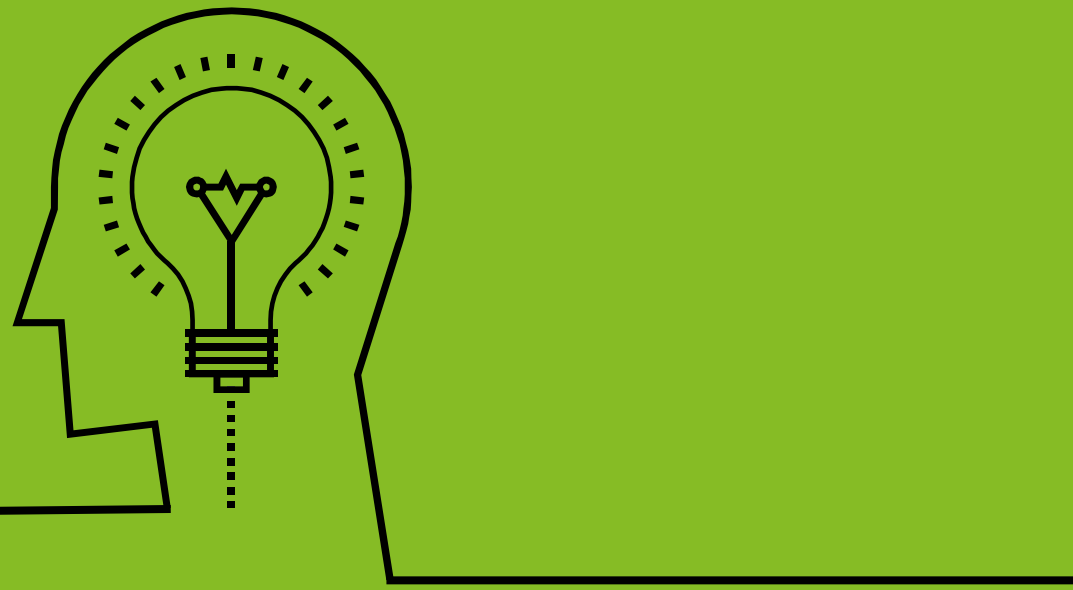
Enforcement perspectives



HHS-OIG's semiannual report: overview

Setting the stage: HHS OIG's Semiannual Report describes OIG's work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations

The table below highlights significant results (across four semiannual periods) of selected audits, evaluations, and enforcement activities

	Reporting Period			
Statistic	***Oct '22- March '23***	***Apr '22- Sept '22***	***Oct '21- March '22***	***Apr '21- Sept '21***
Audit Report Issued	62	114	47	162
Evaluations	19	43	14	46
Expected Audit Recoveries	$200.1 million	$1.19 billion	$1.14 billion	$787.29 million
Questioned Costs	$277.2 million	$2.17 billion	$1.6 billion	$1.17 billion
Potential Savings	$0	$279 million	$162.1 million	$1.24 billion
New Audit and Evaluation Recommendations	213	445	130	506
Recommendations Implemented by HHS Operating Divisions	253	424	265	432
Expected Investigative Recoveries	$892.3 million	$2.73 billion	$1.44 billion	$3.00 billion
Criminal Actions	345	710	320	532
Civil Actions	324	736	320	689
Exclusions	1365	2332	1043	1689

Source: OIG HHS Semiannual Spring 2023, OIG HHS Semiannual Fall 2022, OIG HHS Semiannual Spring 2022, and OIG HHS Semiannual Fall 2021,

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HHS-OIG's semiannual report: additional key findings

COVID-19 pandemic response

- Many state and local immunization programs reported having incomplete individual-level data for the more than 250 million COVID-19 vaccine doses administered by Federal agencies and retail pharmacy partners
- State and local immunization programs funded by CDC faced numerous challenges, including achieving logistical efficiency, obtaining complete vaccine data, combating vaccine hesitancy, and overseeing vaccine providers
- Indian Health Service (IHS) did not fulfill all of the provisions outlined in a Memorandum of Agreement that specified the conditions for receiving COVID-19 vaccines from the CDC

Oversight to better protect nursing home residents

- More than 1300 nursing homes reached infection rates of 75% or more in the first year of the COVID-19 pandemic
- OIG found that psychotropic drug use in nursing homes was relatively constant and about 80 percent of Medicare's long-stay nursing home residents were prescribed a psychotropic drug. The number of unsupported schizophrenia diagnoses increased

Promoting program integrity and good financial stewardship in traditional Medicare

- 2023 Medicare Trustees report projected that assets in the Part A trust fund will be depleted by 2033
- Medicare part B spending on lab tests increased by 17% in 2021, driven by higher volume of COVID-19 tests, genetic tests, and chemistry tests
- Medicare improperly paid physicians an estimated $30 million for spinal facet-joint interventions
- Medicare could have saved up to $216 million over 5 years if program safeguards had prevented at-risk payments for definitive drug testing services

Reducing prescription drug spending for HHS programs and enrollees

- OIG recommends that CMS should bolster its oversight of manufacturer-submitted average sales price data to ensure accurate Part B drug payments

Cybersecurity protection

- OIG provided recommendations for FDA to improve its management of contracts for the acquisition of information technology as it continues to recognize cybersecurity vulnerabilities as major risks

Source: OIG HHS Semiannual Spring 2023

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DOJ Findings: Findings on health care fraud, waste and abuse

Most recent Medicare audits, evaluations, inspections, investigations, and enforcement actions.

Results of nationwide COVID-19 fraud enforcement action

- The US DOJ has announced the results of a nationwide effort to combat COVID-19 related fraud. This coordinated action involved 718 enforcement actions, with 371 individuals facing federal criminal charges for offenses related to alleged COVID-19 fraud amounting to over $836 million.
- The DOJ has so far seized more than $1.4 billion in COVID-19 relief funds that had been misappropriated and has pursued charges against over 3,000 defendants across various federal districts.

National enforcement action results in health care fraud

- The DOJ, along with federal and state law enforcement partners, has announced a nationwide law enforcement action targeting health care fraud and opioid abuse schemes which led to criminal charges against 78 defendants for health care fraud and opioid-related activities, totaling over $2.5 billion in alleged fraud.
- The charges encompass various types of health care fraud, including telemedicine fraud, pharmaceutical fraud, opioid distribution, and clinical laboratory testing fraud. Notably, telemedicine schemes involved the fraudulent submission of over $2 billion in claims. These cases often targeted vulnerable populations, such as the elderly and disabled, and exploited telemedicine services for unlawful financial gains.

Payment of illegal kickbacks and money laundering

- The owner of several compounding pharmacies and others collaborated to create and promote costly compounded medications tailored to individual patient needs.
- They engaged marketers to recruit local doctors to write prescriptions for these expensive compounded medications, offering "investment opportunities" to doctors who prescribed the medications, allowing them to profit from the pharmacy's operations. The pharmacy owner paid illegal kickbacks to these marketers and participated in a money laundering conspiracy.

Source: Justice News | DOJ | Department of Justice Office of Public Affairs | Pharmacy Owner Convicted of Payment of Illegal Kickbacks and Money Laundering | United States Department of Justice

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FBI investigations on health care fraud

The FBI investigates these health care fraud crimes in partnership with Federal, state, and local agencies, Healthcare Fraud Prevention Partnership and Insurance groups such as the National Health Care Anti-Fraud Association, the National Insurance Crime Bureau, and insurance investigative units.

Recent FBI case highlights

- **Illegal kickback payments – gene tests:** California man sentenced to 42 months in federal prison for conspiring with others to pay and receive kickbacks in exchange for the referral of, and arranging for, health care business, specifically pharmacogenetic (pgx) tests. more than $28 million in illegal kickback payments were exchanged by those involved in the conspiracy
- **False claims – DME:** Man admits participating in a scheme with durable medical equipment (DME) companies, telemedicine companies, and doctors to submit false claims to health care benefit programs, including Medicare and TRICARE, based on a circular scheme of kickbacks and bribes. More than $127 million of false and fraudulent claims were submitted to health care benefit programs
- **Telemedicine fraud scheme**: Nurse practitioner charged in connection with a $7.8 million telemedicine fraud scheme involving medically unnecessary DME, including orthotics such as back and knee braces
- **False claims – fraudulent diagnoses:** Ophthalmologist indicted for falsely diagnosing vulnerable patients with ophthalmological diseases and various degenerative eye conditions. The false and fraudulent claims allegedly submitted to Medicare, Medicaid and Tricare totaled $402,536,174. As a result of this, Medicare, Medicaid and Tricare paid approximately $13,317,914

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Improper payments by HRSA to providers for COVID-19 testing and treatment

An audit by the OIG found that an estimated $784M worth of payments to providers through the COVID-19 Uninsured Program (UIP) did not comply with federal requirements.

Why and how OIG conducted this audit

- After congress passed a series of bills to provide funds to eligible hospitals and providers for COVID-19 related testing and treatment of uninsured patients, the OIG conducted an audit to determine whether these payments to 19M patients worth $4.2B went to proper individuals and situations.
- OIG interviewed HRSA officials and HRSA's contractor and looked at health insurance coverage as well as medical and billing records. In total, OIG reviewed a random sample of 300 patients with payments totaling $2.8M.

What OIG found

- OIG found that there were **payments** to providers for claims related to COVID-19 Testing and treatment services that **did not comply** with federal requirements.
- For **240** of the **300** sampled patients, payments made on behalf of uninsured patients to providers for claims related to COVID-19 services **met program terms and conditions.**
- For **58** of the **300** sampled patients, OIG found payments worth **$294K** were **improper** because they were made on behalf of **Insured** patients or for services that were **unrelated to COVID-19.**
- Based on the sampled results, OIG estimates that nearly $**784M of the $4.2B (19%)** UIP payments to providers were **improper.**

OIG recommendations and HRSA comments

- OIG made **recommendations** to HRSA which include **recovering the $294K** worth of improper payments and **identify additional improper UIP payments** made through the program.
- OIG also **made procedural recommendations** for HRSA to **improve future programs** to prevent similar issue.
- HRSA concurred partially with the first recommendation and concurred with the second and third recommendations.

Source: HRSA Made COVID-19 Uninsured Program Payments to Providers on Behalf of Individuals Who Had Health Insurance Coverage and for Services Unrelated to COVID-19 A-02-21-01013 07-13-2023 (hhs.gov)

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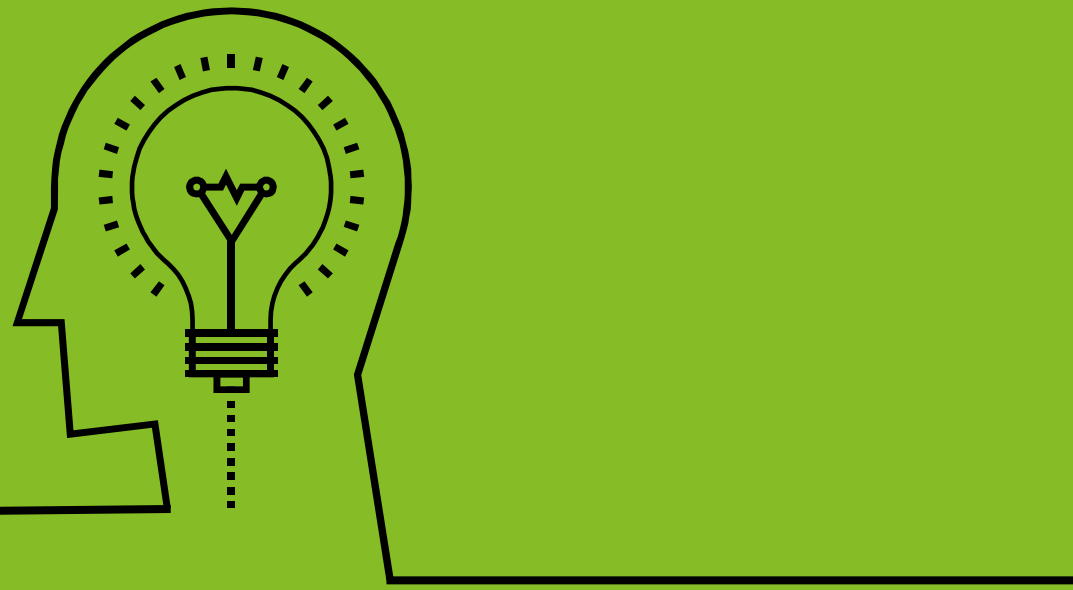
Compliance program effectiveness: Importance of KPIs



What is a key performance indicator (KPI)?

A KPI is a measurement that shows how an organization or department is performing.

A good health care KPI should be well defined, quantifiable, thoroughly communicated, and essential to achieving an organization’s strategic goals.

Source: https://hci.care/practical-guidance-for-selecting-key-performance-indicators-in-healthcare/

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Importance of KPIs to compliance

Tracking KPIs can help a compliance program measure its performance against target goals, monitor known regulatory risks, and identify improvement opportunities for the organization.

1 **Proactively tackle compliance risks and knowledge gaps**

Defined KPIs allow compliance programs to identify where there may be opportunities for education and/or potential compliance risk within the organization

2 **Demonstrate compliance performance against plan**

Setting actionable goals for the program with corresponding data insights allows Compliance leadership to clearly articulate performance and program integrity

3 **Leverage risk-based, data driven approach**

Faced with cost, resource, and regulatory audit pressures, leveraging a risk based, data driven approach to compliance risk monitoring works to modernize a program

4 **Create new business insights**

KPIs enable Compliance departments to work in tandem with other departments to create new insights and areas of opportunity for improvement

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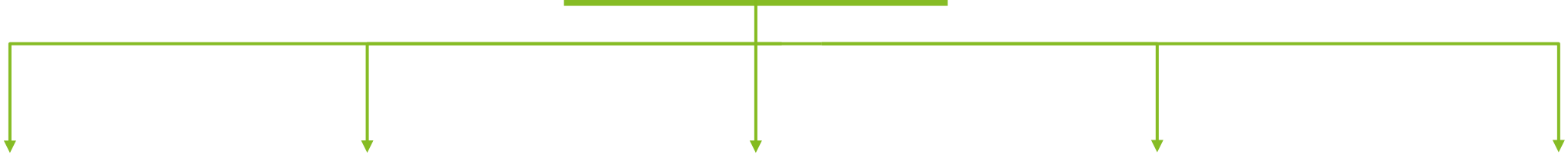
Overview of KPIs and reporting capabilities

Full reporting on compliance-related statistics, outcomes, and trends can demonstrate a compliance program's effectiveness to board-level leaders.

Strong reporting capabilities provide Compliance departments with **important insight into the issues and activities** that the department manages and allow Compliance to share KPIs with senior leadership. Reporting can also help Compliance **proactively identify trending issues** to share with senior leadership and other departments Compliance partners with.

The following five categories represent **exemplary reporting capabilities** that Compliance should provide:



Categorization

- Ability to categorize reported issues by issue type, time to resolve, priority, owner, etc.

Volume

- Access to statistics on the volume of entries received over a period of time

Outcome tracking

- Ability to view outcomes and resolution rates of issues in queue
- Ability to view issues and inquiries triaged to other departments

Patterns

- Identify recurring or repeating gaps, issues, and inquiries identified and/or reported across locations, departments, etc.

Trends

- Identify trends based on issues and inquiries reported following changes in procedures, education provided, etc.

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Compliance reporting categories and metrics – illustrative

Organizations should consider known risk areas and applicable regulations when developing a framework of metrics to track. The below examples illustrate potential metrics that may be used:

Reporting category	Objective	Key metrics
Reporting & investigations	*Measure the quality and consistency of investigations, as well as the tracking, communication, and escalation of investigations*	1. Total # of compliance issues currently open • Education, Regular Inquiries/Concerns, Investigations, Audits 2. Average time to issue resolution 3. Total # of Hotline Issues 4. Total # by Priority Level: Low, Medium, High 5. Total # of compliance investigations • Average compliance investigation cycle time by type • Assignment of issues, investigations (compliance team members, triaging)
Auditing & monitoring	*Measure a compliance program's reporting system, risk assessments, auditing and monitoring work plan, corrective action plans, as well as auditor and vendor oversight*	1. Frequency of code refresh and policy reviews 2. Total # of workplan items • # of Core Compliance Program Activities • # of Risk-Based Auditing & Monitoring Activities • # of Follow-up Activities • # of Operational Risk Areas & Advisory Roles 3. Auditing and monitoring results 4. Audit outcomes, plan for resolving adverse outcomes (qualitative) 5. Status of corrective action plans
Education, training, and awareness	*Measure training, board obligations and responsibilities, communication, competency, and a culture of compliance*	1. Annual Compliance Training Completion % 2. ACO Training Completion % 3. EMTALA Training Completion % 4. Provider Education Completion % 5. New Hire Training Completion % 6. Reach, frequency, and engagement rates of compliance communications
Conflict of interest	*Mitigate risk and maintain a culture of compliance*	1. Total # of Covered Persons 2. Total % of Completed Disclosures 3. Total # of Conflicts Identified 4. Total # of Management Action Plans (MAPs) Implemented 5. Frequency of MAP Monitoring and Follow-ups

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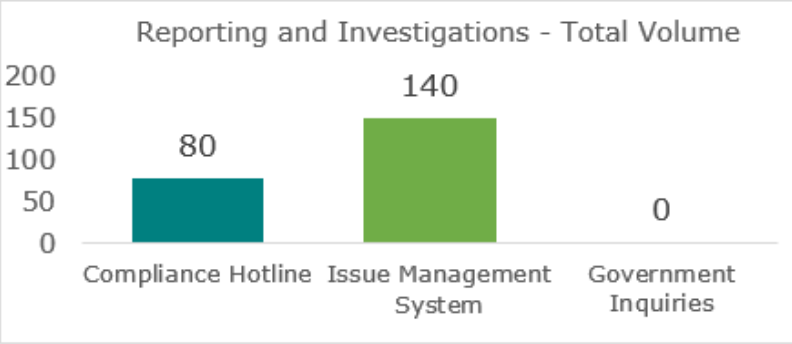
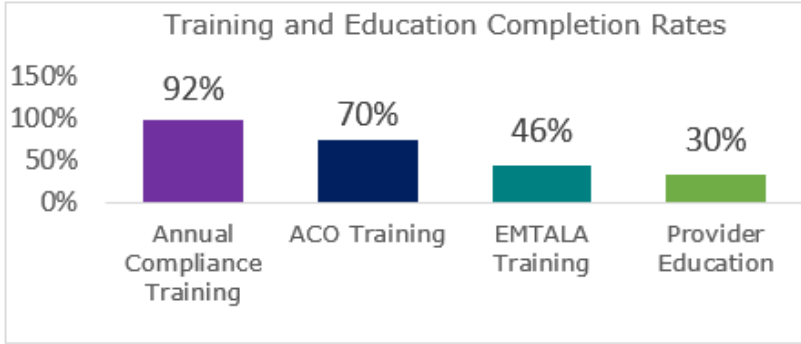
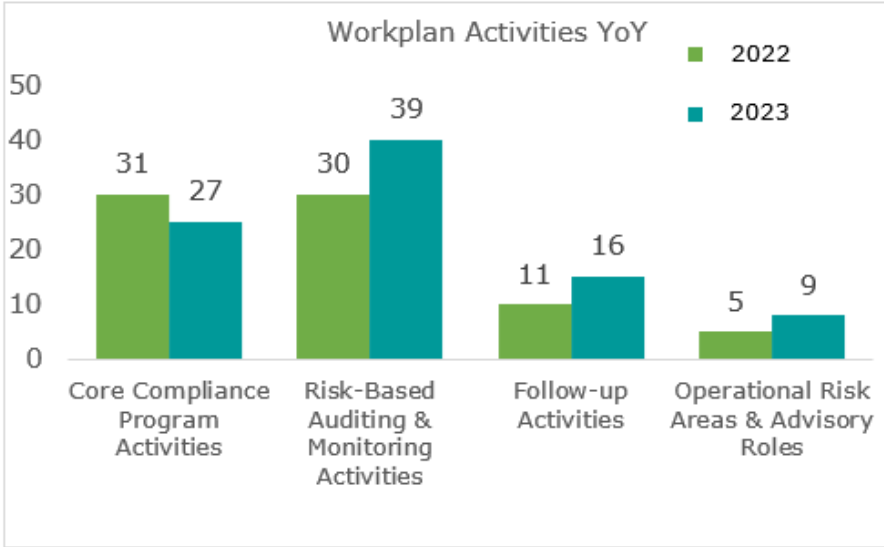
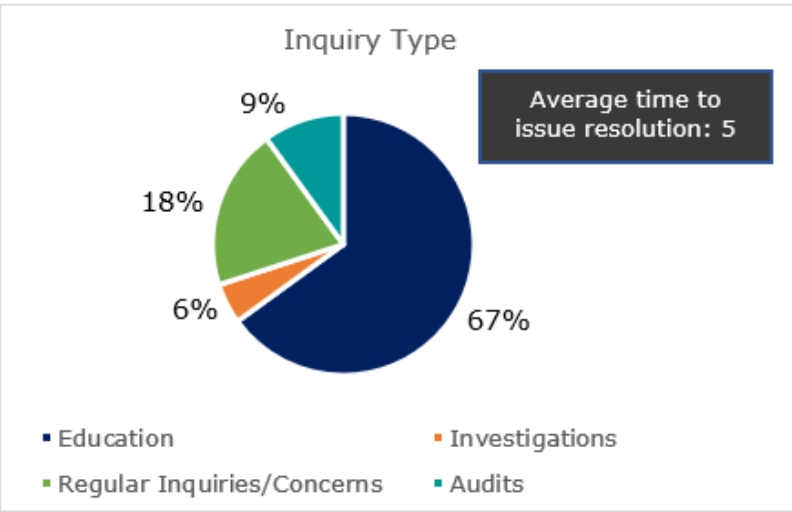
Compliance dashboard – illustrative

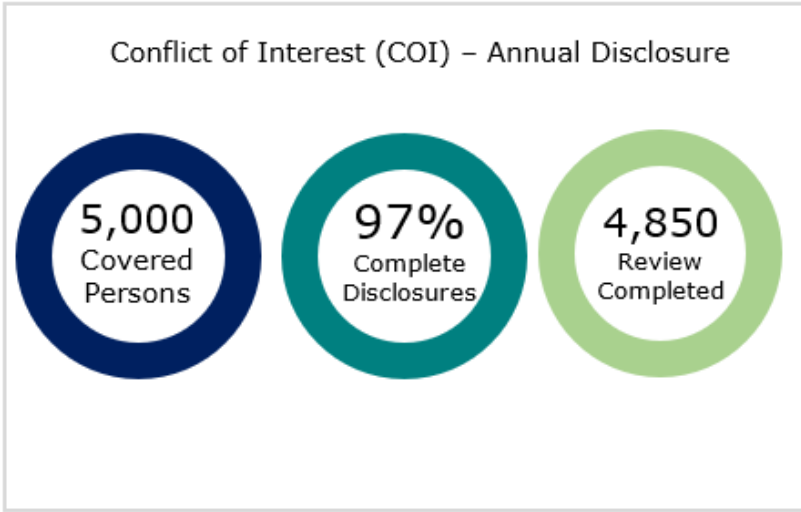
Example compliance dashboard for board-level reporting.











Total # of Conflict Identified: **250**

Additional Review and Follow-up Required: **60**

Total # of Management Action Plan (MAP) Implemented: **50**

Frequency of MAP monitoring and follow-ups: **Quarterly**

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Meet the speakers

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RELEVANT EXPERIENCE

Kelly is a partner with over 25 years of experience in the health care industry. She specializes in providing regulatory, compliance, and risk services. Kelly also serves as a Deloitte client leader on several large academic medical center and health system accounts to help multi-disciplinary teams respond and deliver exceptional client service across a wide variety of areas. She has led numerous compliance and privacy program assessments and risk assessments, helped organizations implement and navigate new regulations and respond to government inquiries and investigations. Many of these projects have involved compliance with Federal regulations such as Medicare Conditions of Participation, new Medicare payment models/programs and other clinical, coding or billing matters. Kelly is a regular advisor to board members and senior leaders in health care organizations and presents regularly on emerging regulations, compliance, and risk matters.

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RELEVANT EXPERIENCE

Heather has over 17 years of experience providing compliance program and digital transformation, enterprise and strategic risk, operational improvement and regulatory compliance and risk remediation, governance, and internal audit services to health care organizations, including health systems and payers. She assists clients with the facilitation of enterprise-wide risk initiatives, including responding to significant business and regulatory changes, operational improvement initiatives and digital transformations. Additionally, Heather leads compliance function assessment, implementation, and optimization initiatives aimed at adopting leading practices, refining operating models, and deploying digital capabilities to improve value and reduce costs.

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