AI & GenAI in Healthcare: Trends, Governance and Internal Audit

Wednesday, December 4 – Friday, December 6, 2024
Mystic Marriott Hotel, Groton, CT

Agenda

1 | *Explore current viewpoints and emerging trends on how AI & GenAI are being adopted and managed in the healthcare industry*

2 | *Gain insights into the current regulatory landscape, including legislation being considered at both federal and state levels*

3 | *Examine how compliance, internal audit and GenAI intersect, including regulatory and ethical considerations for using GenAI in healthcare and the potential of GenAI to facilitate compliance and internal audit tasks*

4 | *Q&A*

How to Ask Questions

We will save time for Q&A at the end of the presentation
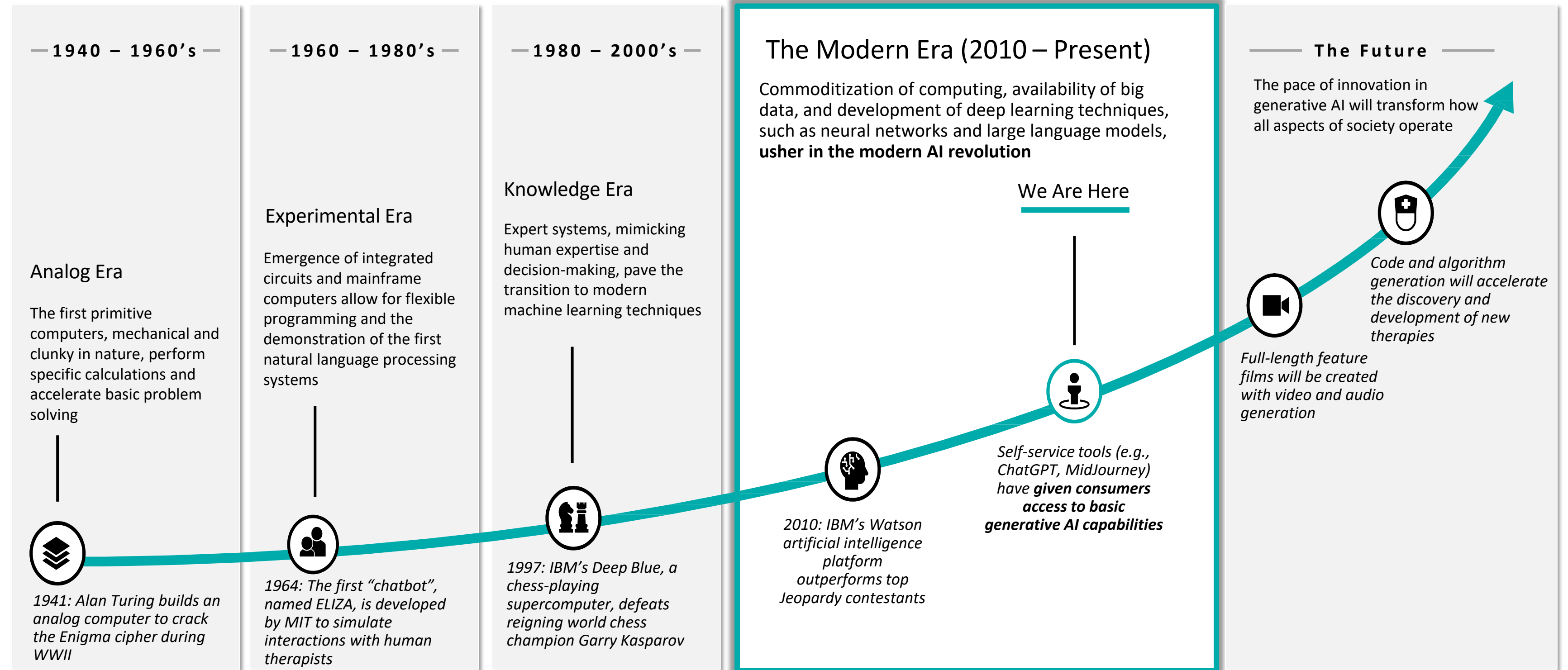
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Explore current viewpoints and emerging trends on how AI & GenAI are being adopted and managed in the healthcare industry

Generative AI – How did we get here?

Generative AI is the next evolution in the journey of Artificial Intelligence

The Computing and Artificial Intelligence Innovation Curve

1940 – 1960's

Analog Era

The first primitive computers, mechanical and clunky in nature, perform specific calculations and accelerate basic problem solving

1941: Alan Turing builds an analog computer to crack the Enigma cipher during WWII

1960 – 1980's

Experimental Era

Emergence of integrated circuits and mainframe computers allow for flexible programming and the demonstration of the first natural language processing systems

1964: The first "chatbot", named ELIZA, is developed by MIT to simulate interactions with human therapists

1980 – 2000's

Knowledge Era

Expert systems, mimicking human expertise and decision-making, pave the transition to modern machine learning techniques

1997: IBM's Deep Blue, a chess-playing supercomputer, defeats reigning world chess champion Garry Kasparov

The Modern Era (2010 – Present)

Commoditization of computing, availability of big data, and development of deep learning techniques, such as neural networks and large language models, **usher in the modern AI revolution**

We Are Here

2010: IBM's Watson artificial intelligence platform outperforms top Jeopardy contestants

*Self-service tools (e.g., ChatGPT, MidJourney) have **given consumers access to basic generative AI capabilities***

The Future

The pace of innovation in generative AI will transform how all aspects of society operate

Code and algorithm generation will accelerate the discovery and development of new therapies

Full-length feature films will be created with video and audio generation

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Generative AI has several core capabilities across search, summary and generation

	INTELLIGENT SEARCH	SUMMARIZATION	CONTENT GENERATION
Description	*Utilization of the semantic context of queries to provide more accurate and relevant results to improve search algorithms*	*Extraction of requested or valuable information from data, and presentation in a concise format*	*Creation of new original content across different media types (e.g., text, audio, picture)*
Problems Addressed	• Knowledge query and access • Document query and access	• Text summarization • Data classification	• Written draft generation & editing • Code writing and testing • Language translation • Artwork generation
Examples	1. ***Literature Review*** *– Search of relevant medical and scientific literature related to a topic of choice* 2. ***People Search*** *– Search of an organization's people to find expertise in a given area*	1. ***Literature Summarization*** *– Synthesis of key results, statistics and conclusions of a research paper or document* 2. ***Meeting Summarization*** *– Transcription and summarization of meeting minutes to highlight key information (e.g., discussion points, decisions, tasks, next steps)*	1. ***Marketing Design*** *– Creation of highly-personalized marketing materials* 2. ***Translation*** *– Translation of documents across languages*

Why AI in health care?

AI is transforming industries by driving innovation and creating value, extending benefits beyond technical specialists.

94% of top executives believe AI is crucial for their future success, highlighting its significant potential.[1]

In health care, AI has become an immediate necessity, especially in the wake of financial challenges posed by the end of the COVID-19 Public Health Emergency.[2]

AI can be utilized to help address **health disparities,** providing opportunities for **cost reduction** or **revenue generation**.

Post-pandemic, AI has been instrumental in helping hospitals tackle issues such as **supply chain disruptions**, **workforce shortages**, **increased administrative demands,** while improving operational efficiency and reducing clinician burnout.

Some key issues facing health care providers today

It is evident that Generative AI has the potential to transform health care.....but by how much and in what ways?

STAFFING SHORTAGES

Persistent COVID-19 effects such as burnout, retirements, vaccine mandate opposition, and industry competition have worsened health care staff shortages. This is especially felt in rural and underserved hospitals, leading to closures of units and hindered services like labor, delivery, and emergency surgeries.

RISING COSTS & REVENUE CYCLE MANAGEMENT

Inflation, staff shortages, and supply chain issues elevate healthcare costs. Sustainability of value-based care relies on evolving reimbursement models. Economic instability and the end of COVID-19 aid intensify revenue cycle pressures amid economic uncertainty and paused Medicaid expansions.

COMPLIANCE & HEALTH PLANS

Providers are expected to navigate complex compliance and health plan issues due to changing regulations, increased digitization, and data security concerns. They also need to adhere to new Affordable Care Act and Medicare policies, especially those emphasizing value-based care.

DATA-ANALYTICS INTEGRATION & UTILIZATION

The rise in medical data volume requires robust, real-time processing and data quality solutions. Increased cyber threats heighten privacy and security concerns. Non-standardized data formats cause interoperability issues hindering seamless integration for patient care. Electronic health records (EHRs) have underutilized patient data, and effective data governance structures are absent.

Process Innovations and AI Plays

PREDICTIVE ANALYTICS FOR WORKFORCE PLANNING	'HOSPITAL AT HOME' TECH	VALUE-BASED CARE OPTIMIZATION	FRAUD DETECTION SYSTEMS	RISK MANAGEMENT AI PLATFORMS	REGULATORY COMPLIANCE ENGINES	STREAMING ANALYTICS PLATFORMS	SMART CYBERSECURITY

- PREDICTIVE ANALYTICS FOR WORKFORCE PLANNING
- 'HOSPITAL AT HOME' TECH
- VALUE-BASED CARE OPTIMIZATION
- FRAUD DETECTION SYSTEMS
- RISK MANAGEMENT AI PLATFORMS
- REGULATORY COMPLIANCE ENGINES
- STREAMING ANALYTICS PLATFORMS
- SMART CYBERSECURITY

- AI-ENABLED TELEHEALTH SERVICES
- ADMINISTRATIVE TASK AUTOMATION
- PREDICTIVE BILLING
- PREDICTIVE ANALYTICS FOR RESOURCE ALLOCATION
- SMART CONTRACT AI
- QUALITY MEASURE/ VALUE-BASED CARE TRACKING
- INTEROPERABILITY AND DATA HARMONIZATION
- DATA MARKETPLACES

- PERSONALIZED & ADAPTIVE MED-ED LEARNING
- AI-POWERED RECRUITMENT & RETENTION WORKFLOWS
- SMART SUPPLY CHAIN MANAGEMENT
- CONTRACT MANAGEMENT OPTIMIZATION
- CLINICAL DECISION SUPPORT SYSTEMS (CDSS)
- AUTOMATED DATA HOSTING SOLUTIONS
- DATA QUALITY MANAGEMENT TOOLS

Health care providers and use of Generative AI (GenAI)

Improved patient care

GenAI can help health care providers:
- **Identify diseases** earlier and more accurately
- **Increase speed and accuracy** of basic triage
- Create **personalized treatment** plans
- Provide virtual health assistance, including medication reminders
- Improve customer care with **personalized, automated communication** between patients and providers, such as intelligent chatbots for preliminary triage diagnostics

Improved efficiencies and reduced costs

GenAI can amplify traditional AI-enabled uses cases to further reduce health care costs by:
- **Automating tasks** such as scheduling appointments, auto-populating intake forms, auto-procedure coding (international Classification of Diseases, 10th Revision, Healthcare Common Procedure Coding System), and managing patient records
- **Enabling medical simulation** for more effective training and research
- **Automating revenue cycle functions** such as claims editing, prior authorization and auto-form filling, and denial appeals
- **Predicting and monitoring** maintenance needs
- Using **enhanced telemedicine** and **surgical robots**

Better decision-making

GenAI can supply providers with access to information and insights in areas like:
- **Diagnostics and screening**—using deep learning-based AI algorithms to automatically detect complex anomalous patterns in images within seconds, particularly in radiology
- **Clinical trial support**—identifying trends in large datasets by quickly mining accurate, relevant, evidence-based information that has been curated by medical professionals
- **Evidence-based recommendations**—providing relevant findings from patient records, as well as outcome predictions
- **Value-based care**—identifying and accelerating delivery of offerings
- **Digital twins**—creating a digital representation of a person's physical attributes that keeps a record of medical history accessible to health care providers through the electronic health record (EHR)

# How are GenAI investments shaping the future of healthcare for Providers?

List of use cases, relative value, and relative feasibility based on Gartner's 2023 Use-Cases for GenAI Prism (Payer and Provider) with investment size based off survey of 90 LSHC executives

TOP GEN AI USE CASE INVESTMENT – HC PROVIDER
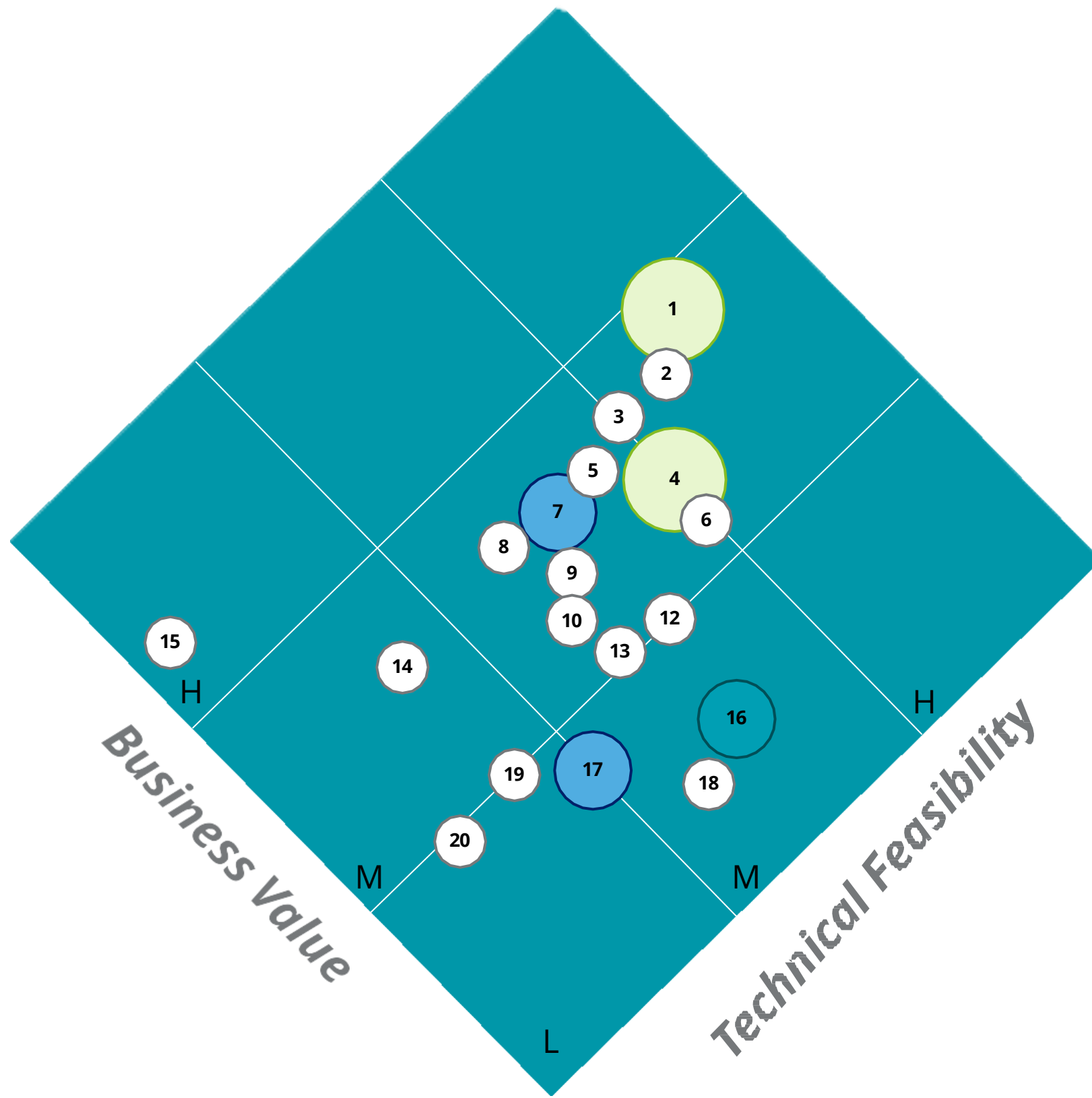
Clinical Documentation Automation: These use cases capture the largest portion of GenAI spend by promising to decrease by an average of 9 hrs/week that clinicians currently spend on EHR documentation

Clinical Coding Automation: Despite mixed levels of value and feasibility, clinical coding automation captures a considerable focus of GenAI spend, in line with the focus on better measuring outcomes as part of delivering value-based care

Administrative Support Automation: Automating administrative support such as asking questions to third parties about authorization requirements, claims, and payment is low hanging fruit for as these tasks are highly repetitive and hence more easily automated

Use Cases

1: Ambient Digital Scribe for real-time documentation 2: Augmenting data analysis and interpretation
3: Automating patient care navigation
4: Autogenerating clinical documentation and messages 5: Auto-composing clinical messages and personalized patient education materials
6: Medical literature discovery for comprehensive research
7: Autonomous clinical coding for streamlined processes 8: Autogenerating Health Care consumer messaging for outbound communication
9: Health Care consumer language translation for improved accessibility
10: Enhancing patient education through autonomous processes

11: *[Removed due to lack of relevance to US providers]* 12: EHR search and summarization for efficient information retrieval
13: Clinical trial patient identification through autonomous processing
14: Autogenerating differential diagnosis and treatment plans
15: Autonomous Virtual Primary Care for personalized patient support
16: Health Care administrative assistant for operational efficiency
17: Clinician performance analysis for quality assessment 18: Autogenerating personalized patient health summaries
19: Clinical encounter simulation for realistic training
20: Clinical condition diagnosis for accurate assessments

How are GenAI investments shaping the future of healthcare for Payers?
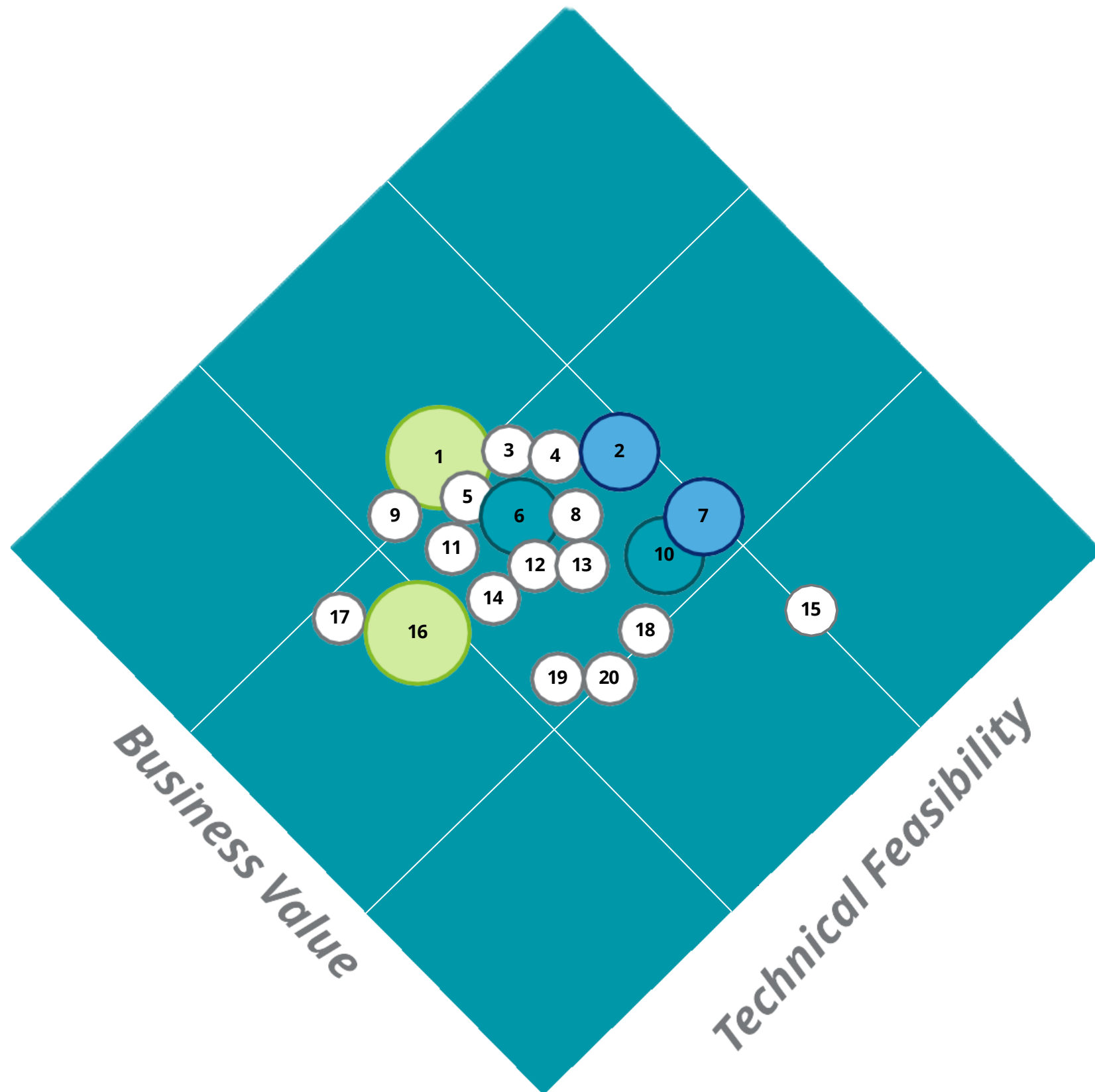
Digital Broker Services: AI driven support for brokerage and member support services provide an opportunity for a personalized member experience while also saving organizations valuable time and money

Member Communications Automation: Member communication around topics such as plan benefits and specific policies can be hugely accelerated by infusing Gen AI capabilities to often to communication that can be tedious to draft

Policy Administration Automation: The use of Gen AI for automating policy administration and working with legacy administrative coding fall in the sweet spot of considerable value and feasibility making it a common investment for payers

Use Cases

1: Utilizing a digital broker for insurance services
2: First-draft member communications automation
3: Member EOB and provider bill matching tool
4: GenAI medical records search in care management 5: GenAI medical records search in risk or quality assessment
6: Automated policy administration for streamlined processes
7: Generating and maintaining policy forms for effective communication
8: Provider service chat for efficient communication 9: Autonomous underwriting and actuarial calculations
10: Legacy administrative system coding for system efficiency

11: Analytics for group reporting for data-driven insights 12: Regulatory summarization for compliance management 13: Care management content generation for personalized plans
14: Ambient Digital Scribe in care management for real-time documentation
15: Health Care consumer language translation for diverse member interactions
16: Virtual member service for personalized member support 17: Virtual 24-hour nurse chat for immediate Health Care support
18: Payment integrity case identification for fraud prevention 19: Content refinement for empathy inclusivity in member interactions
20: Encounter role play for staff training.

AVERAGE % OF GEN AI BUDGET

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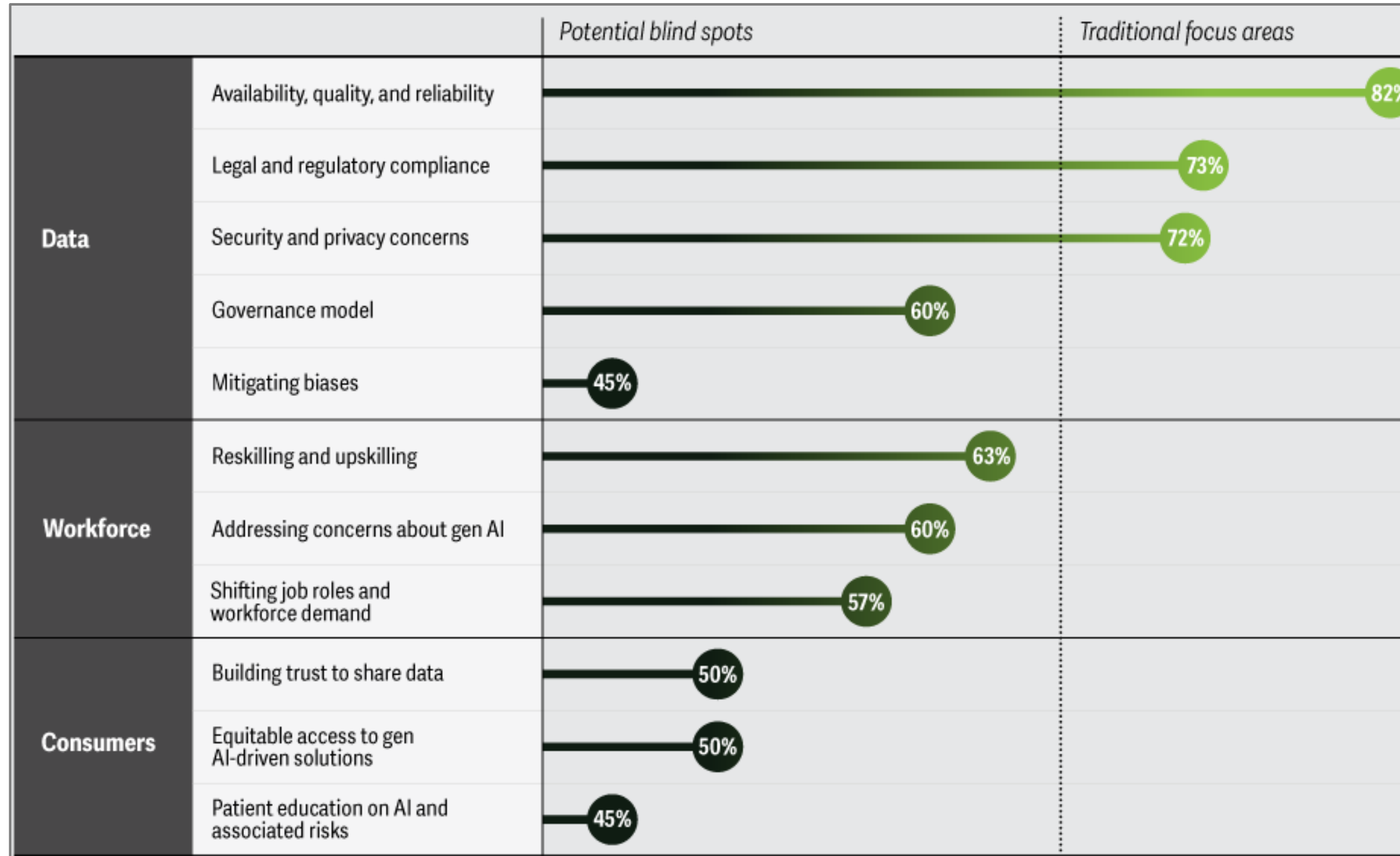
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List of use cases, relative value, and relative feasibility based on Gartner's 2023 Use-Cases for GenAI Prism (Payer and Provider) with investment size based off survey of 90 LSHC executives

The Generative AI outlook in health care: Opportunities and challenges

A recent Deloitte 2024 Health Care Generative AI Outlook Survey found that **70%** of executives are highly focused on data considerations like **data availability**, **quality**, **compliance**, **security**, and **privacy** during implementation.

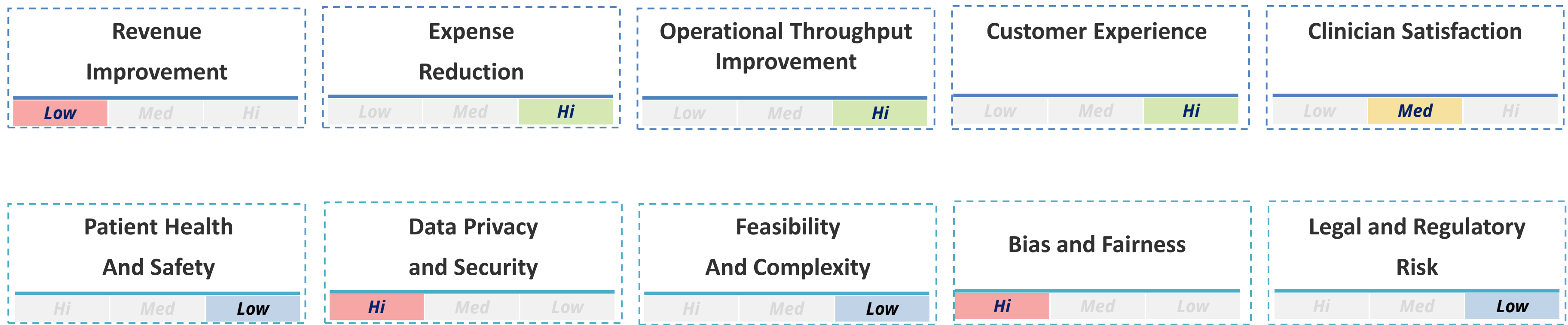## Considerations for implementing Generative AI in health care organizations

		Potential blind spots	Traditional focus areas
Data	Availability, quality, and reliability		82%
	Legal and regulatory compliance		73%
	Security and privacy concerns		72%
	Governance model	60%	
	Mitigating biases	45%	
Workforce	Reskilling and upskilling	63%	
	Addressing concerns about gen AI	60%	
	Shifting job roles and workforce demand	57%	
Consumers	Building trust to share data	50%	
	Equitable access to gen AI-driven solutions	50%	
	Patient education on AI and associated risks	45%	

Critical areas for implementation of Generative AI

1. Effective governance: Empower teams with clear decision-making strategies and encourage a culture of learning and innovation.

2. Consumer trust and engagement: Actively engage with consumers to understand their needs and concerns, and tailor AI solutions that they are comfortable with.

3. Workforce buy-in: Emphasize on improving workforce literacy in Generative AI and position it as an ally, not a threat, to foster trust among users.

4. Scalability of solutions: Prioritize scalability by implementing enhanced machine learning operations (MLOps) to ensure dependable and efficient AI processes.

Notes: Data shows percentage of respondents rating 4 or 5 on a scale of 5 (5 being highest) when asked their greatest considerations to implement Generative AI in their organization. N = 60.
Source: Deloitte 2024 Health Care Generative AI Outlook Survey | Apply generative AI in health care | Deloitte Insights

Illustrative Use Case: Ambient Documentation

Generate real time clinical notes based on AI voice-to-text capture between the provider and the patient while in the exam room

Revenue Improvement	Expense Reduction	Operational Throughput Improvement	Customer Experience	Clinician Satisfaction
Low Med Hi	Low Med **Hi**	Low Med **Hi**	Low Med **Hi**	Low **Med** Hi

Patient Health And Safety	Data Privacy and Security	Feasibility And Complexity	Bias and Fairness	Legal and Regulatory Risk
Hi Med **Low**	**Hi** Med Low	Hi Med **Low**	**Hi** Med Low	Hi Med **Low**

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Gain insights into the current regulatory landscape, including legislation being considered at both federal and state levels

Health care's position in the current AI policymaking context

In the emerging AI policy landscape, regulating the use of AI in health care and life sciences is one of the highest priorities in the private sector use of AI.

Health care is unique given its existing privacy protections and the potential risks at stake with unregulated use of AI.

It is also important to recognize that policymakers have taken a broad focus on regulating AI technology across forms and applications, not just Generative AI, with potential impacts on a variety of AI tools used for health care decision making and operations.

1. Health care has been governed by HIPAA for over two decades
Health care has an existing privacy framework in place that will need to be considered in the context of new regulation.

2. Use of AI in health care is inherently higher risk
Use of AI for health care diagnostics, decision making, claims processing, or coverage decisions is considered higher risk given its potential impact on patient care, patient safety, and civil rights such as non-discrimination.

3. Health care data is a high-value target
Access to health care data is considered a valuable resource to improve consumer experiences; however, health care data is also a target for cyber crime. Therefore, transparency and data security is an integral pillar of regulating AI models.

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What is the pulse on AI in Washington?

The White House: Biden's Executive Order and AI in the 2024 Election

On October 30, 2023, President Biden signed an executive order (EO) on the "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." This follows a series of actions the current and previous administrations have taken on AI since 2019.[1,2] **The federal agencies have made progress towards the EO's directives** and have pending deadlines for health care mandates this October and December.

Looking towards the 2024 elections, **both Presidential candidates have signaled where they may act to regulate AI**.

State legislatures have taken action on AI, while Congress still explores a path forward

The **state legislative landscape to regulate AI has been very active** with over 20 states passing legislation to regulate AI.

Within Congress, lawmakers continue to hold hearings, release reports, and introduce bills on AI. However, **Congress is not likely to pass comprehensive AI legislation soon** and may struggle to keep pace with rapidly evolving technology. [3,4,5,6]

Department of Health & Human Services regulates AI use in drugs, devices, and health IT

Several agencies within HHS have advanced regulation on AI within existing authorities. **The Food and Drug Administration (FDA) was one of the earliest agencies to begin to take action on AI and has issued relevant guidance over the last five years.** In March 2024, the FDA published a paper outlining its regulatory focus for both drugs and medical devices. The Assistant Secretary for Technology Policy (ASTP's), formerly the Office of the National Coordinator (ONC), **final rule with algorithm transparency provisions for certified health IT was published in December 2023**.[9]

Federal Trade Commission increases oversight of algorithm bias & discrimination

The FTC is one of the lead enforcement agencies for unfair or deceptive practices with AI, unauthorized disclosures of health information, and algorithm bias.[10]

The FTC continues to issue business guidance on AI and has conducted enforcement related to facial recognition and unauthorized data disclosures.

To meet the demands of the evolving technology landscape, the FTC has hired over a dozen technologists to support AI-related investigations.

Federal agencies are starting to fulfill directives under the President's EO on AI

On October 30, 2023, President Biden signed an EO on Safe, Secure, and Trustworthy AI. The sweeping EO directed the federal agencies to initiate rulemakings, issue guidance, and develop task forces that aim to protect patients and consumers from AI-related risks.

Progress on select Executive Order directives relevant to Life Sciences & Health Care stakeholders

HHS AI TASK FORCE

HHS was directed to establish an AI Task Force to provide regulatory clarity and catalyze AI innovation in health care.

In January 2024, HHS convened the task force, co-chaired by Syed Mohiuddin, a counselor to the HHS deputy secretary, and Micky Tripathi, national coordinator for health information technology. **The task force is directed to develop an AI strategic plan and safety program by October 29, 2024.**

GUIDANCE ON FEDERAL AGENCY AI USE

The EO directed agencies to advance AI governance and innovation while managing risks from the use of AI in the Federal Government.

On March 28, 2024, OMB issued final guidance on agency use of AI. It called for additional transparency and reporting requirements on agency AI processes/systems, incorporation of opt-out mechanisms for the public, and enacted special requirements for health care and insurance use cases.

NATIONAL SCIENCE FOUNDATION AI ENGINES

The National Science Foundation was directed to fund and launch AI-focused NSF Innovation Engines within 150 days to promote research & development.

Regional Innovation Engine awards were announced in January 2024. The Piedmont Triad Regenerative Medicine Engine will tap the world's largest regenerative medicine cluster to create and scale breakthrough clinical therapies, including by leveraging AI.

OTHER DIRECTIVES

The Executive Order contained a number of other directives that may be relevant to Life Sciences & Health Care Stakeholders that the White House announced as complete on April 29, 2024:

1 HHS was directed to publish a **plan addressing the use of automated or algorithmic systems in the provision of public benefits and services** administered by the Secretary (e.g., Medicare, Medicaid).

2 HHS was directed to develop a strategy for ensuring the safety and effectiveness of AI deployed in the health care sector.

By October 29, HHS has been directed to develop a strategy for regulating the use of AI or AI-enabled tools in drug-development processes.

*OMB- Office of Management and Budget

Congress is in the exploratory stages of developing AI legislation with a focus on health care

While some existing laws lay the groundwork for regulating AI in certain use cases, Congress is in the early phases of considering broader AI legislation to regulate government and nongovernment use and development of the technology.[1,2,3]

Members of Congress have been focused on themes such as:

- *Liability for AI outcomes*
- *Privacy*
- *Data transparency standards*
- *Generative AI disclosures*
- *FTC oversight authority*
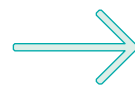
Senate activity

- **Majority Leader Chuck Schumer** (D-NY) is leading a group of four senators to spearhead the chamber's AI initiatives and introduced the SAFE Innovation Framework in June 2023.[4] The working group released a Roadmap for AI Policy in the Senate in May 2024 and reiterated comprehensive legislation is unlikely.
- **Senator Bill Cassidy** (R-LA), ranking member of Senate Health, Education, Labor, and Pensions (HELP) committee, released a policy paper on the use of AI in the context of life sciences, health care, education, and employment. He discussed liability for AI use and privacy protections.[5]
- **Senators Josh Hawley (R-MO) and Richard Blumenthal (D-CT)** announced a legislative framework to regulate AI with a focus on high-risk AI, liability for civil rights/privacy violations, and data transparency standards.[6]
- **Senator John Thune (R-SD)** introduced a bipartisan bill with several committee leaders to require companies deploying "critical-impact" AI (e.g., health care) to submit risk assessments to the Department of Commerce.[9]
- The Senate Finance Committee held a hearing on February 8, 2024, on health care and AI. During the hearing, **Chair Ron Wyden (D-OR)** discussed his bill the Algorithm Accountability Act.[10]

House activity

- On February 20, 2023, House leadership established the bipartisan House Task Force on Artificial Intelligence comprised of 12 Democrats and 12 Republicans members.[7]
- In the House of Representatives, **Rep. Ted Lieu (D-CA-36)** has led a bipartisan group to introduce legislation to establish a National AI Commission to focus on AI regulation.[8]
- The **House Energy & Commerce Committee** held a series of hearings on the role of AI across industries such as health care, telecommunications, and energy.
- Other AI-focused bills introduced in the House have focused on **national security, disclosures for Generative AI,** and **empowering the FTC to assess automated decision systems.**[9]

On April 7, 2024, Senator Maria Cantwell (D-WA) and Congresswoman Cathy McMorris Rodgers announced an industry-agnostic data privacy bill with bipartisan, bicameral support that includes algorithmic provisions, titled the **American Privacy Rights Act of 2024 (APRA)**.

Bipartisan Senate AI Working Group : Roadmap for AI Policy in the Senate

On May 15, 2024, the Bipartisan Senate AI Working Group comprised of Majority Leader Chuck Schumer (D-NY), Senator Mike Rounds (R-SD), Senator Martin Heinrich (D-NM), and Senator Todd Young (R-IN) released their Roadmap for AI Policy in the United States Senate. The Roadmap was developed following numerous stakeholder meetings and nine AI insight forums that convened over 150 participants including developers, researchers, industry leaders, and union leaders.
The Roadmap identifies areas of consensus that warrant further bipartisan consideration in this Congress and in the future.

INDUSTRY AGNOSTIC POLICY RECOMMENDATIONS
which may also apply the Health Care

Increase funding for non-defense AI innovation to at least at least **$32 billion per year and calls for emergency appropriations** to fill the gap between current spending levels and the NSCAI-recommended level

Development of legislation related to **training, retraining, and upskilling the private sector workforce to successfully participate in an AI-enabled economy**

Encourages **enforcement of existing laws and** for committees to consider any **gaps in the application of existing law to AI systems with high impact.**

Pass a **strong comprehensive federal data privacy law**. The legislation should address issues related to data minimization, data security, consumer data rights, consent and disclosure, and data brokers.

Consider whether there is a need for additional standards, or clarity around existing standards for **liability of AI developers and deployers if their products or actions cause harm to consumers**.

HEALTH CARE SPECIFIC RECOMMENDATIONS

Legislation that supports **further deployment of AI in health care** and implements appropriate guardrails and safety measures to protect patients.

Support the **NIH in the development and improvement of AI technologies** with a focus on data governance.

Ensure that HHS, including **FDA and ASTP, has the proper tools to weigh the benefits and risks of AI-enabled products** so it can provide a predictable regulatory structure for product developers.

Legislation to **promote transparency for providers and the public** about the use of AI in medical products and clinical support services.

Policies to promote AI innovation that meaningfully improve health outcomes/efficiencies in health care delivery, including **CMS reimbursement mechanisms**.

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HHS has deployed AI to administer government programs and has advanced rulemaking for AI use in health care and life sciences

HHS' Office of the Chief AI officer, established in 2021, coordinates AI use across the department, developed a trustworthy AI playbook, and publishes its AI use cases publicly. HHS is generally considered the agency with health care within its purview; however, other agencies in their broad rule making could have an impact on health care such as the Department of Commerce, the Department of Justice, and the FTC.

Centers for Medicare and Medicaid Services (CMS)

- Since 2018, **CMS has used AI/machine learning (ML) to automate medical record review** functions within Medicare Advantage RADV audits.[1]

- CMS was able **to increase its compliance review efficiency of hospital price transparency machine- readable files using automated tools**, resulting in increased enforcement action between 2022 and 2023.[2]

- In February 2024, CMS issued guidance on the **use of AI to make coverage decisions in Medicare Advantage** stating that AI tools may only assist in decisions if regulatory requirements for coverage determinations are based on a patient's individualized circumstances.[3]
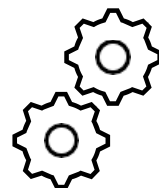
Assistant Secretary for Technology Policy (formerly ONC)

- In December 2023, ASTP published a final rule that included requirements for algorithm transparency for certified health IT.[4,5]

- Health IT developers are required to **make information available on the development, evaluation, fairness, effectiveness, and ongoing monitoring for predictive decision support technologies that interface with electronic health records.**
  (*Further detail in appendix*)

Food and Drug Administration (FDA)

- The FDA continues to receive **a large number of submissions for drug, biologic, and devices with AI/ML components** and expects that number to increase over time.[5]

- **In March 2024, the FDA published a paper outlining its regulatory focus for both drugs and medical devices, signaling that additional guidance and rulemaking is forthcoming.**[6]

- A **Digital Health Advisory Committee was established in October 2023** to advise the FDA on the regulation of digital health technologies (e.g., AI/ML, virtual reality, wearables) and is accepting applications for membership through December 2023.[7]
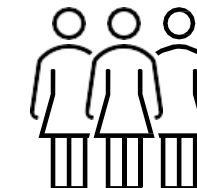
Office of Civil Rights (OCR)

- The OCR finalized modifications to ACA Section 1557 for **protections against algorithmic discrimination through the use of patient care decision support tools,** which include automated and non-automated tools, mechanisms, methods, and technology to provide patient care.

- The OCR director has participated in **interagency events to discuss the potential impact of AI on civil rights** through enforcement, education and outreach, interagency coordination and policy.

The FTC is one of the lead enforcement agency for unfair or deceptive AI practices and algorithm bias

FTC has signaled potential enforcement areas[2,3,4,5]

Discrimination or bias in AI

In an April 2023 release, FTC and three other federal agencies pledged to uphold fairness and equality in AI. The agencies will seek to **reduce bias within data sets**, **prevent discriminatory outcomes**, and **promote transparency about how data is used**.

Deceptive AI advertising

In a February 2023 blog post, FTC warned businesses that **false or unsubstantiated claims about a product's efficacy are their "enforcement bread and butter."** They warned businesses against exaggerating what an AI product can do.

Protecting the privacy of health information

In a July 2023 blog post, FTC uses examples of its recent enforcement actions against health technology companies to warn businesses on how they use and share health data. They warned against **improper sharing or receipt of consumer's health information** and **use of tracking technologies** that contradict privacy promises.

Key takeaways

- Under Chair Lina Khan, the FTC has taken an **active role** on health care privacy and AI.

- The **FTC has not issued formal rulemaking on AI** but has provided blog posts and guidance signaling the rules of emphasis in potential future enforcement actions.

- As of November 21, 2023, the **FTC authorized the staff to issue civil investigative demands** for investigations into products & services using AI.

"As companies race to deploy and monetize A.I., the Federal Trade Commission is taking a close look at **how we can best achieve our dual mandate to promote fair competition and to protect Americans from unfair or deceptive practices.**"
- Lina M. Khan, *FTC Chair, New York Times, May 3, 2023*[1]

Many state governments have enacted AI-related legislation

While federal policymakers have not enacted broad AI legislation, AI-related provisions are being introduced and enacted in state legislatures across the United States:

- Eleven states have enacted a data privacy law that includes a provision regulating the use of AI for profiling purposes
- Twelve states require businesses to perform a data protection impact assessment for high-risk profiling activities
- Colorado is the only state to enact legislation that provides protection from unfair discrimination in insurance rate-setting processes
- Utah passed legislation that requires clear disclosure to consumers that they are interacting with generative AI
- Florida passed legislation that political advertisements using AI-generated content are required to display a specified disclaimer
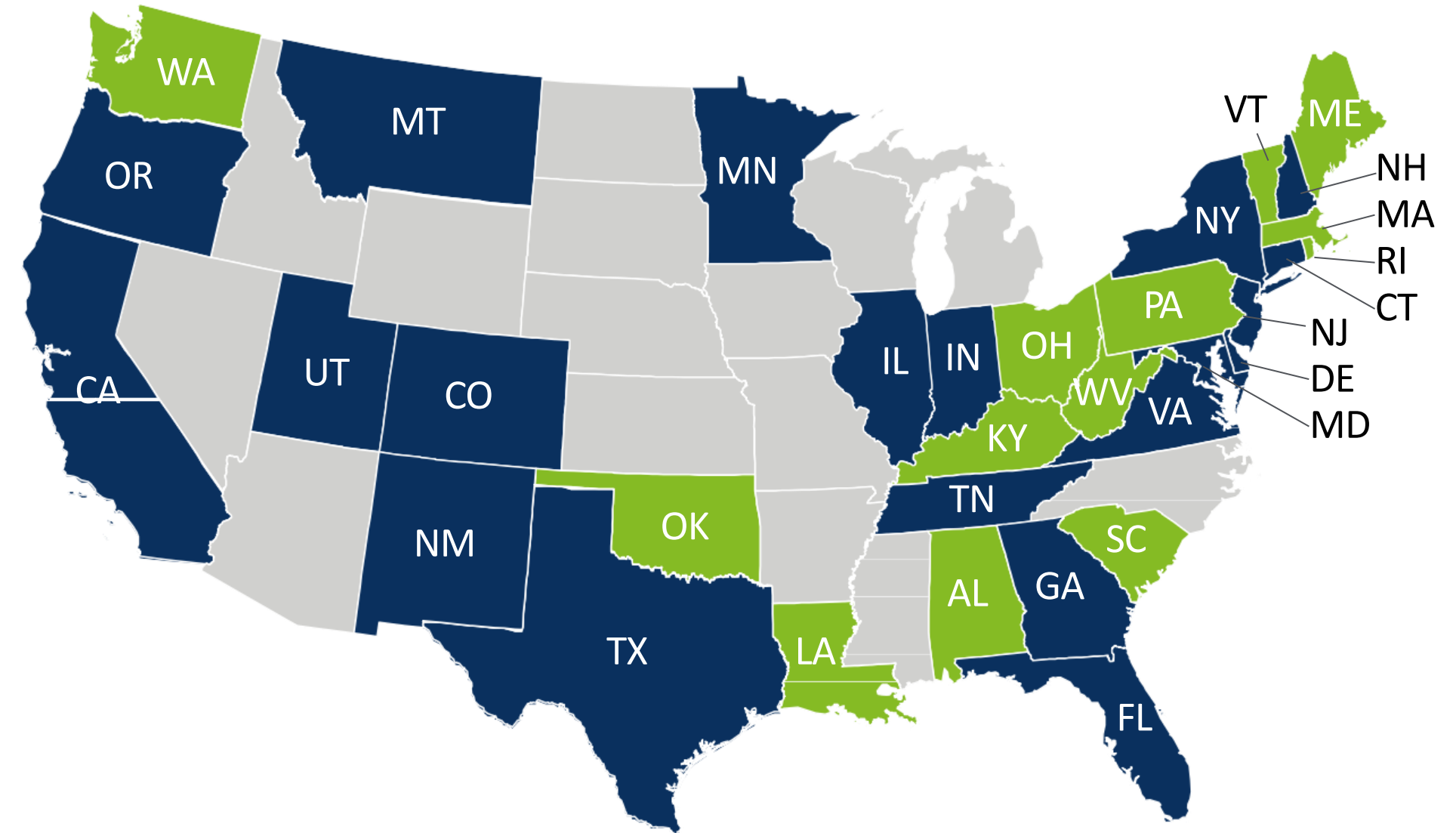
Notable AI-related provisions under consideration:

- **Oklahoma-** Introduced a bill that requires health insurers to disclose the use of AI algorithms and submit AI systems to Oklahoma Department of Insurance for review
- **Oklahoma and New York-** Introduced an AI bill of rights that are focused mainly on disclosure of AI interaction to consumers

- ▬ Enacted AI-related legislation (20)
- ▬ Pending AI-related legislation (13)
- ▬ No AI-related legislation

Policymakers are exploring the government's role in regulating AI in health care across several domains

PRIVACY
Protecting sensitive patient, member and consumer data from being shared inappropriately while balancing existing privacy protections and allowed uses established through federal and state privacy laws

TRANSPARENCY
Provide users, government officials, and the public information on data sourcing, AI model risks, and when AI or AI-enabled technologies are used in decision-making or content generation, which may be achieved through certification, auditing, or reporting.

DATA BIAS
Preventing algorithms built on biased data sets that may produce inaccurate predictions or perpetuate health inequities or unfair health outcomes

HUMAN INTERVENTION
Maintaining human decision-making involvement in high-risk uses of AI such as patient care or safety

SECURITY
Guarding security of individual health information and implementing protections for health care organizations to avoid cyberattacks and mitigate their impact

Across all these issues, policymakers are exploring questions around liability for negative outcomes and federal preemption of state laws

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Examine how compliance, internal audit and GenAI intersect, including regulatory and ethical considerations for using GenAI in healthcare, trust, and the potential of GenAI to facilitate compliance & internal audit tasks
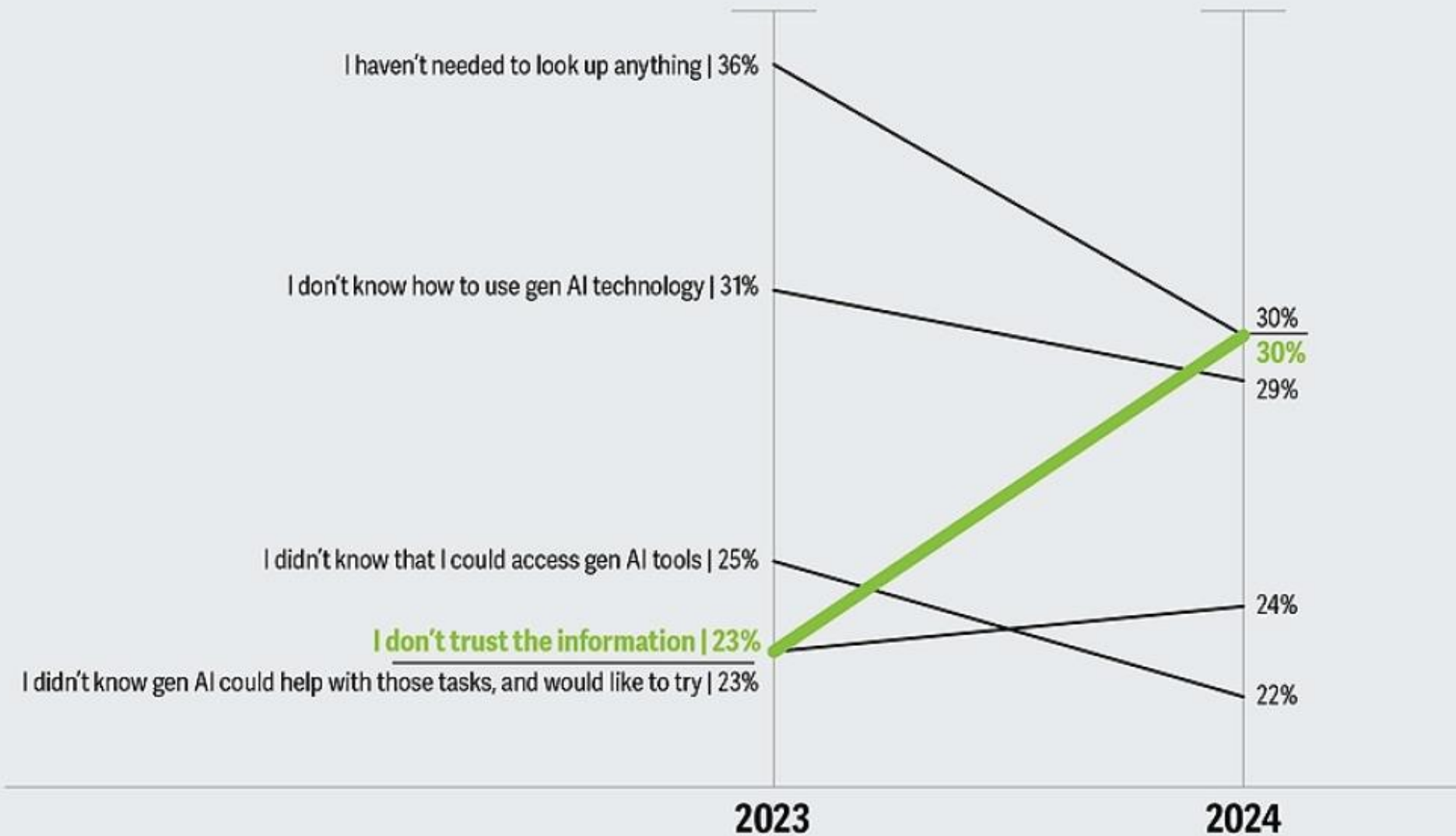
Health care consumer trust in Generative AI
Deloitte's Center for Health Solutions surveyed more than 2,000 US adults in March 2024 about their use of gen AI in health care.

Consumers are increasingly wary of the health care information that generative AI may provide

Why consumers aren't using gen AI for health- or wellness-related purposes

I haven't needed to look up anything | 36%

I don't know how to use gen AI technology | 31%

I didn't know that I could access gen AI tools | 25%

I don't trust the information | 23%

I didn't know gen AI could help with those tasks, and would like to try | 23%

2023 → 2024: 30% / 30% / 29% / 24% / 22%

2023   2024

Notes: N in 2024 = 1,054; N in 2023 = 1,020. The results represent the number of respondents who have not used gen AI for any health- or wellness-related reasons.

Source: Deloitte Center for Health Solutions' 2024 Health Care Consumer Survey.

General optimism but increasing distrust

- **66%** of consumers feel generative AI has the potential to **reduce patient wait times** and lower individual healthcare costs
- Adoption of for health reasons **has not significantly changed** year over year (37% of consumers using it in 2024 versus 40% in 2023)
- **30%** of consumers not using generative AI for health and wellness purposes indicated they "**don't trust the information**"

https://www2.deloitte.com/us/en/insights/industry/health-care/consumer-trust-in-health-care-generative-ai.html

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AI in Medicare Advantage: Ethical and Operational Challenges

Key Findings from U.S. Senate Permanent Subcommittee on Investigations Report: The country's three largest Medicare Advantage (MA) insurers obstruct seniors' ability to receive post-acute care.

Increased Denials Rates

- Large insurers used AI to increase denial rates for post-acute care, significantly impacting seniors.
- One company reported denials in post-acute care were 16 times higher than the companies' overall denial rates.

Financial Incentives

- In 2018, one large payer predicted to save more than $660 million from denying prior authorization requests for inpatient facilities.
- They are predicted $77 million in savings over three years from AI deployment in skilled nursing facilities.

Operational Practices

- Automated processes sped up claims decisions but led to higher denial rates; one post-acute care data business instructed not to assist providers with prior authorization questions.

Regulatory and Ethical Concerns / Actions

- The subcommittee is recommending CMS collect prior authorization data, conduct audits, and enhance regulation around insurers' internal committees to address potential biases and cost-cutting pressures.
- CMS is performing audits and implementing new policies expected to save the healthcare industry $15 billion over 10 years.
- If CMS identifies an insurer as non-compliant, it is allowed to issue notices and warning letters and request corrective action plans, enforcement letters, enrollment and marketing sanctions and civil monetary penalties.

> " *It's past time that legislators and regulators hold plans accountable and protect patient care.*
>
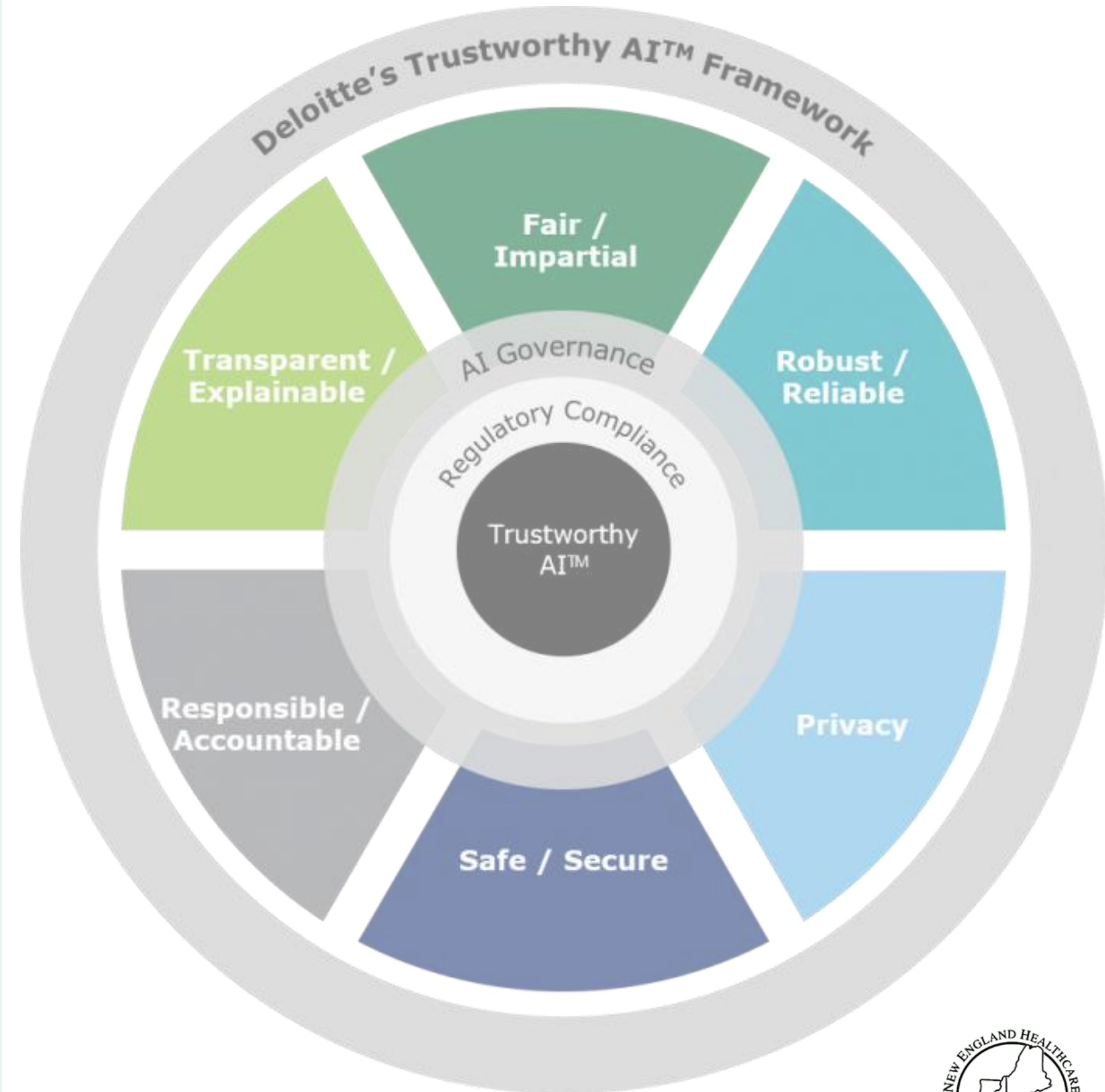> -Chip Kahn, Federation of American Hospitals President and CEO

Artificial Intelligence (AI)
to advance health care with trust at the center

As AI continues to mature, organizations and policymakers alike recognize the potential benefits and associated risks. In response, **frameworks to promote "trustworthy AI" are guiding decision-making for many organizations and rule-making by policymakers**.

Integrating an understanding of public policy into AI strategy and design can help organizations advance their technology strategy in a manner directionally aligned with policy trends while maintaining a competitive edge.

For the health care industry, there are unique public policy considerations regarding the use of AI to ensure **patient safety and to promote ethical and equitable health outcomes.**

Deloitte's Trustworthy AI™ Framework

- Fair / Impartial
- Robust / Reliable
- Transparent / Explainable
- AI Governance
- Regulatory Compliance
- Trustworthy AI™
- Privacy
- Responsible / Accountable
- Safe / Secure

Source: Deloitte's Trustworthy AI Framework

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Governance of Artificial Intelligence

National Association of Corporate Directors (NACD) AI and Board Governance Report

In September, the NACD released a report detailing the boardroom's role in AI governance, aimed at helping directors understand the fundamentals of underlying AI technologies.

The report emphasizes that AI applications are already influencing businesses and underscores the need for boards to oversee AI's unique risks to capitalize on its opportunities.

Additionally, the report addresses the operational and regulatory issues that can shape a company's AI journey.

Preparing for AI Governance

NACD 2023 survey data showed that 95% of directors believe **AI will impact their business within the next year**. However, only 28% report that AI is regularly discussed in board meetings. As boards anticipate AI's significant impact, they should assess their readiness and prepare for oversight in the five areas

01 Impacts on Strategy and Risk
Understand the company's current engagement with and use of AI and how to integrate AI into discussions of strategy and risk.

02 Committee Responsibility
Leverage the strengths of existing committees to oversee the various components of AI where they would be most appropriately governed.

03 Board Composition
Evaluate board composition in context of changes stemming from AI. The technology may warrant new skills, experiences, and backgrounds on the board to provide effective oversight.
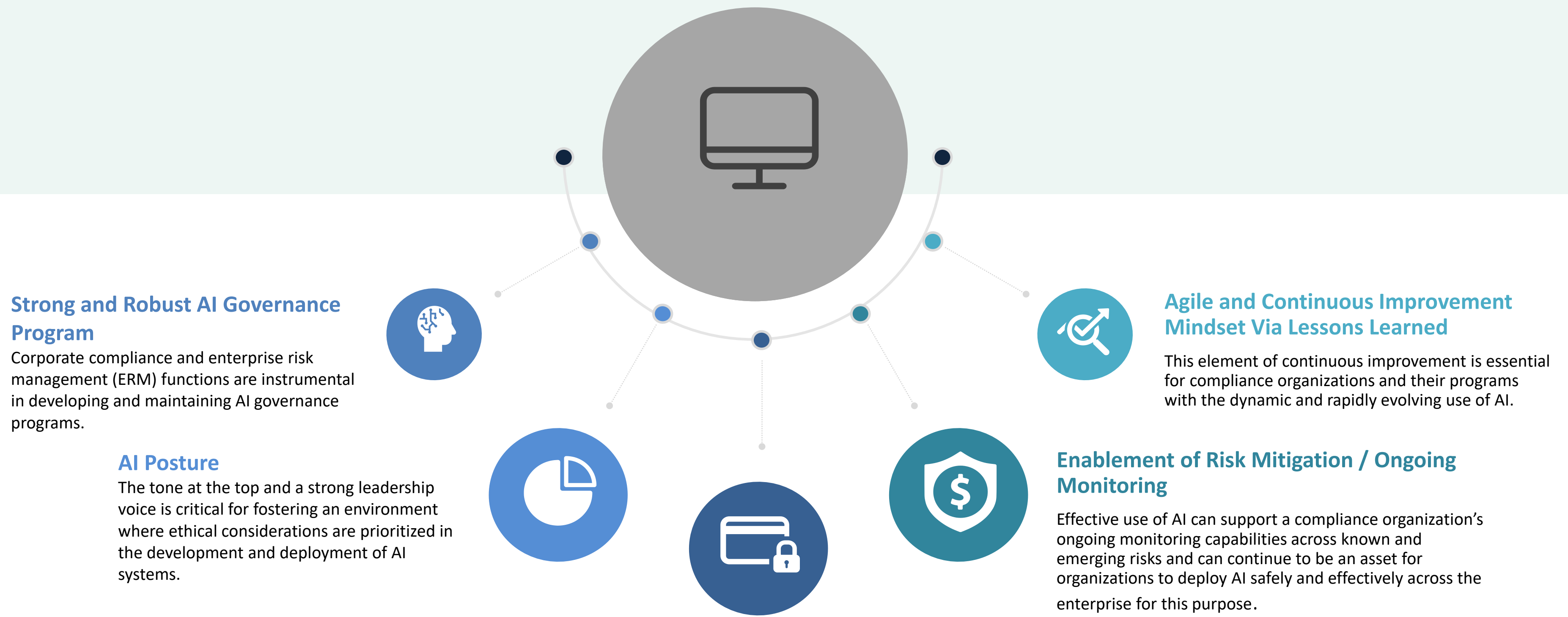
04 Director Education
Invest in ongoing director-specific education, including management presentations, outside experts, personal engagement with AI research, or attendance at AI events.

05 Management Reporting
Work with management to receive much more frequent, forward-looking updates about the company's AI initiatives.

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Updated Department of Justice (DOJ) Guidance: Why trust and secure AI matters

Strong and Robust AI Governance Program

Corporate compliance and enterprise risk management (ERM) functions are instrumental in developing and maintaining AI governance programs.

AI Posture

The tone at the top and a strong leadership voice is critical for fostering an environment where ethical considerations are prioritized in the development and deployment of AI systems.

Agile and Continuous Improvement Mindset Via Lessons Learned

This element of continuous improvement is essential for compliance organizations and their programs with the dynamic and rapidly evolving use of AI.

Enablement of Risk Mitigation / Ongoing Monitoring

Effective use of AI can support a compliance organization's ongoing monitoring capabilities across known and emerging risks and can continue to be an asset for organizations to deploy AI safely and effectively across the enterprise for this purpose.

Inventory and Risk Identification of AI Use

This foundational step enables organizations to effectively manage and mitigate risks while aiding in compliance with legal, ethical, and regulatory standards.

Illustrative Use Cases for Legal, Risk & Compliance

CATEGORY	USE-CASES
Overall	• **Enterprise Policy Chatbot:** Generative AI can leverage Enterprise Policy data to create a searchable knowledge-surfacing GAI interface to allow associates to get answers more efficiently than searching for information manually through other channels.
Legal	• **eDiscovery Data Processing and Review:** AI can quickly process and review vast amounts of data to identify relevant documents and information for a case. • **Legal Research:** AI can automate the process of legal research, sifting through large volumes of legal texts, case laws, and precedents to identify relevant information. Generative AI can summarize these findings in a concise and easy-to-understand format. • **Policy and Contract Generation:** Generative AI can generate policy documents and contracts based on company standards and legal requirements. This can help ensure consistency and accuracy in these critical documents. • **Automated Invoice Review:** AI can review legal invoices, identify billing errors, and ensure compliance with billing guidelines.
Compliance	• **Compliance Monitoring:** Generative AI can help conduct more targeted monitoring reviews while significantly reducing time spent performing review of unstructured data. • **Compliance Risk Identification & Mitigation:** Generative AI can automate data analysis, regulatory monitoring, and recommendations that enable real-time accuracy and streamlined collaboration across the risk identification and mitigation cycle
Risk	• **Regulatory Compliance Data Analysis & Reporting:** AI can automate the process of regulatory reporting, ensuring that the company is always in compliance with reporting requirements. Generative AI can generate reports in the required format, reducing the risk of errors and omissions.

The Role of Compliance, Privacy, and Internal Audit Professionals in AI

Educate Yourselves About AI Technology

Familiarize yourself with AI applications relevant to your field. Participate in training sessions, webinars, and workshops.

Understand the Risks and Opportunities

Identify potential risks (e.g., data privacy, bias) and opportunities (e.g., efficiency, enhanced analytics) associated with AI.

Stay Informed on Regulatory Concerns

Monitor guidance from regulators and agencies to ensure compliance with evolving standards and best practices.

Establish Governance and Oversight

Collaborate with leadership to develop policies and procedures that ensure responsible AI use within your organization.

Leverage AI Tools in Your Work

Use AI for data analysis, process automation, and other functions to enhance productivity and decision making.

Understanding these next steps allows an organization to embed AI considerations into risk and compliance plans

Integration with Existing Systems

Ensure AI systems can seamlessly integrate with existing health care IT systems. Maintain high data quality standards to ensure AI systems have access to accurate and reliable data.

Cross-Functional Teams

Work closely with IT, data science, and legal teams to ensure a holistic approach to AI risk management and compliance.

Implement Continuous Monitoring

Use AI tools to continuously monitor compliance with established controls and detect any irregularities in real-time. Ensure that AI models are regularly updated to reflect new data and emerging risks.

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Meet the speakers

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RELEVANT EXPERIENCE

Kelly is a partner with over 26 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 18 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.

QUESTIONS