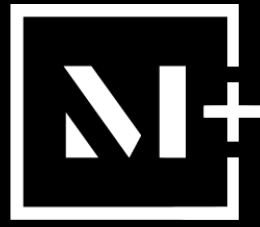




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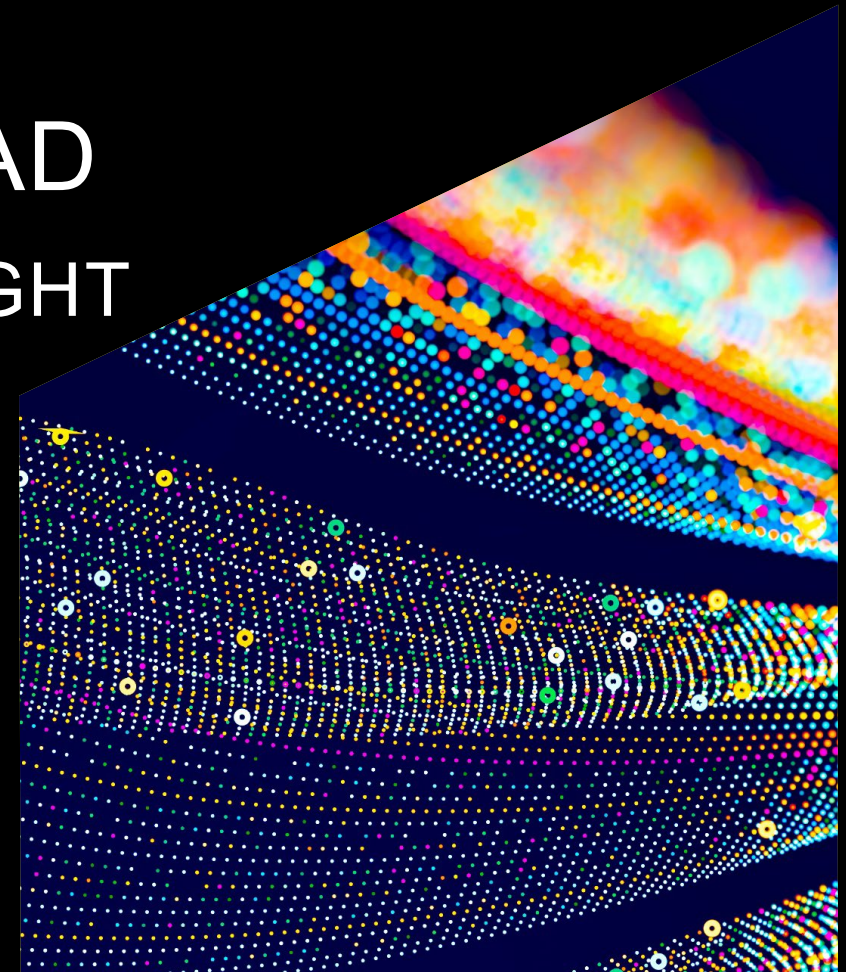
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AI AND THE NEXT FRONTIER: UNDERSTANDING WHAT'S AHEAD

HEALTH POLICY, REGULATORY OVERSIGHT AND MARKET ACCESS

Deborah Godes, Vice President
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November 8, 2023



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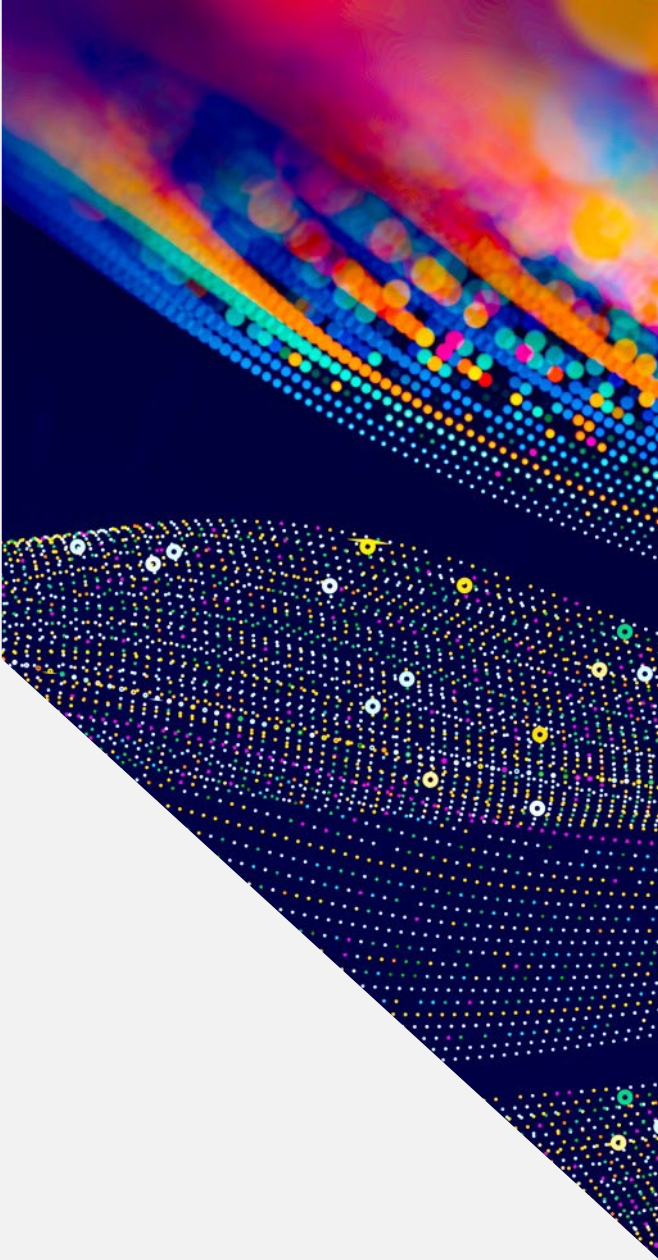
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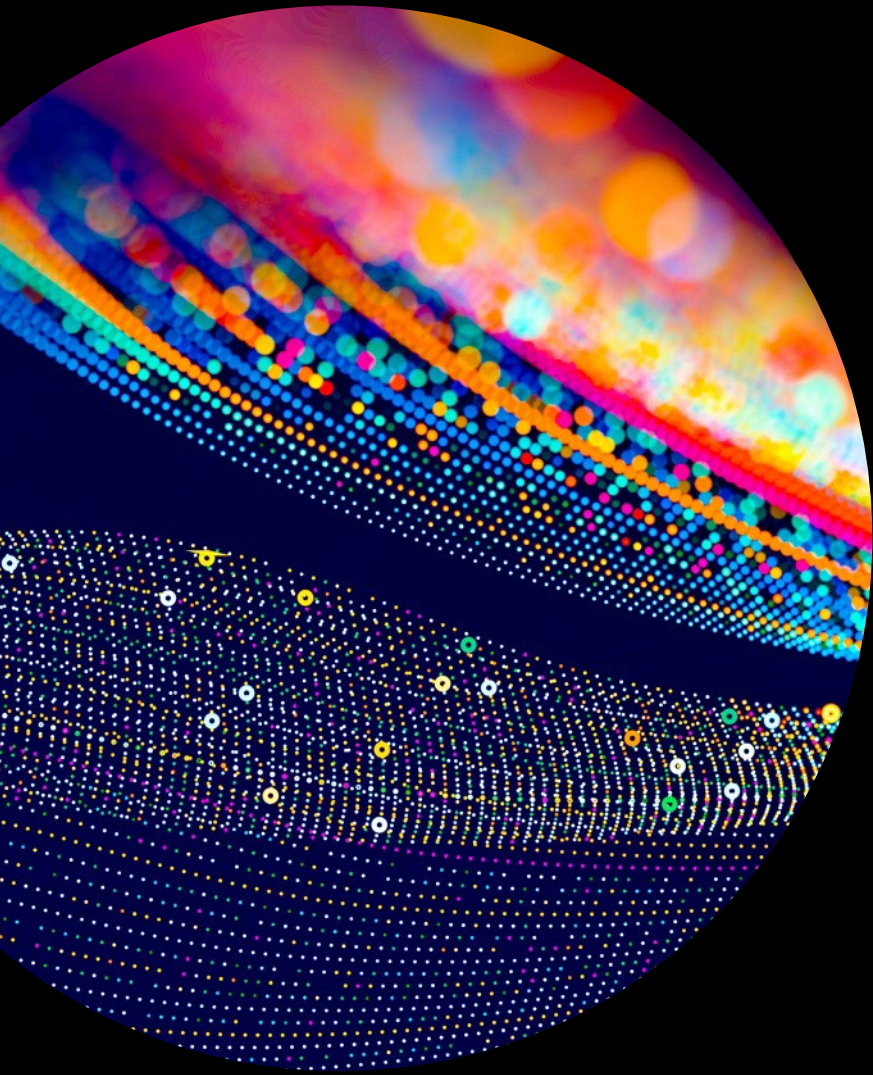
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AGENDA

- Level Set on AI
- Recent Update: Executive Order
- Congressional Interest
- Regulatory Landscape
- Coding and Payment



UNDERSTANDING THE CONCEPTS

AI and its Use-Cases in Healthcare

UNDERSTANDING THE CONCEPTS

AI: Study and development of computer systems that can copy intelligent human behavior

- Goal of AI is to create systems that think and act rationally and act like humans
- Types of AI that are relevant to healthcare:
 - Natural language processing
 - Rule-based expert systems
 - Physical robots
 - Robotic process automation

UNDERSTANDING THE CONCEPTS

Machine Learning: Field of study that gives computers the ability to learn without explicitly being programmed

- Subfield of AI
- Uses data and algorithms to mimic human learning, which improves the program's accuracy over time

APPLICATIONS IN HEALTHCARE

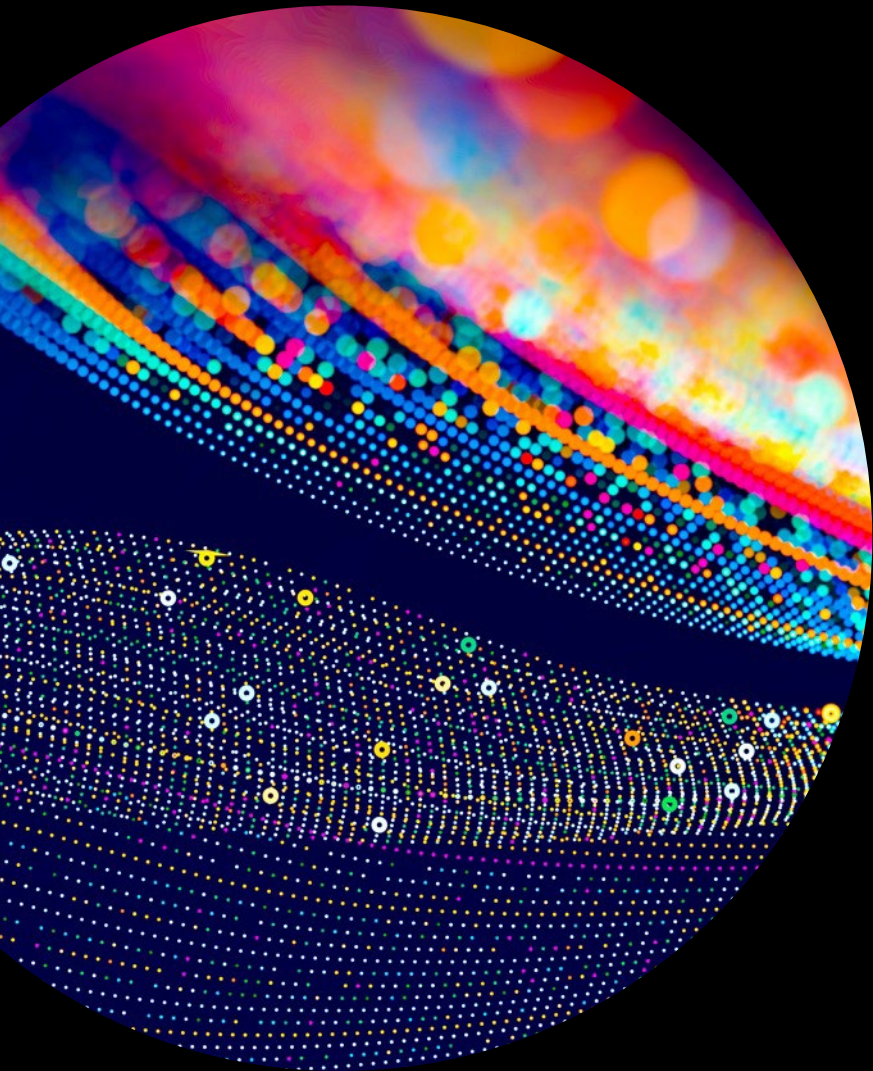
Use of AI and machine learning in healthcare is a growing and evolving field with great potential

Patient Care

- Improved decision-making
- Accelerating innovation in drug discovery and development
- Monitoring and managing patient health
- Personalized messaging and communication using patient data

Administrative Processes

- Claims processing
- Clinical documentation
- Revenue cycle management
- Medical records management



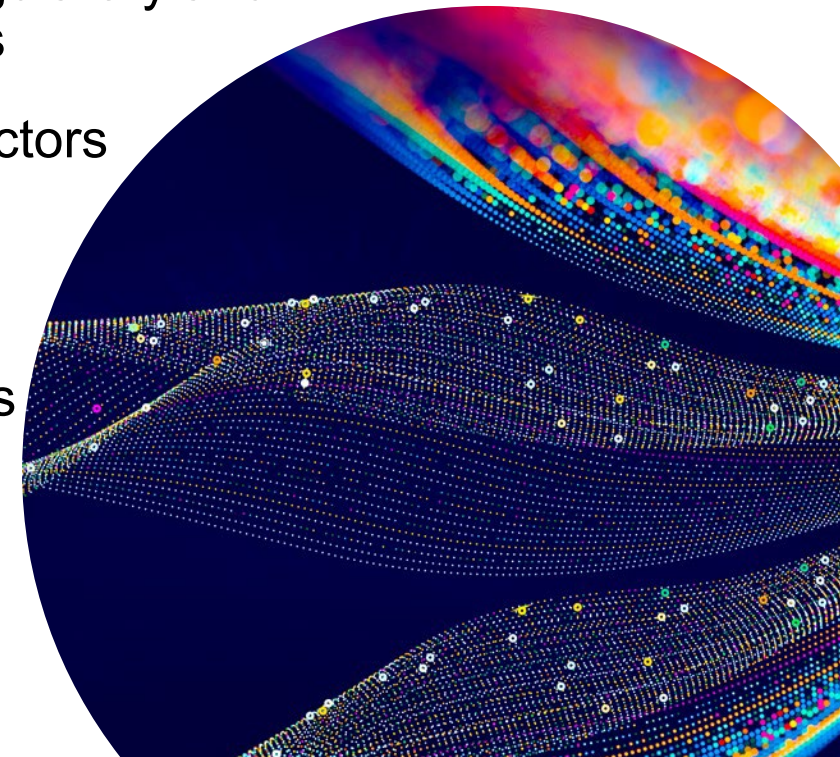
RECENT UPDATE: EXECUTIVE ORDER

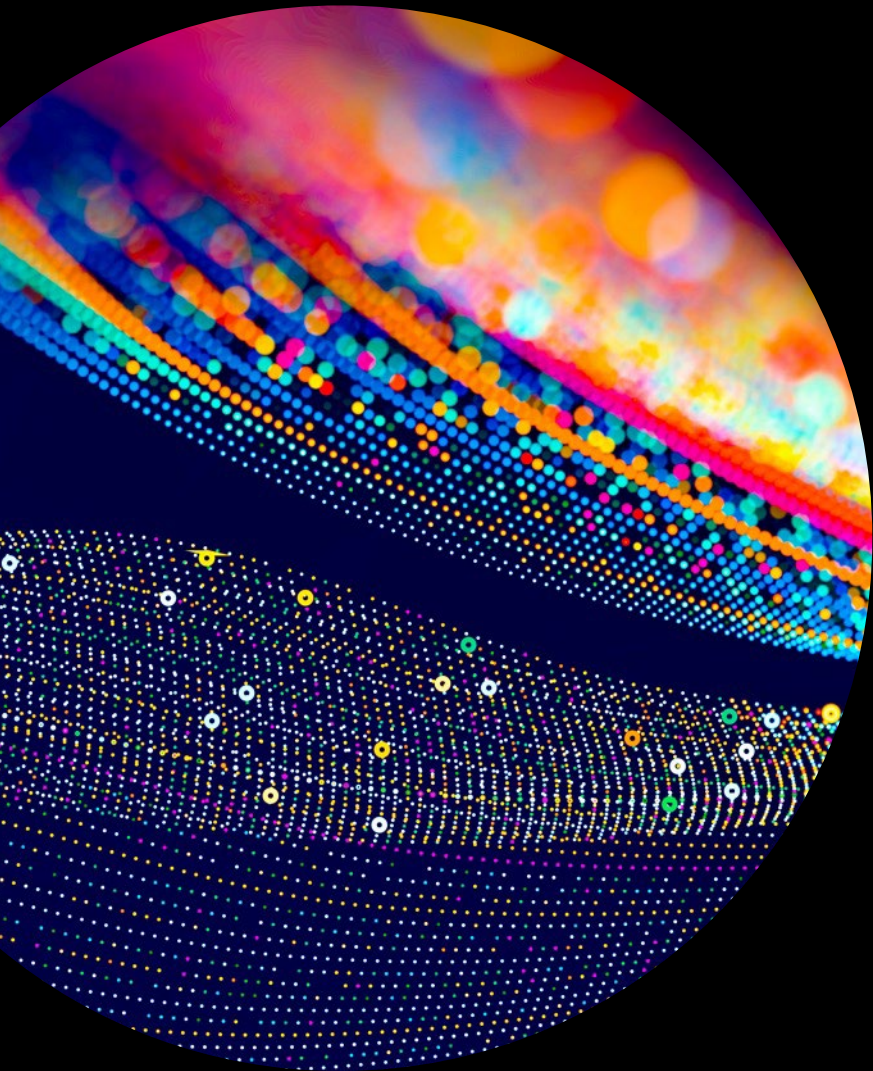
The President issued a wide-ranging AI Executive Order on October 30, 2023.

EXECUTIVE ORDER ON AI

Key Takeaways

- Significant impact on technology companies developing “foundation models,” and with government contractors and others developing advanced AI systems
- Directs action, reevaluation and potential changes in existing regulatory and enforcement schemes that could affect a variety of organizations
- There are healthcare specific directives and sector agnostic directives
- Numerous federal agencies/divisions involved
- A range of opportunities for formal and informal engagement to shape AI policy and standards, including through new task forces
- Impact of election year





CONGRESSIONAL INTEREST

Increasing interest from both sides of the Capitol,
but more education for policymakers is needed.

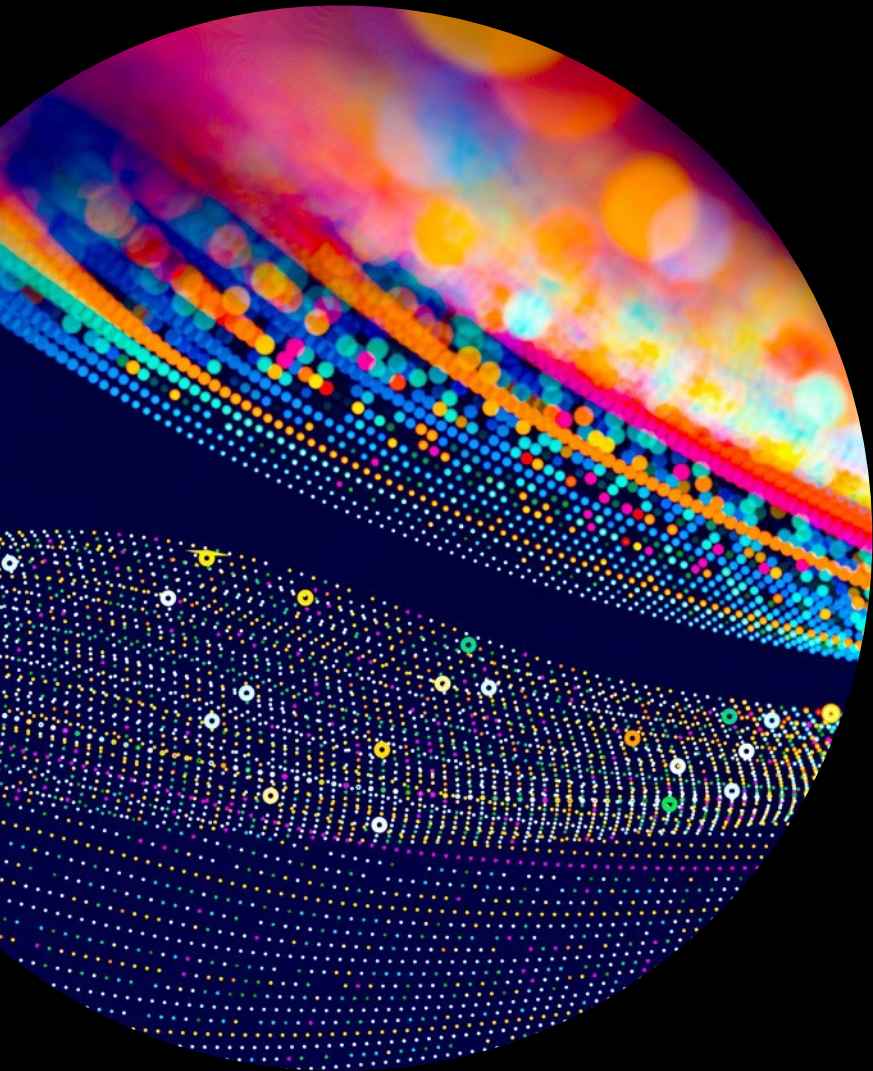
CONGRESSIONAL INTEREST IN AI

Key Efforts

- Senate Majority Leader Chuck Schumer (D-NY) continuing to hold roundtables and listening sessions
- Senate Ranking Member of HELP Committee, Bill Cassidy (R-LA), released white paper and request for feedback on AI in healthcare
- Senate HELP Subcommittee holding hearing this week on the use of AI in healthcare
- House Energy and Commerce Committee undertaking series of hearing on AI, including healthcare

Key Takeaways

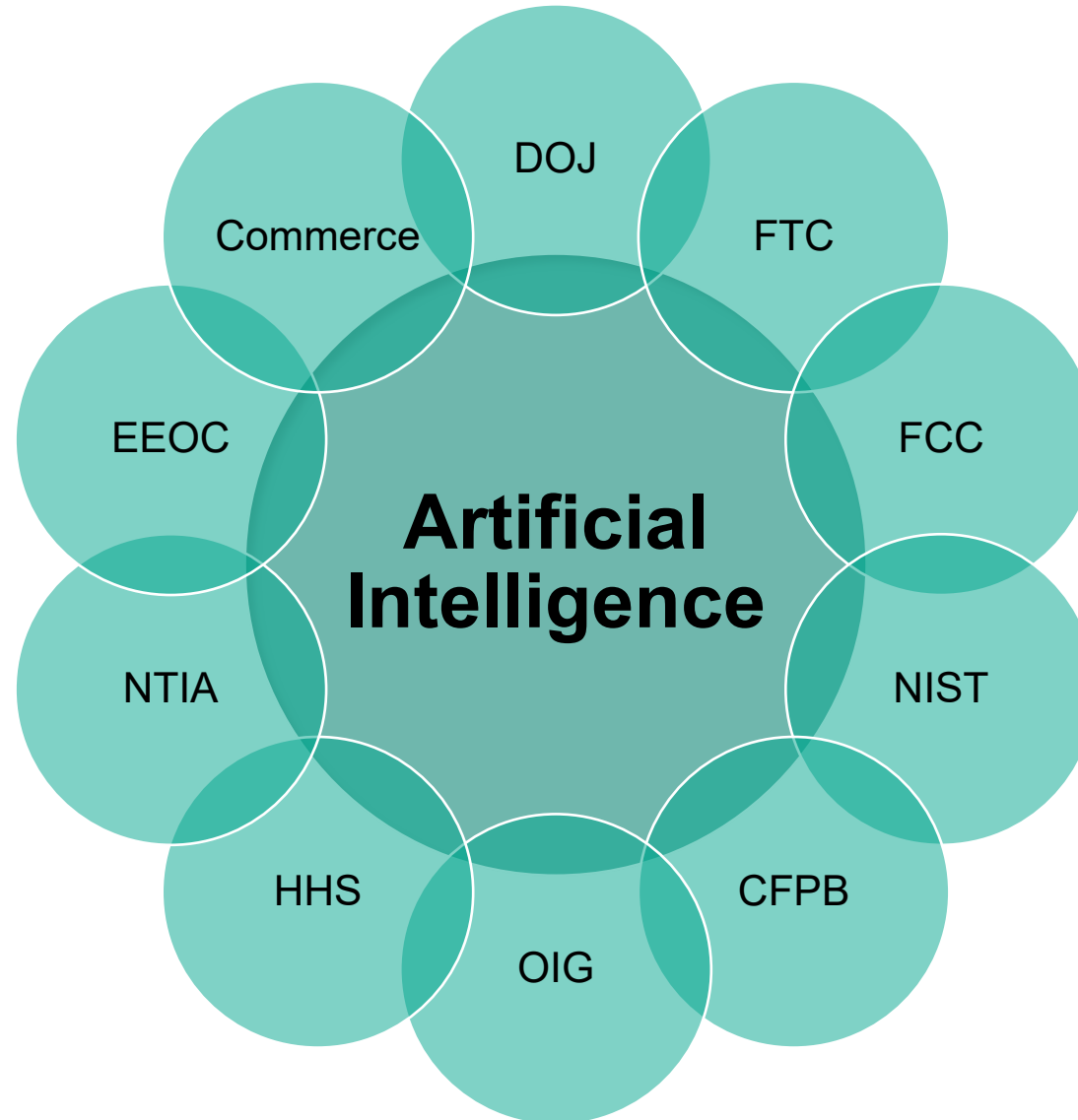
- Congress is digging into understanding the use of AI across sectors, including healthcare
- Need for reinforcement of AI vs. AI in healthcare
- Engagement and education is needed to understand risks and benefits of regulations of AI in healthcare



REGULATORY LANDSCAPE

How can regulation balance supporting innovation and protecting patients, providers and consumers of healthcare?

WHO IS REGULATING ALL OF THIS?



AVOID OVERREGULATING AI VS. NEEDED SAFEGUARDS



Drafts, frameworks and non-binding guidance



Often more managing immediate risks and safety concerns



National vs. state-specific approaches

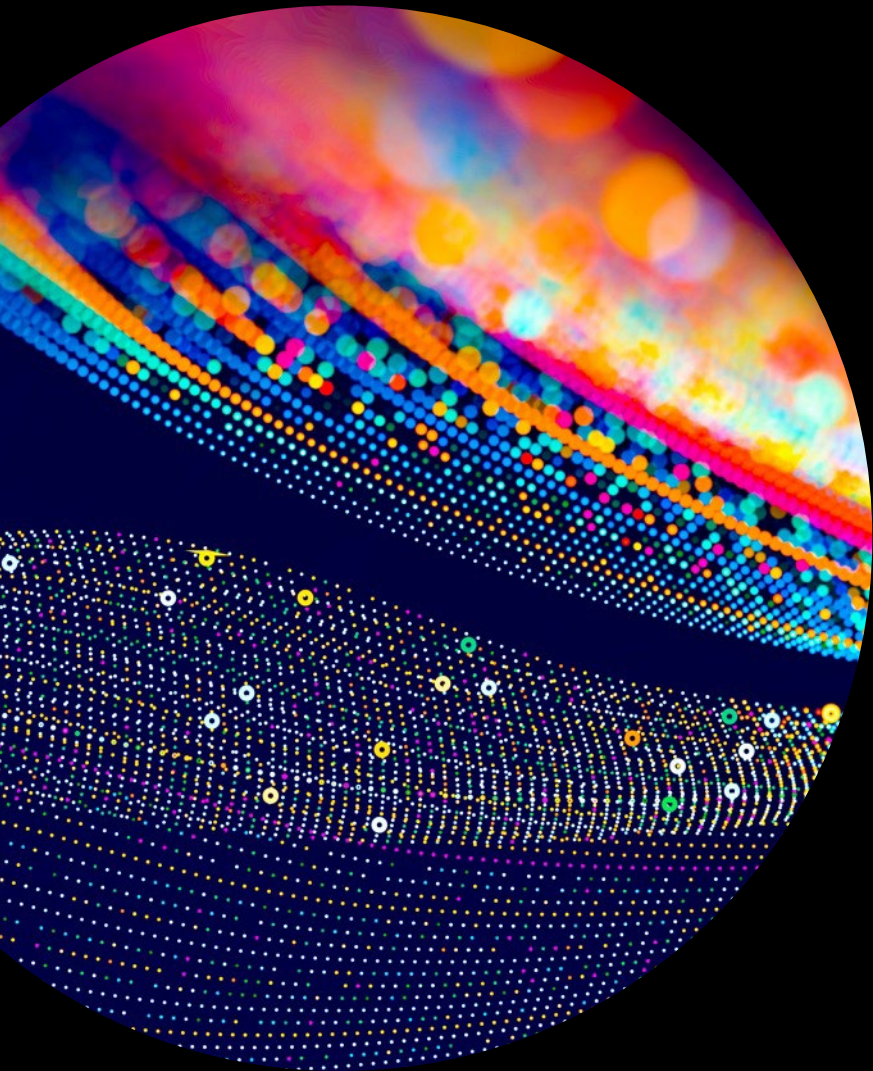
SHAPING THE REGULATORY ENVIRONMENT



Other stakeholders: state AGs; state regulators; boards of medicine



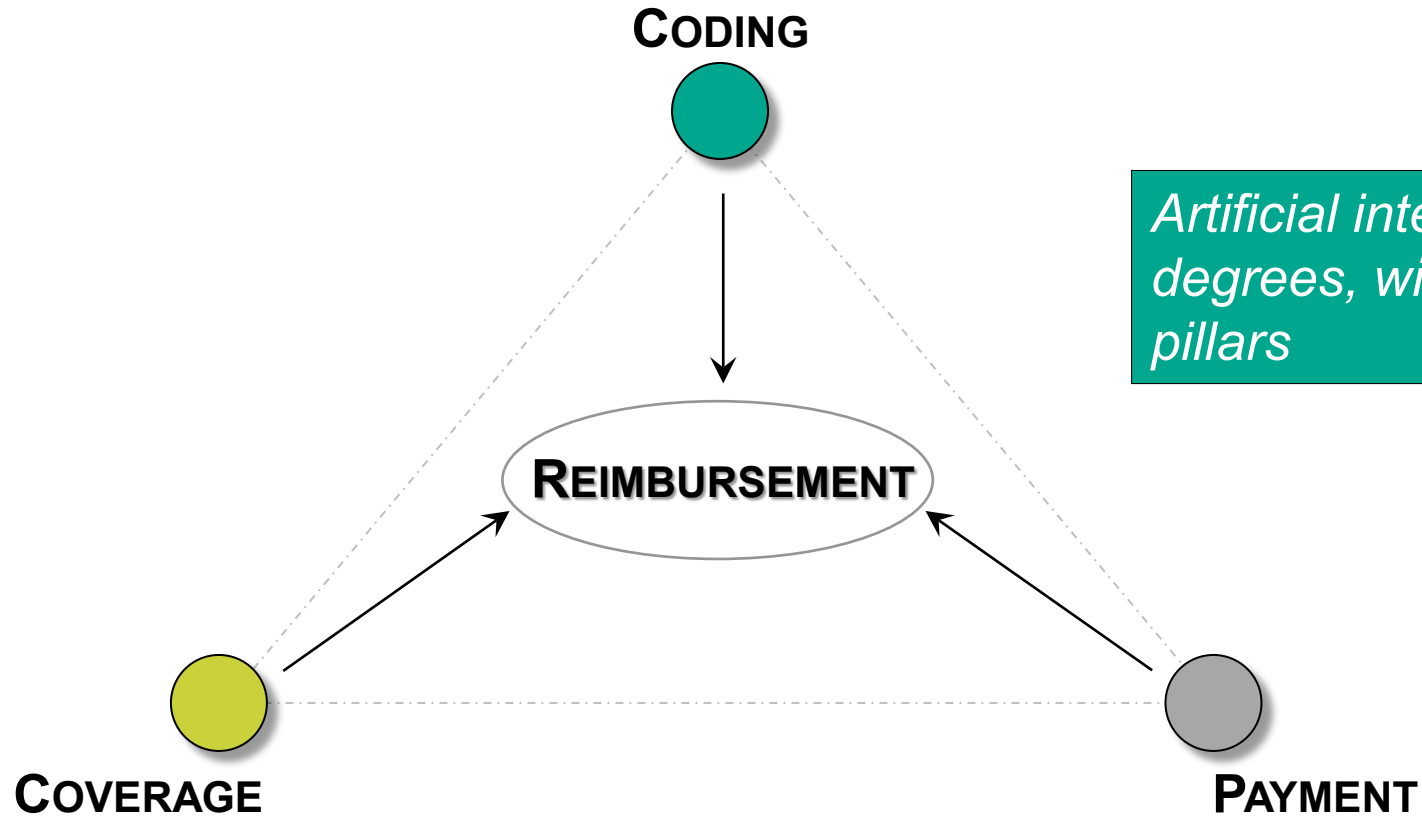
Other influencers: trade associations (AMA, AHA, PhRMA); think tanks; politics



CODING AND PAYMENT

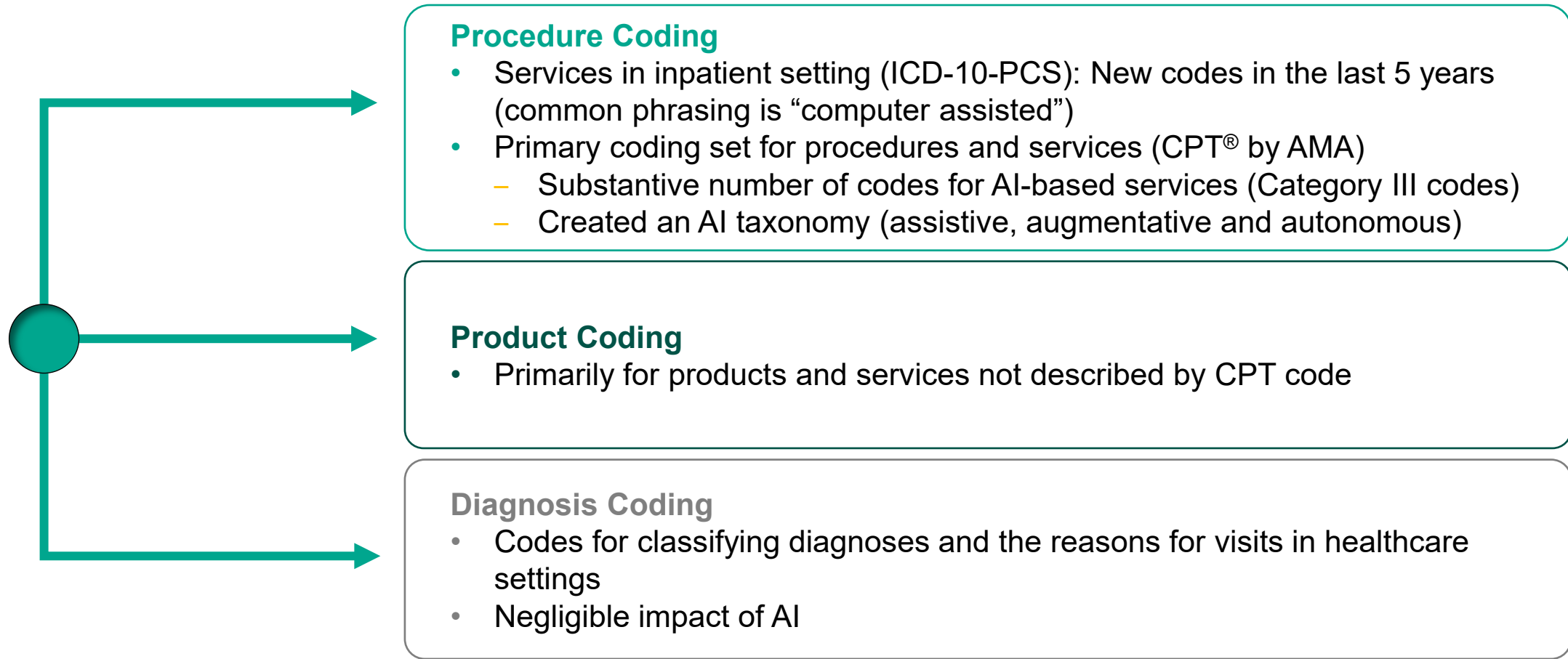
What the current state-of-play and important considerations are for the future of reimbursement.

PILLARS OF REIMBURSEMENT

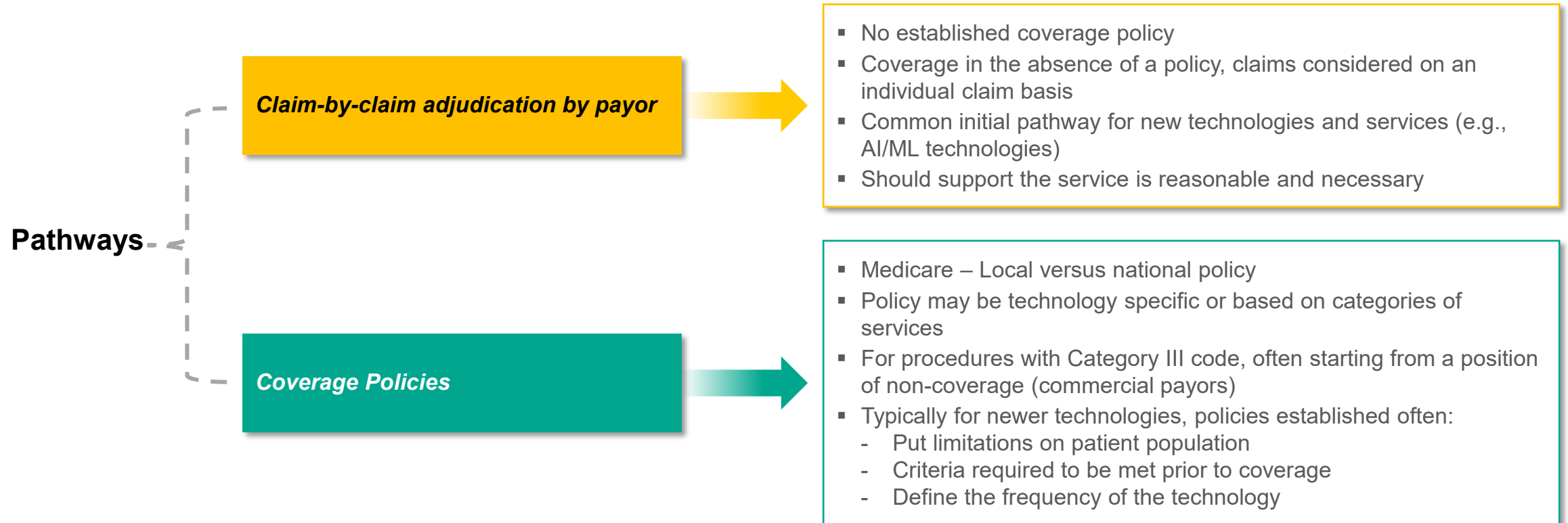


Artificial intelligence has emerged, in varying degrees, within each of these reimbursement pillars

INFLUENCE ON CODING



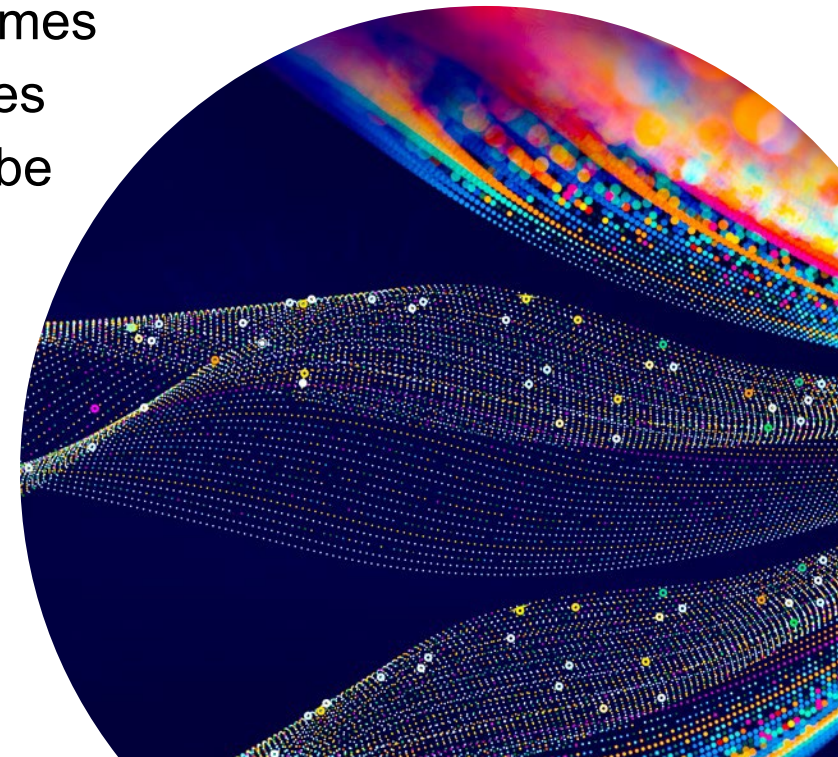
COVERAGE OF AI SERVICES



Variability in the coverage positions taken by the payors – many still reviewing on a claim-by-claim basis, but some coverage policies beginning to emerge

COVERAGE TAKEAWAYS

- Coding may impact the coverage position taken by payors
- Important to understand the implications of the different coverage positions
- Key considerations to drive changes in a negative coverage policy:
 - Evidence to demonstrate that the technology improves outcomes
 - Physician or professional society support via clinical guidelines
 - Cost savings is not a consideration under Medicare but may be persuasive for non-Medicare payors



EARLY EXPERIENCES WITH PAYMENT

- AI-based technologies have leveraged existing pathways under Medicare for incremental payment
 - Pathways: New technology add-on payment and new technology ambulatory payment classification (APC)
 - Payment amount reflective of the cost to the hospital for delivering the service/care
 - Pathway for ~2-3 years following market availability
- Limited number of technologies priced nationally under the different Medicare fee schedules
 - CMS continues to grapple with how to price AI-based technologies
 - Seek input from stakeholders through the different payment system regulations

COMMON THEMES IN REIMBURSEMENT

Early movers have had initial success in obtaining reimbursement in all three settings

Coding: Established pathway with potential framework for classifying these types of technologies

Coverage: Limited coverage policies to date based on newness of the technologies and limited utilization

Payment: Success in obtaining payment in the different settings but majority of decisions have been on a case-by-case basis rather than broader policy, uncertainty remains

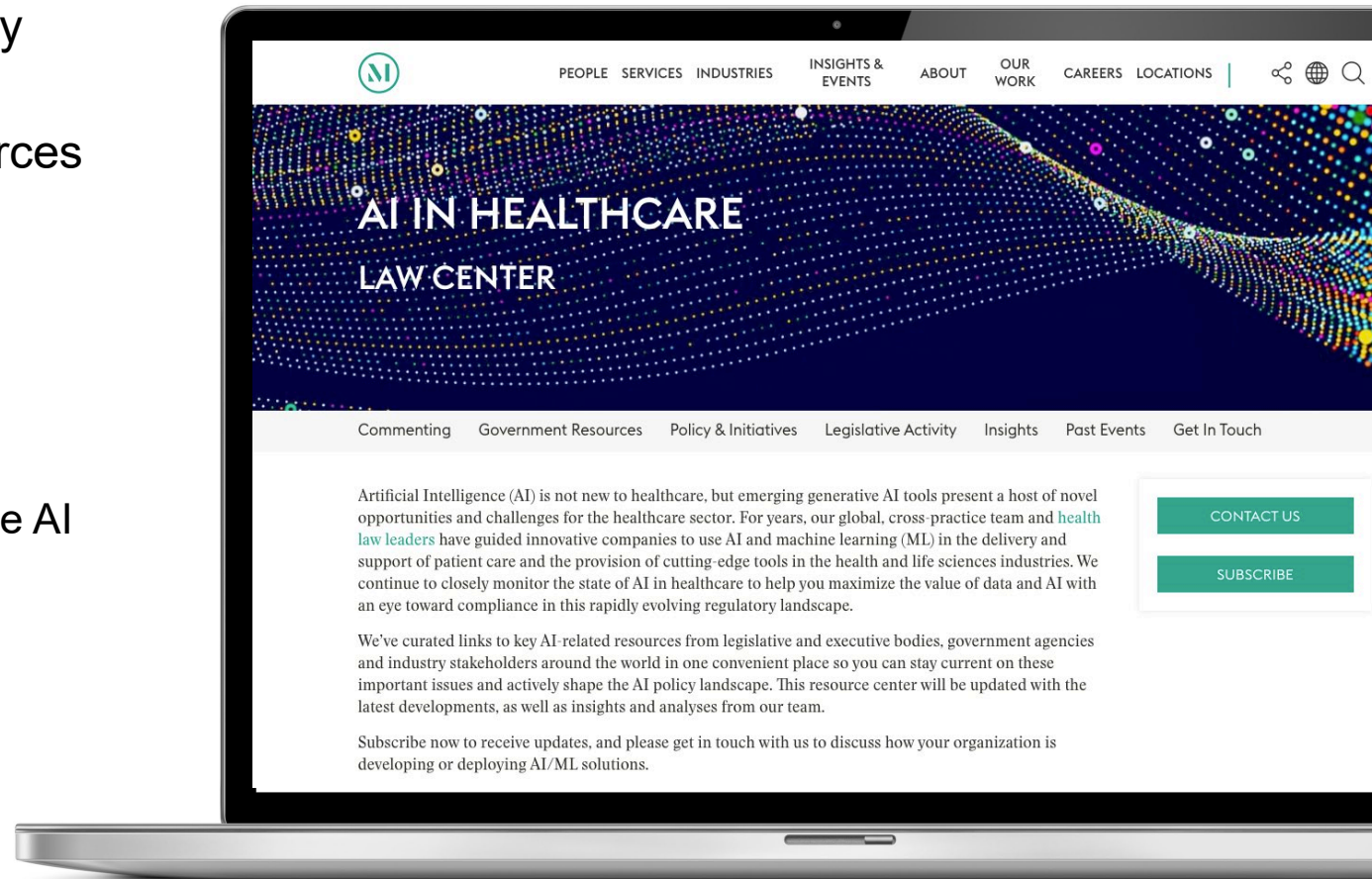
Critical to stay engaged and monitor continued developments in reimbursement

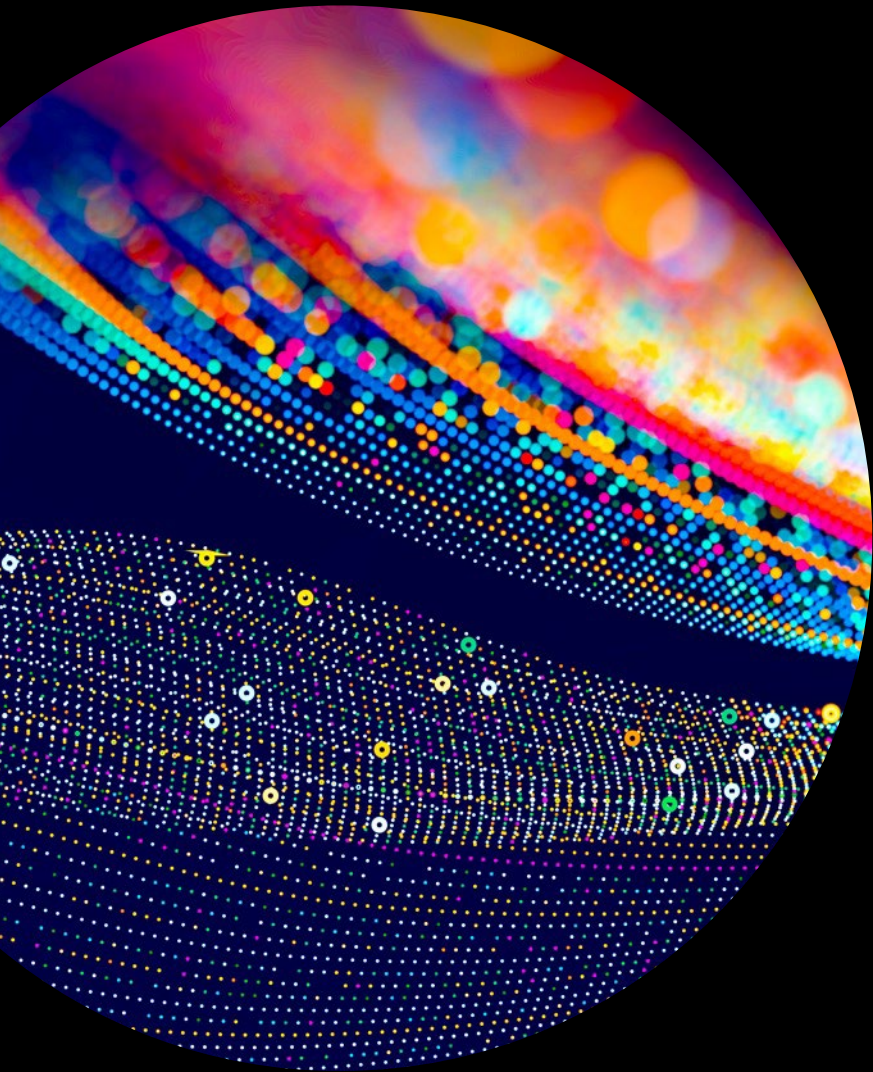
ADDITIONAL RESOURCES

The McDermottPlus and McDermott Will & Emery teams are following this rapidly developing landscape, providing clients with essential resources to navigate, advocate and prepare for upcoming changes.

- Visit our [AI in Healthcare Resource Center](#)
- Read our [+Insight](#) on the AI Executive Order
- Listen to the Health Policy Breakroom [podcast](#) on the AI Executive Order

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THANK YOU