AI Policy: Federal Overview and Short Term Trends

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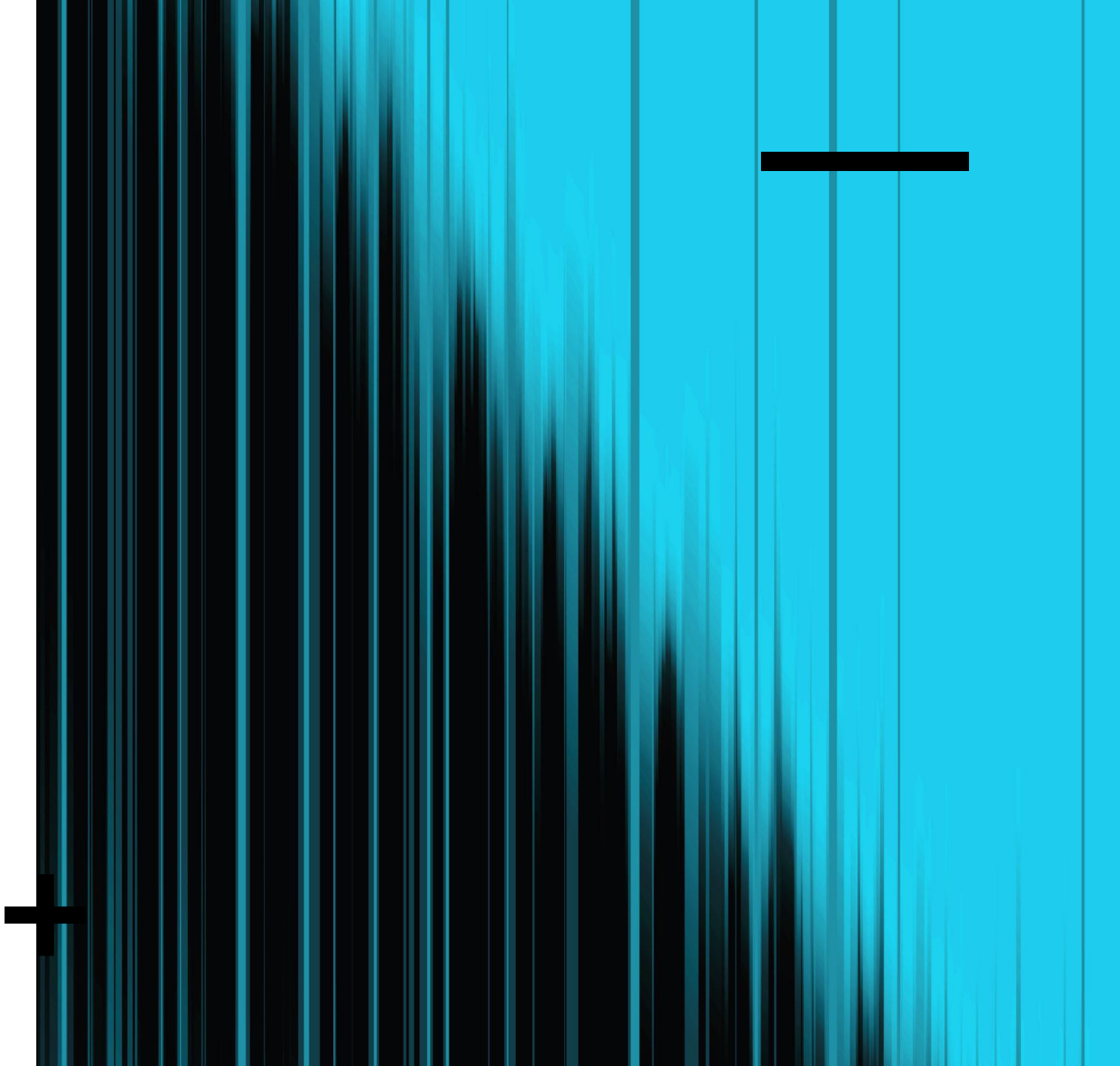

Robb Walton

Principal

Robb is co-head of the Access and Reimbursement division of the health practice at the BGR Group.

Robb came to the firm in 2017 after spending a decade as a health policy staffer in Congress. Most recently, Robb was Senior Health Policy Counsel for Senator Bill Cassidy (R-La.) where he managed the health policy team and developed the Senator's health care agenda for his role on the Health, Education, Labor and Pensions (HELP) and Finance committees. During his time with Sen. Cassidy, Robb worked on and passed legislation related to physician payment reform (MACRA), Medicare, Medicaid, private health insurance, mental health, and health information technology (HIT). Robb started his career on Capitol Hill as committee staff for HELP Committee Ranking Member Mike Enzi (R-Wyo.). During his time on the committee, Robb worked on the debate over the Affordable Care Act and subsequent implementation and oversight.

Robb received his Bachelor of Arts degree in history and philosophy from the University of Maryland where he was inducted into the Phi Beta Kappa Society. He received a Master of Arts degree in American Government and Public Policy from Georgetown University and a J.D. from American University, Washington College of Law, where he was honored Cum Laude and was Vice President of the Student Bar Association. Robb is a member of the Maryland Bar and resides in McLean, VA where he lives with his wife and two daughters.

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Federal Landscape Context

- AI is a relatively new topic for federal policymakers, who are still grappling with understanding its complexities and implications.

- Unlike some other issues, there is bipartisan cooperation and a deliberate approach to developing AI policy.

- This presents an opportune moment for AAPAN members to engage with policymakers and advocate for their priorities in the evolving AI landscape.

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Key Congressional Developments

- Schumer-Rounds AI Working Group
- Senate HELP AI White Paper
- Bipartisan Privacy Bill
- AI Governance and Transparency Act
- House Bipartisan AI Taskforce
- Senate Finance Committee Hearing on AI in Health Care
- Medicare Transaction Fraud Prevention Act

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Schumer (D-NY)-Rounds (R-ND) AI Working Group

Overview:

- Established by Senate Majority Leader Chuck Schumer (D-NY) and Senator Mike Rounds (R-SD), the bipartisan working group aims to address the opportunities and challenges posed by artificial intelligence (AI) technologies.
- Focuses on a comprehensive approach to AI policy, encompassing increased federal funding, research for safe AI usage, and efforts to counter global competition, particularly from China, to ensure U.S. leadership in setting global standards.
- The group is expected to produce policy recommendations aimed at promoting AI innovation, addressing regulatory challenges, ensuring national security, and advancing ethical AI practices. These recommendations will inform legislative initiatives and policy frameworks to guide AI development and deployment in the United States.

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Senate HELP AI White Paper

Overview:

- In September, Ranking Member Cassidy (R-LA) released a White paper exploring the potential benefits and risks of AI in sectors such as health care, education, and workforce safety, seeking to understand its effects on society and industry.
- Topics included integration of AI in medical innovation, enhancing disease detection, safeguarding health data privacy, and addressing the ethical implications of AI in decision-making processes.

Implications:

- Could be basis of legislation next year in HELP Committee

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Bipartisan Privacy Bill

Overview:

- House and Senate Committees released draft legislation to set clear national data privacy rights and protections, including enforcement mechanisms and a private right of action for individuals.
- Includes provisions to protect health-related data and information, ensuring compliance with existing federal privacy requirements under HIPAA. It also empowers individuals with the right to opt out of algorithmic decision-making processes that impact various aspects of their lives, such as health care, credit opportunities, education, insurance, and access to public accommodations.
- Resistance from Sen. Cruz (R-TX) (Commerce Ranking Member) over concerns for burden on small businesses.

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AI Governance and Transparency Act (HR 7532)

Overview:

- House Oversight Committee advanced legislation through committee
- Focuses on increasing transparency, oversight, and responsible use of federal AI systems.
- The legislation requires public notice of AI systems used by federal agencies through AI Governance Charters. It emphasizes the importance of transparency in the use of AI systems and aims to mitigate potential risks associated with their deployment.

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House Bipartisan AI Taskforce

Overview:

- House established a bipartisan Task Force on AI to explore how Congress can ensure America continues to lead in AI innovation.
- Co-chaired by Speaker Mike Johnson (R-LA) and Minority Leader Hakeem Jeffries (D-NY), the 12-member bipartisan taskforce aims to produce a comprehensive report with guiding principles, recommendations, and bipartisan policy proposals related to AI development and governance.
- Topics to be considered include AI innovation, national security, economic competitiveness, and ethical considerations.

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Senate Finance Committee Hearing on AI in Health Care

Overview:

- The Panel featured testimony from experts in the field including academics and stakeholders.
- The committee discussed various aspects of AI's role in health care, including:
  - –Algorithm bias and discrimination,
  - –AI's impact on prior authorization decisions,
  - –Use of AI by Medicare Advantage plans
  - –Transparency in AI algorithms

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Medicare Transaction Fraud Prevention Act

Overview:

- Senators Cassidy (R-LA) and Braun (R-IN) introduced legislation to use AI in combating Medicare fraud.
- The bill establishes a two-year pilot program that would utilize AI-powered algorithms to analyze Medicare claims data and identify suspicious billing patterns associated with DME and diagnostic testing.
- DME and diagnostic testing are frequently the target of fraudulent schemes. If successful, AI algorithms could be expanded to integrate further in CMS fraud detection capabilities.

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Key Regulatory Developments

- AI Executive Order
- AI Cyber Challenge
- President Biden to Issue EO on Protecting Personal Data
- HHS Releases Final Rule on Health IT Interoperability and Algorithm Transparency
- HHS Releases Guiding Principles to Address Algorithm Bias
- FDA Releases Paper on AI

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White House AI Executive Order

Overview:

- The White House issues an executive order outlining a comprehensive framework for governing AI across federal agencies.
- Mandates concrete safeguards to ensure AI safety and security, protect privacy, advance equity and civil rights, promote innovation and competition, and bolster American leadership worldwide.
- Emphasizes transparency in AI use, upskilling of AI talent within agencies, and strengthening of governance mechanisms to address potential risks and maximize benefits.

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AI Cyber Challenge (AIxCC)

Overview:

- Collaboration between ARPA-H and DARPA to expand AI-enabled technology to safeguard health care infrastructure from cyberattacks.
- Two-year competition with over $20M prize asking competitors to design novel AI tools and capabilities to find and fix vulnerabilities in software used in critical infrastructure.

Implications:

- Could spur AI technology development, incentivize participation, and enhance cybersecurity in health care.

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President Biden to Issue EO on Protecting Personal Data

Overview:

- February the White House announced the President will issue an Executive Order aimed at protecting Americans' sensitive persona data from exploitation by "countries of concern."
- Aimed at protecting genomic data, biometric data, personal health data, geolocation data, financial data, and certain types of personally identifiable information.

Implications:

- Regulations could emerge from this to safeguard personal data, prevent exploitation, and ensure compliance with privacy standards.

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HHS Releases Final Rule on Health IT Interoperability and Algorithm Transparency

Overview:

- HHS ONC released a final rule advancing patient access, interoperability, and standards in healthcare.
- Established transparency requirements for AI and other predictive algorithms integrated into certified health IT.

Implications:

- Could encourage more interoperability and transparency in healthcare IT systems.
- First major concrete requirement at federal level around transparency of AI algorithms.

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HHS Releases Guiding Principles to Address Algorithm Bias

Overview:

- In December, HHS highlighted a paper developed by a technical expert panel providing guiding principles to the health care community aimed at addressing bias resulting from algorithms used in healthcare.

- These guiding principles include the following:
  - Promote health and health care equity during all health care algorithm life cycle phases.
  - Ensure health care algorithms and their use are transparent and explainable.
  - Authentically engage patients and communities during all health care algorithm life cycle phases and earn trustworthiness.
  - Explicitly identify health care algorithmic fairness issues and tradeoffs.
  - Establish accountability for equity and fairness in outcomes from health care algorithms.

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FDA Releases Paper on AI

Overview:

- The FDA released a comprehensive white paper outlining its plans and strategies regarding the integration of AI in healthcare.
- The paper reaffirms the FDA's commitment to promoting the responsible and ethical development, deployment, use, and maintenance of safe and effective medical products that incorporate or are developed with AI.
- It highlights the potential of AI to enable major advances in medical product development, risk reduction, and innovation.
- It outlines the FDA's approach to leveraging AI for regulatory processes, including product evaluation, approval, and post-market surveillance.

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Themes and Trends

- **Privacy and data protection**: Emphasis on protecting personal data and establishing clear national privacy rights.
- **Safeguards around Equity and Bias**: Implementation of measures to address equity concerns and mitigate bias in AI applications within healthcare, aiming to ensure fair and transparent decision-making processes.
- **Regulatory frameworks and oversight**: Focus on increasing transparency, oversight, and responsible use of AI systems.
- **Public-private partnerships and collaboration**: Engagement of stakeholders to balance regulation and innovation in AI development.