

ARTIFICIAL INTELLIGENCE AND STATE MEDICAL BOARDS

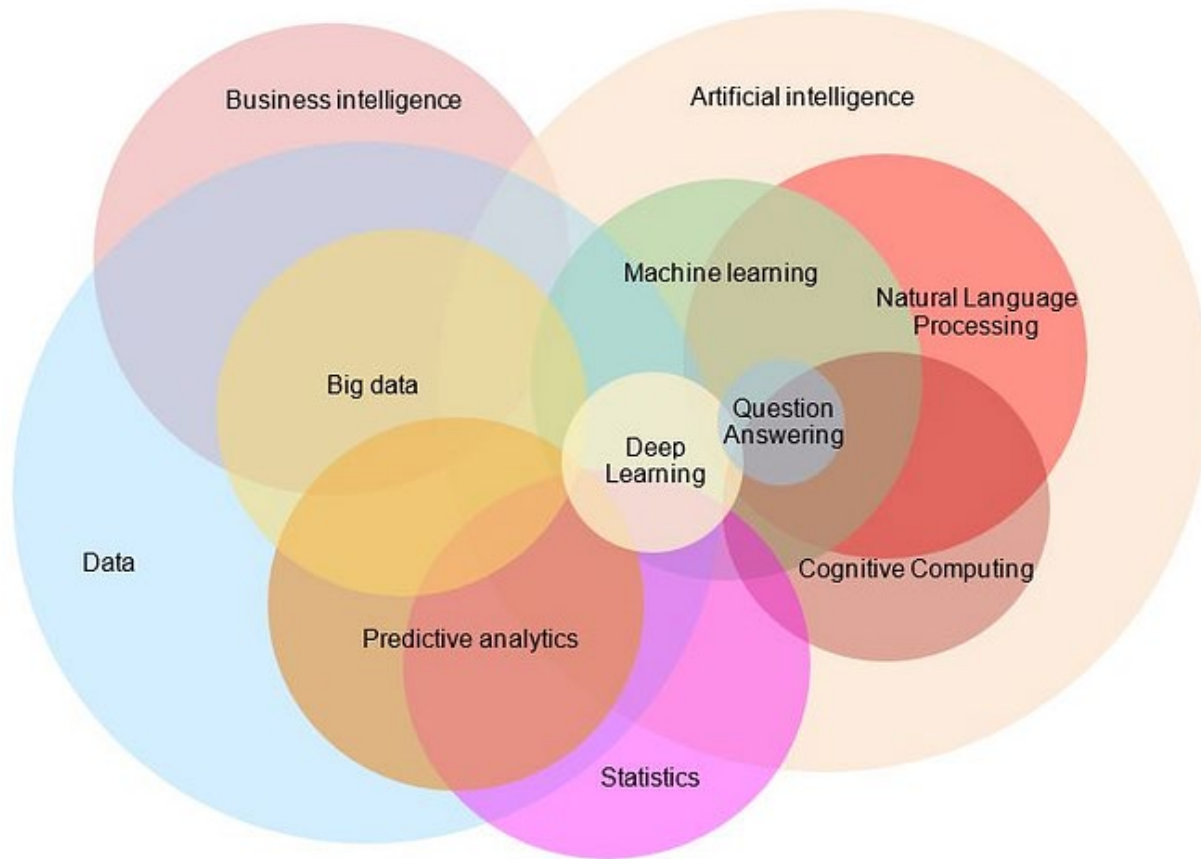


**New York State Board of Medicine Meeting
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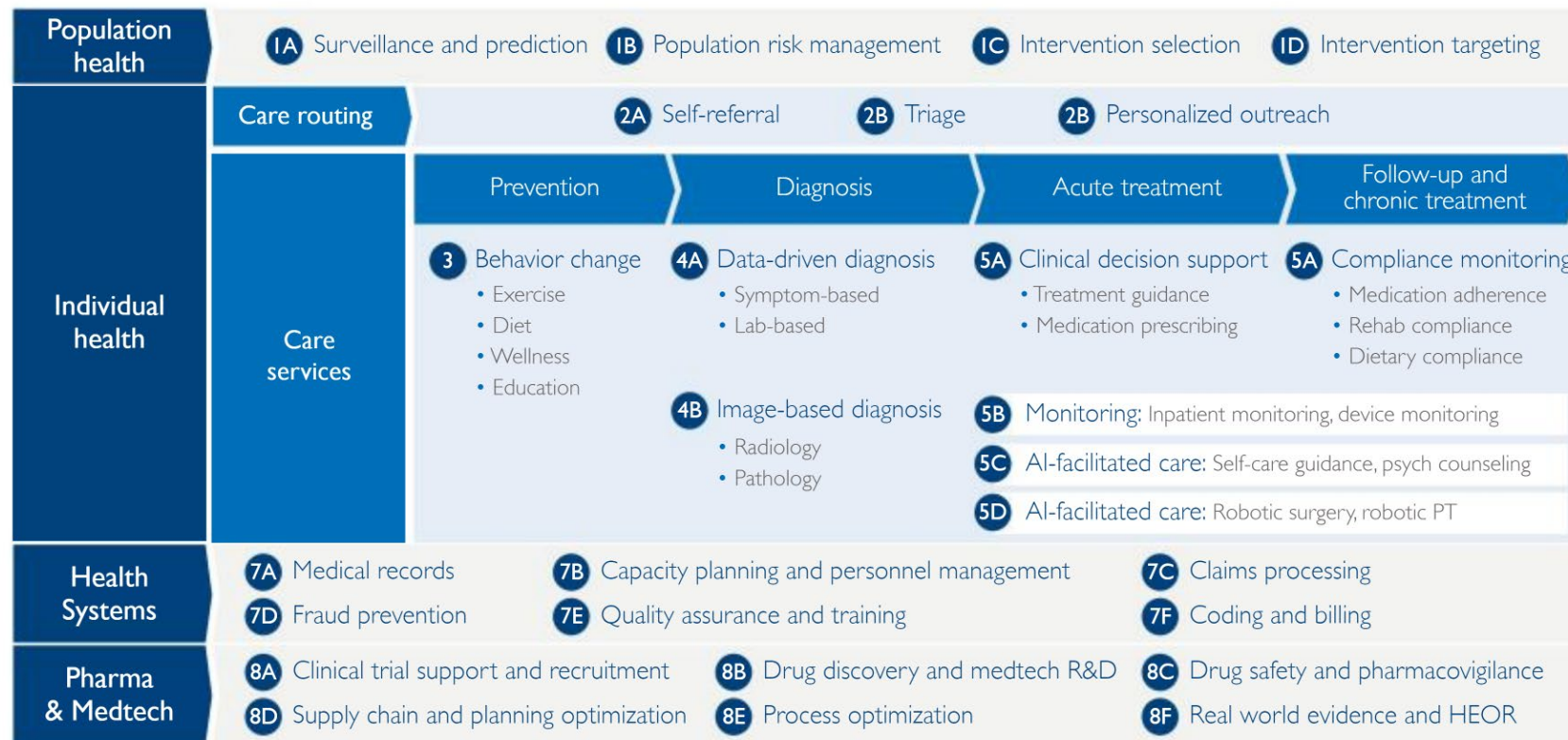
ARTIFICIAL INTELLIGENCE – WHAT IS IT?



- A vague and amorphous term
- Generally, the attributes we think of include *things that seem to mimic human cognition or behavior*
- Modern AI systems tend to rely on *machine learning*, a process by which systems are exposed to *large data sets* and provided conclusions to specific problems (e.g., identifying cancerous cells in radiology images)
- While modern AI systems can provide high quality insights, their reasoning can be a *black box* and generative AI systems can “*hallucinate*”
- We generally have demonstrated a generally *lack of understanding* of how these systems work and where their weaknesses may lay
- AI is *technology*

AI IN HEALTHCARE – MANY USE CASES

Figure 2: Framework of all AI Use Cases in Healthcare



- ALSO:
 - Consumer use
 - Health and wellness apps and other tools
 - More knowledge and tools for self-care/self diagnosis
 - “Off-label” use
 - Using a tool beyond the developer’s intention
- Use cases are increasing

Figure from USAID’s “Artificial Intelligence in Global Health: Defining a Collective Path Forward”
<https://www.usaid.gov/cii/ai-in-global-health>

AI IN HEALTHCARE – MANY POTENTIAL ISSUES

- **Privacy**
 - Training Data
 - Data Gathered in Deployment
 - Cybersecurity
- **Consumer Protection**
- **Non-Discrimination**
- **Informed Consent**
- **Tort Liability**
 - Medical Malpractice
 - Institutional Liability; Vicarious Liability
- **Products Liability**
 - Manufacturing and Design Defects
 - Learned Intermediary Doctrine and Failure-to-Warn
 - Breach of Warranty
- **FDA Approval and Manufacturer Liability**
- **ONC Certification Program**
- **Confidentiality and Trade Secrets**
- **Emerging State Legal and Regulatory Requirements**
 - Georgia
 - Utah
 - Colorado

ALSO CONSIDER THE CHANGING HEALTH CARE SERVICES LANDSCAPE

New Technologies

- User lack of familiarity
- Unknown weaknesses and faults
- Blurry lines between areas of responsibility

Industrialization of Health Care Services

- Drive for efficiencies, best practices
- Highest and best use of professional services
- Related impact on professional discretion?

Tech-Enabled Consumer

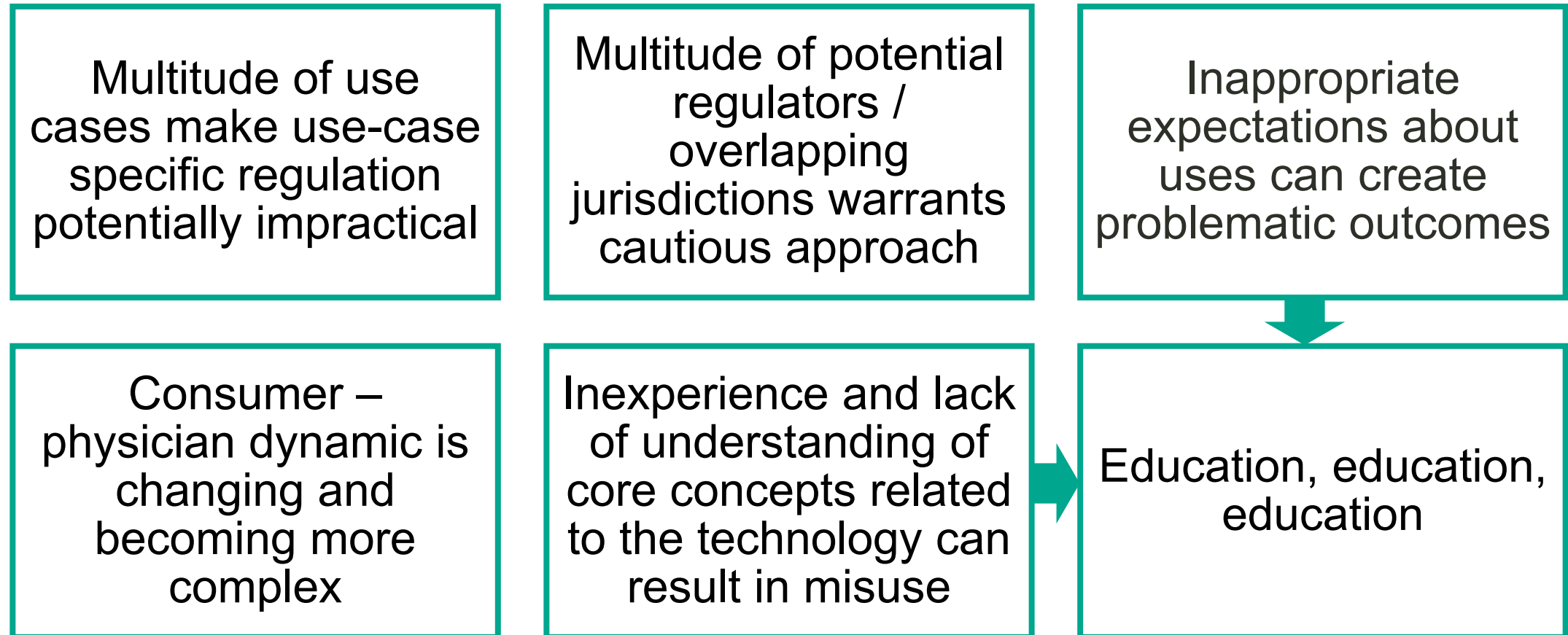
- Higher and different expectations
- “Partners” in health care services?
- Erosion of trust in institutions

AI = The Shiny New Object

MEDICAL BOARDS – WHERE THE RUBBER HITS THE ROAD

- No other regulatory bodies
 - are as well positioned to consider the benefits and impact of AI in care delivery
 - are seeing the impact of the changing health care services landscape as immediately
 - are required to be composed of physicians
 - have the jurisdictional mandate that is as immediately relevant
- Medical boards are uniquely positioned to help define the shape and scope of technology-enabled care delivery

AI IN HEALTHCARE – THOUGHTS ON REGULATION



APPENDIX

SELECT AI LAWS, REGULATIONS AND GUIDANCE

- Driving US Innovation in Artificial Intelligence: A Roadmap for Artificial Intelligence Policy in the United States Senate, The Bipartisan Senate AI Working Group
 - https://www.schumer.senate.gov/imo/media/doc/Roadmap_Electronic1.32pm.pdf
- ONC Final Rule: Health Data, Technology, and Interoperability
 - <https://www.mwe.com/pdf/understanding-oncs-health-ai-transparency-and-risk-management-regulatory-framework/>
- CFPB, DOJ, EEOC and FTC Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems
 - https://www.ftc.gov/system/files/ftc_gov/pdf/EEOC-CRT-FTC-CFPB-AI-Joint-Statement%28final%29.pdf
- FDA SAMD Guidance
 - <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>
- Presidential Executive Order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence
 - <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/>
- White House Office of Science and Technology Policy, Blueprint for an AI Bill of Rights
 - <https://www.whitehouse.gov/ostp/ai-bill-of-rights/>
- Colorado Consumer Protections for Artificial Intelligence Law
 - <https://leg.colorado.gov/bills/sb24-205>

THANK YOU

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