

May 2, 2024

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The Honorable Dr. Ami Bera
Cofounder, Health Care Innovation Caucus
Member House Task Force on Artificial Intelligence (AI)
172 Cannon House Office Building
Washington, DC 20515

Dear Representative Bera,

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the current state of artificial intelligence (AI) and how it shapes the healthcare industry. LUGPA currently represents 150 urology group practices in the United States, with more than 2,100 physicians providing approximately 35% of the nation's urology services.

AI is increasingly adopted across various healthcare settings, including hospitals, clinics, and private practices. Independent urology practices, such as those represented by LUGPA, integrate AI to enhance diagnostic accuracy, personalize patient navigation, and optimize practice management. Areas such as diagnostic imaging, patient engagement, and predictive analytics benefit from AI. Challenges include awareness, data privacy concerns, and the need for robust training programs for healthcare providers.

AI applications can be found in the following settings:

- Clinical treatment settings: diagnostics and AI-assisted surgery diagnostics
- Practice Optimization: scribing, revenue cycle management, virtual nursing assistants.
- Care Management: digital patient engagement, patient navigation, clinical pathways.

AI differs from other healthcare technologies by its ability to learn and adapt to new information without explicit reprogramming. AI supports existing technologies through enhanced data analysis, improved diagnostic accuracy, and operational efficiency.

Although AI technologies are being lauded for their ability to streamline processes, reduce the burden on healthcare professionals, and potentially improve patient outcomes, there needs to be more in the discourse regarding the financial sustainability of integrating AI into healthcare systems, particularly concerning reimbursement models. The initial investment in AI technology and the ongoing costs associated with its implementation and maintenance can be substantial and raise essential questions about the long-term financial viability of AI within healthcare institutions.

Despite the early proliferation of pioneers within this field, most of these companies are not yet profitable and operate at significant losses. Their survival is contingent on any number of 'anticipated' developments and uncertain timelines, including maturation of the technology and broader adoption of their solutions. If the path to profitability for AI companies is longer than anticipated, or if the market for AI solutions does not expand as expected, there could be a contraction in the number of companies providing these technologies. A decrease in competition may result in fewer AI options available to healthcare providers and could drive up the costs for the technologies that remain. Such an outcome would have significant implications for clinicians and healthcare organizations relying on AI to enhance their workflows.

According to Dr. Evan Goldfischer, MD, LUGPA President and Director of Research at Premier Medical Group, clinical efficacy must lie at the core of robust reimbursement policies for AI technologies in healthcare. "Before reimbursement, AI efficacy must undergo thorough validation through clinical trials and real-world testing, following standardized protocols. Policymakers must establish clear benchmarks and criteria for evaluating AI performance in improving patient outcomes. We should prioritize accountability by ensuring that reimbursement is tied directly to AI's ability to deliver tangible clinical benefits and with clinicians leading the charge in crafting accountable reimbursement policies," said Goldfischer.

Clinical evidence regarding the efficacy and accuracy of AI-driven healthcare solutions are found in several key areas:

- **Diagnostics:** AI has shown high accuracy in detecting diseases such as breast cancer, lung cancer, and cardiovascular conditions through medical imaging like mammography and CT scans.
- **Pathology:** AI effectively analyzes biopsy samples, helping to identify diseases like skin cancer and prostate cancer with precision comparable to expert pathologists.
- **Ophthalmology:** AI algorithms identify conditions like diabetic retinopathy in retinal scans, often outpacing human experts in speed and matching them in accuracy.
- **Predictive Analytics:** AI models predict patient outcomes, such as deterioration and readmission risks, by analyzing electronic health record (EHR) data.
- **Personalized Medicine:** AI helps tailor treatment plans based on individual genetic profiles and disease characteristics, enhancing effectiveness.
- **Mental Health:** AI monitors and intervenes in mental health, analyzing speech patterns to detect conditions like depression.

Dr. Scott Sellinger, the President-Elect of LUGPA and President of the Advanced Urology Institute argues that many areas of healthcare data contain untapped resources to help improve outcomes. "In the evolving digital health landscape, we must broaden our strategy to include and standardize overlooked data like patient-reported outcomes. These vital insights, currently scattered and unorganized, are essential for customizing healthcare to actual patient needs. To effectively utilize this data, we should develop uniform protocols for its collection, processing, and integration into health systems and encourage community participation through incentives like financial rewards, regulatory benefits, or better reimbursement for contributing institutions. Standardizing and making patient-reported data accessible will enhance AI-driven healthcare's precision and personalization, ensuring it reflects real patient experiences," comments Sellinger.

Given the extraordinarily well-developed and sophisticated infrastructure already in place to collect and analyze data to assist in benefit and coverage determinations, payer dependency on AI-dependent algorithms and processes must be transparent, accountable, and subject to scrutiny. LUGPA would highlight the following possible untoward consequences should guardrails not be well-developed and explicit:

- **Bias:** AI systems can inadvertently perpetuate biases in their training data, leading to discriminatory practices. AI algorithms may disproportionately consider some demographics "riskier" than others from a payer perspective, which could adversely affect a patient's coverage experience.
- **Lack of Accountability:** When AI makes decisions, it can be challenging to assign responsibility for those decisions. Clear policies must be in place to determine accountability for errors or adverse outcomes.
- **Data Privacy Concerns:** AI system's use of personal health information raises significant privacy concerns. Ensuring that AI systems are secure and compliant with data protection laws is paramount.
- **Standardized Reporting:** Create standardized reports that are publicly shared by payers that detail AI decision-making processes, data sources, and performance metrics. This standardization helps in maintaining consistency and reliability across different AI systems and use cases.
- **Explainable AI:** Some AI systems, particularly those based on deep learning, can be so complex that their decision-making process is not entirely understandable, even to experts. While this complexity is beyond the capability to resolve definitively, it underscores the importance of developing AI systems that are as transparent and explainable as possible.

Transparency must be at the center of any AI policy. "Transparency isn't just a buzzword—it's the bedrock of trust. Establishing independent validation bodies and granting patients access to their health data and AI decisions are critical steps towards fostering accountability and trust in an AI-driven healthcare milieu," comments Dr. Goldfischer.

In a viewpoint published by the Brookings Institution, Bob Kocher, MD, and Zeke Emanuel, MD, PhD, make the case that current AI technology could reproduce the disparities in access, treatment, and outcomes that are baked into the healthcare data sets that power these tools, while missing elements of clinical intuition that may not be reflected in the data. "AI is only as good as the humans programming it and the system in which it operates. If we are not careful, AI could not improve healthcare, but instead unintentionally exacerbate many of the worst aspects of our current healthcare system," Drs. Kocher and Emanuel wrote.¹

As shared by Shirley Lee, NP, a health equity advocate, "It's imperative that we shift to AI trained on diverse datasets that genuinely reflect the full spectrum of our communities. We need stringent regulations and a commitment to ethical AI to break these cycles of inequality. Including diverse voices in AI development isn't a bonus—it's critical. In order for this to happen, funding must be established for medical research that is representative of our population (race, gender, ethnicity). President Biden's Executive Order on Women's Health research is a significant step forward and needs to be expanded to

¹ Emily Rappleye. "Physician viewpoint: AI could 'unintentionally exacerbate many of the worst aspects' of healthcare," Becker's Health IT, March 6, 2019. <https://www.beckershospitalreview.com/healthcare-information-technology/physician-viewpoint-ai-could-unintentionally-exacerbate-many-of-the-worst-aspects-of-healthcare.html>

address the diversity of our nation.”

In addition to ensuring transparency and diversity in any new AI policy governing healthcare, Dr. Mara Holton, LUGPA Policy Chair and President Anne Arundel Urology, argues robust validation protocols are also needed, with penalties imposed for errors. "In the rapidly evolving field of AI-driven healthcare, ensuring the accuracy of information isn't just about maintaining standards—it's about safeguarding lives. We need to institute rigorous, continuous validation protocols specifically for AI tools, overseen by a strengthened regulatory framework that doesn't shy away from imposing penalties for inaccuracies. Healthcare professionals must be thoroughly trained not just to use AI but to critically evaluate and question its outputs. Every piece of data must be scrutinized under a microscope of ethical and technical scrutiny before it reaches any clinical decision-making process. In this new digital health era, let accuracy be the litmus test determining whether an AI application makes it to the frontline of patient care," commented Dr. Holton.

There are several notable examples of AI applications that have significantly improved patient outcomes and streamlined healthcare processes:

- **Diagnostic Imaging:** AI technologies, such as deep learning algorithms, have been applied extensively in diagnostic imaging. For instance, Google's DeepMind developed an AI system that can accurately diagnose over 50 eye diseases by analyzing 3D retinal scans, matching or surpassing expert-level accuracy. This application speeds up the diagnostic process and increases diagnostic accuracy, which is crucial for timely and effective treatment.
- **Predictive Analytics:** IBM Watson for Health uses AI to analyze vast amounts of data from medical records to predict patient risks and outcomes. This technology has been used to predict the deterioration of heart failure patients with high accuracy, allowing for earlier interventions that can significantly improve outcomes.
- **Robotic Surgery:** AI-powered robotic systems, such as the da Vinci Surgical System, enhance the surgeon's capabilities by stabilizing movements and providing high-definition, magnified, 3-D views of the surgical site. This precision reduces recovery times and minimizes complications, enhancing surgical outcomes.
- **Scribing and Medical Documentation:** AI applications (Dragon, Suki, Saykara) in medical scribing are revolutionizing how healthcare providers document patient encounters, significantly easing the administrative burden on medical professionals.
- **Clinical Decision Support Systems (CDSS):** These AI tools assist clinicians in making decisions by providing evidence-based recommendations based on clinical pathways. They integrate data from a comprehensive medical history with the latest research to suggest the best treatment options, improving care quality and efficiency.

Dr. Jason Hafron, LUGPA Board Member and CMO of Michigan Urology Institute, believes clinicians should also be involved in algorithm design. "In the age of AI integration, clinicians must take the reins in designing ethically sound algorithms. We can't afford to delegate this responsibility; it's our duty to ensure AI reflects our ethical standards and clinical expertise. Let's demand transparency, confront biases, and prioritize patient privacy from the ground up. By actively involving clinicians in algorithm design, we can forge a future where AI enhances patient care while upholding our ethical principles," commented Dr. Hafron.

Privacy must also be emphasized when constructing new AI rules. "Integrating privacy from the very beginning of AI system design is crucial, not optional. By constructing AI algorithms to operate effectively on minimal or anonymized data, we safeguard patient identities without compromising the functionality of these systems. Anonymization and pseudonymization of sensitive information before it ever touches the AI, alongside strict adherence to data minimization principles, are non-negotiable practices. These strategies ensure that only essential data is used, significantly enhancing the privacy of patient information. This proactive approach to privacy is fundamental in building trust and efficacy in healthcare AI applications," comments Victor Lee, Founder and CEO of Prevea and Former Technical Lead of NSA's Metadata Interoperability Program.

Adherence to robust regulations, policies, frameworks, and standards is paramount in the dynamic landscape of AI utilization. Entities leveraging AI must uphold stringent guidelines such as HIPAA and GDPR, alongside ethical frameworks like the AMA Code of Medical Ethics. Additionally, when AI is deployed in clinical decision support, adherence to clinical guidelines from reputable organizations like the American Urological Association (AUA) and the National Comprehensive Cancer Network (NCCN) is crucial.

Establishing actionable mechanisms for supervision and enforcement, including regular audits, real-time monitoring, and collaborative oversight committees comprising clinicians, tech leaders, and healthcare administrators, ensures ongoing compliance. By fostering collaboration between regulatory bodies and industry stakeholders, we can establish a framework where AI-driven innovations prioritize patient safety, privacy, and ethical integrity.

As AI continues to integrate with healthcare, several key trends are poised to reshape the industry:

- **Advanced Diagnostics:** AI will increasingly be used to enhance diagnostic accuracy through deeper analysis of medical imaging and data, enabling earlier and more precise disease detection.
- **Personalized Medicine:** AI-driven personalized treatment plans will become more common, using patient-specific data to optimize therapies and improve outcomes.
- **Wearable Health Tech:** The development of sophisticated wearable devices that monitor and predict health issues in real-time will expand, allowing for continuous patient monitoring and proactive health management.
- **Telemedicine Integration:** AI will enhance telemedicine by improving remote diagnostics and patient monitoring, making healthcare more accessible and efficient.
- **Drug Discovery and Development:** The use of AI to streamline the drug discovery and development process will continue to grow. AI can significantly reduce the time and cost associated with bringing new drugs to market by predicting how different compounds will behave and identifying the most promising candidates for further development.

Advancements in predictive AI within clinical pathways represent a significant breakthrough in healthcare, but their rapid evolution also raises important considerations, cautions Dr. Holton. "While predictive AI has the potential to revolutionize patient care by forecasting outcomes and personalizing treatment plans, there are concerns surrounding clinical accuracy, algorithm bias, and the impact on clinician-patient relationships. Policymakers must ensure that clinician leaders hold key roles in designing accountability measures, particularly concerning clinical accuracy and workflow compatibility.

Additionally, efforts should be made to enhance clinician training and support to effectively integrate predictive AI into clinical practice while maintaining the human touch in patient care. It's crucial to remember that clinicians should remain at the center of decision-making, and AI should be viewed as a tool to support, not replace their expertise," comments Holton.

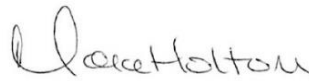
In community practice settings, where resources are often limited, AI could be transformative in enhancing healthcare accessibility and quality, but only if supported by the right policies, notes Dr. Jeff Spier, LUGPA Secretary and President, Rio Grande Urology." To truly democratize AI in healthcare, Congress needs to prioritize specific legislative actions. First, subsidies or grants should be made available to community-based clinics to help them acquire and implement AI technologies. Additionally, Congress should mandate that AI healthcare providers offer scalable solutions compatible with the diverse systems used in smaller practices. They must also enforce stringent standards to ensure these tools are user-friendly and support training programs that help community health workers effectively utilize AI. By implementing these focused recommendations, we can ensure that the benefits of AI in healthcare reach every corner of our community, regardless of the clinic's size or budget," Spier concluded.

On behalf of LUGPA, we thank Representative Bera for providing us with this opportunity to comment on AI policy. Please contact Dr. Mara Holton at 410.504.4004 or mholton@aurology.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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