Written Testimony Of Mark Sendak, MD, MPP Co-Lead, Health AI Partnership Population Health & Data Science Lead, Duke Institute for Health Innovation

Chairman Wyden, Ranking Member Crapo, and members of the committee, my name is Mark Sendak, and I appreciate the opportunity to serve on the panel today and offer my testimony. I must note that any views expressed today and in my written testimony are my own and may not necessarily reflect those of my employer or the institutions that participate in a multistakeholder partnership of which I am proud to serve in a leadership role.

I serve as the Population Health & Data Science Lead at the Duke Institute for Health Innovation (DIHI for short) and the Co-Lead of Health AI Partnership. I studied mathematics and health policy before completing medical training and have been developing and implementing AI technologies for over a decade.

Since DIHI's founding in 2013, our team has led the development and responsible implementation of over 20 AI technologies for clinical care.¹ We were the first in the US to implement a deep learning model in routine clinical care.² We were the first to implement Model Facts labels (similar to nutrition facts labels) for AI tools that laid the groundwork for ONC's final rule on algorithm transparency.^{3,4} We have incubated four companies to commercialize AI products built at Duke and we help healthcare organizations across the country validate these technologies.

Our team has demonstrated the benefits of AI in healthcare. Duke dramatically improved the quality of sepsis care using our Sepsis Watch system.⁵ Duke proactively manages chronic diseases in Medicare patients by using AI to identify patients at risk of complications.⁶ Duke has now extended this chronic disease management approach to all patients.

But my comments today will not focus on the amazing work I've been a part of at Duke. Today, I'm speaking with you primarily as the Co-Lead of Health AI Partnership.

In 2018, a mentor asked me "how do we get AI out of the ivory tower?" At that time, my experience with AI at Duke was unimaginable to people outside a few exceptional islands of excellence. And there was minimal building of infrastructure to advance the use of AI in low-resource settings.

In 2021, I helped launch Health AI Partnership to advance the safe, effective, and equitable use of AI in all healthcare organizations. We exist to get AI out of the ivory tower.

The Senate Finance Committee can take concrete action to advance accountability, equity, privacy, and transparency in the use of AI in healthcare. The Medicare program ensures the delivery of high-quality care for beneficiaries through conditions of participation and other

mechanisms. There is a unique opportunity for this Committee to strengthen Medicare controls on the use of AI and to facilitate investments in technical assistance, technical infrastructure, and training.

First, we can address guardrails.

Through Health AI Partnership, we work with twenty organizations across the US to surface and disseminate AI best practices. We interview leaders and run case-based workshops on complex topics. We develop practical resources for healthcare leaders asking basic questions: how do I evaluate different externally built AI products? How do I navigate the new FDA clinical decision support guidance? How do I assess the potential future impact of this AI product on health inequities? How do I align organizational processes with the White House Blueprint for an AI Bill of Rights?

Health AI Partnership resources and programs provide guardrails for high-resource organizations that are rapidly accelerating their use of AI. Adoption of these guardrails by hospitals could be required for Medicare program participation. But guardrails only serve the few organizations that are already on the AI adoption highway.

We must also address the more critical need for roads, onramps, and bridges—the core infrastructure investments needed to ensure that all people in the US benefit from AI in healthcare.

Most healthcare organizations in the US need an onramp to the AI adoption highway. They are struggling with clinician burnout. They face razor thin or negative margins. They are entirely dependent on external EHR vendors for technology expertise and assistance. Simply put, they do not have the resources, personnel, or technical infrastructure to embrace guardrails for the AI adoption highway.

Core infrastructure investments are needed for technical assistance, technology infrastructure, and training:

- Technical Assistance: A national hub-and-spoke network is needed to diffuse AI expertise beyond centers of expertise to low-resource settings. Hubs can provide operational and technical support to sites implementing AI, similar to existing programs that extend specialist expertise to low-resource settings.^{7,8}
- Technology Infrastructure: Technology infrastructure that is distinct from EHRs is required to facilitate the efficient evaluation and clinical integration of AI tools. This infrastructure allows sites to test many AI products simultaneously with ongoing monitoring. Without addressing this capital investment, a market failure will continue preventing AI developers from efficiently commercializing products.⁹
- **Training programs:** Broadly accessible programs targeting clinical, technical, and operational leaders are urgently needed to equip the healthcare workforce with the foundational knowledge required to locally govern AI. Healthcare will increasingly become AI-enabled and local AI governance will be a core competency.

Congress has tackled this type of challenge before. Fifteen years ago, Congress enabled the broad adoption of EHRs through funding technical assistance programs and technology infrastructure investments.¹⁰ That funding supported the purchase of EHRs along with 62 regional extension centers to support EHR implementations in low-resource settings. While EHRs are far from perfect, federal programs did successfully diffuse the technology across the country. We need similarly bold action now.

Enacting Medicare controls and infrastructure investments to advance the safe, accountable, equitable, private, and transparent use of AI in healthcare will take time and be iterative. I look forward to continuing to share learnings from Health AI Partnership and am eager to support future work conducted by the Senate Finance Committee.

Thank you, again, for this opportunity, and I look forward to answering your questions.

References

- 1. Sandhu S, Sendak MP, Ratliff W, Knechtle W, Fulkerson WJ, Balu S. Accelerating health system innovation: principles and practices from the Duke Institute for Health Innovation. Patterns. 2023;4(4):100710.
- 2. Sendak MP, Ratliff W, Sarro D, Alderton E, Futoma J, Gao M, et al. Real-World Integration of a Sepsis Deep Learning Technology Into Routine Clinical Care: Implementation Study. JMIR medical informatics. 2020 Jul 15;8(7):e15182.
- 3. Sendak MP, Gao M, Brajer N, Balu S. Presenting machine learning model information to clinical end users with model facts labels. npj Digital Medicine. 2020 Mar 15;3(41):1–4.
- 4. https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technologyand-interoperability-certification-program
- 5. <u>https://www.wsj.com/articles/how-hospitals-are-using-ai-to-save-lives-11649610000</u>
- Sendak MP, Balu S, Schulman KA. Barriers to Achieving Economies of Scale in Analysis of EHR Data. A Cautionary Tale. Applied Clinical Informatics. 2017 Aug 9;8(3):826–31. Available from: <u>https://www.thieme-</u>

connect.com/products/ejournals/abstract/10.4338/ACI-2017-03-CR-0046

- 7. https://projectecho.unm.edu/
- 8. <u>https://dason.medicine.duke.edu/</u>
- 9. <u>https://www.statnews.com/2022/05/24/market-failure-preventing-efficient-diffusion-health-care-ai-software/</u>
- Lynch K, Kendall M, Shanks K, Haque A, Jones E, Wanis MG, et al. The Health IT Regional Extension Center Program: Evolution and Lessons for Health Care Transformation. Heal Serv Res. 2014;49(1pt2):421–37.