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Annabelle Huffman, Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Bldg.
Washington, DC 20515
Sent by email to [REDACTED]

Dear Ms. Huffman:

I am pleased to submit the following responses to Committee members' questions following the September 3, 2025 hearing entitled, "Examining Opportunities to Advance American Health Care through the Use of Artificial Intelligence Technologies."

Hon. Gus Bilirakis:

Question: As Congress considers potentially legislating artificial intelligence (AI) in health care, what role do you see health care accreditation playing to address the ever-changing landscape of AI?

Answer: The Joint Commission (TJC), which inspects and accredits healthcare facilities, would be an excellent mechanism for ensuring that healthcare organizations are operating robust, useful AI governance processes. Because the Centers for Medicare and Medicaid Services (CMS) accepts TJC accreditation as satisfying Medicare Conditions of Participation, these two organizations could partner to describe standards that healthcare facilities should meet and then verify that they are meeting them, working with organizations that fall short to help them improve. This framework would be flexible enough to account for changes in the AI landscape: they could adjust standards as needed to meet new challenges. It would also allow these bodies to arrive at standards that balance safe use of AI with the need to encourage AI adoption so that all patients can benefit from these innovative technologies.

Hon. Earl L. "Buddy" Carter:

Question 1(a): How can the Trump Administration and Congress best protect the American public from this major national security risk [the risk that bad actors could use powerful AI technologies alongside research tools like gene synthesis...to create and spread deadly pathogens]?

Question 1(b): What steps must be taken in the forthcoming nucleic acid synthesis screening framework?

Answer: I am unable to answer these questions because they are outside my areas of expertise. My testimony and expertise relate to uses of AI by well-intentioned actors in the healthcare and health insurance systems.

Question 2: What steps could Congress consider to promote more adoption of third-party certifications and assurance frameworks to ensure AI systems in healthcare are secure and aligned with regulatory expectations?

Answer: To the extent that the Representative is asking about the security of AI systems (i.e., ensuring that they are not vulnerable to hacking and misuse), I am not able to answer, as cybersecurity is out of my areas of expertise. In terms of other regulatory expectations—for example, the expectation that

healthcare organizations who serve Medicare recipients operate provide safe, high-quality care, there is much that Congress can do. Specifically:

1. Congress can wield its power as a healthcare purchaser to ensure that any AI tool that is used by providers who bill federal health programs meet expectations for performance, safety, and fairness. It could, for example, require providers to use only models that meet health IT certification standards issued by the Office of the National Coordinator for Health Information Technology (ONC). (Certification is currently voluntary.) It could encourage ONC to expand those standards to encompass evolving forms of health AI that are not deeply addressed in the existing HTI-1 rule, such as generative and agentic AI systems.
2. Congress can modernize the Food and Drug Administration's (FDA) authority to better enable it to appropriately regulate AI tools. Presently, FDA cannot regulate many types of AI tools that implicate patients' access to safe, high-quality care. Further, for those tools it does subject to clearance processes, it is saddled with a clearance framework that was not designed for software and is an especially poor fit for software that learns and changes over time.
3. Congress can direct CMS to require, as a Medicare Condition of Participation, that healthcare facilities that bill Medicare have an AI governance process. For further information, please see my response to Rep. Bilirakis above.

Hon. Mariannette Miller-Meeks:

Question 1(a). What can be done to ensure that breakthrough artificial intelligence diagnostic tools play a more significant role in preventive care in the future?

Answer: A plethora of AI tools on the market use patients' existing health information to better detect early signs of disease. For example, I recently evaluated an AI tool that reads screening EKGs stored in patients' electronic health records to look for signs of a serious cardiac condition that human readers often miss, hypertrophic cardiomyopathy. In addition to tools that look for specific health conditions, other tools can turbocharge our ability to identify patients who could benefit from additional preventive care services. Unfortunately, there is a gap between the wide availability of AI innovations and the limited extent to which healthcare organizations have actually adopted them. Two problems explain this gap. First, it is costly for healthcare organizations to vet, deploy, and monitor AI tools. Some tools may be cheap to turn on, but it can be expensive to conduct ongoing monitoring to ensure they are delivering good results for patients and clinicians. Second, many clinicians do not trust AI. They know that they are accountable when AI tools fail and patients are harmed. To address the first problem (cost), Congress could ensure health insurance reimbursement for AI tools with proven effectiveness and make more grant funding available for healthcare organizations to create and operate AI governance processes. Improved early disease detection could provide a huge return on this investment for federal health programs. Creating governance processes would also help address the second problem (the trust deficit). Clinicians who know their organization is scrutinizing AI tools before adopting them, carefully designing plans to deploy them, and evaluating how well they are working are more likely to be willing to use those tools.

Question 1(b): What role do you recommend for Congress and the Department of Health and Human Services (HHS) in ensuring that technologies proven to lead to better outcomes and reduced long-term costs are consistently reimbursed across Medicare, Medicaid, and commercial payers?

Answer: Medicare coverage determinations are the linchpin. They not only determine the coverage available to the 69 million Americans enrolled in Medicare but also influence coverage decisions made in other government health programs and the commercial sector. CMS's current coverage determination processes can be used to ensure that timely coverage decisions for AI tools are made for

Medicare, but it may be helpful for Congress to direct CMS to explicitly articulate a plan for taking in proposals for AI coverage and making decisions about AI tools. Ideally, Congress would give CMS additional resources to perform these determinations, because the volume of new AI tools that the agency would potentially be asked to consider is enormous and accelerating over time, and because new expertise within the agency may be needed to make informed decisions.

Question 2: Would you support a government-wide effort to modify healthcare-related programs—like HRSA’s Rural Health Care Services Outreach Program—to explicitly list AI tools as eligible technologies, like how telehealth is named?

Answer: I would certainly support efforts to expand the availability of federal funding for healthcare organizations to evaluate, deploy, and monitor AI technologies. It would be especially valuable to make funding available in geographic areas where patients have lower access to AI technologies than patients cared for by large, urban medical centers. The Rural Health Care Services Outreach Program seems quite suitable for providing grant funds to healthcare organizations in rural areas, where adoption of AI lags. Providing funding is critical because (1) many, if not most, AI tools do not produce cost savings or substantial revenue growth for healthcare organizations; and (2) evaluating and monitoring AI tools entails costs. In short, at present, adopting AI usually costs healthcare organizations money. Furthermore, small and rural healthcare organizations are less likely than academic medical centers to have structures in place for AI governance; creating and staffing those structures involves start-up costs. Grant funding could help jumpstart action by organizations that are “AI interested” but not currently making much use of AI, helping to ensure that all patients can share in the benefits of AI-augmented care. Even if programs like the Rural Health Care Services Outreach Program already seem to include AI-related projects within their scope of funding, it would be helpful to name that explicitly. As a frequent grant applicant, I know that listing something in a funding opportunity as a priority or particular interest for the funder encourages people to apply for funding in that area.

Thank you for the opportunity to provide these responses. I would be happy to discuss these or other issues relating to AI further with Committee members and staff.

Sincerely,

A handwritten signature in blue ink that reads "Michelle Mello". The signature is fluid and cursive, with the first name being more prominent than the last.

Michelle Mello, JD, PhD
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