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Answers to Questions for the Record  
Subcommittee on Health  
House Committee on Energy and Commerce  
*Understanding How AI is Changing Health Care*  
November 29, 2023

## Questions for the Record

Siemens Medical Solutions USA, Inc. (Siemens Healthineers)

United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

Re: November 29, 2023, hearing titled, “Understanding How AI is Changing Health Care”

January 5, 2024

### **The Honorable Mariannette Miller-Meeks**

**1.** We currently have a regulatory structure in place where some Artificial Intelligence (AI) technologies, such as clinical decision support software, must go through multiple agencies to reach providers. While I believe AI should be used to augment patient care for providers, do you believe this regulatory environment is sustainable? And what are some ways Congress can work to foster safe and effective deployment of AI technologies at the point of care to give every patient access to the highest quality care?

#### Response:

Safety and efficiency are core values throughout the life cycle of every one of Siemens Healthineers’ medical devices and algorithms. With the rapid acceleration in development and innovation of AI in medical devices, the need for the regulatory environment to be able to balance these principles without hampering innovation and adoption will be critical.

We believe this must start with both a broad acknowledgement that a flexible regulatory approach is needed, as a one-size-fits-all mentality could seriously inhibit the possibilities that come with AI, as well as efforts to facilitate global harmonization and the development of appropriate international consensus standards.

Currently, the Federal Drug and Administration (FDA) is highly active and has been engaging a broad range of stakeholders to improve regulatory review and postmarket monitoring of medical devices under the Food, Drug & Cosmetics Act. It will be imperative that the FDA continues this engagement to ensure that the future regulatory landscape keeps pace in providing clarity around issues such as stand-alone versus integrated AI products, as well as closely monitors and enforces intended use.

We are comfortable and confident in the regulatory process today. However, we believe the biggest impediment to AI being adopted by physicians, to provide patients access to the benefits of this technology, lies with the inconsistent and unpredictable payment for AI by CMS through Medicare.

**2.** Healthcare systems who adopt autonomous AI need to see sustainable, well-founded fee-for-service payment mechanisms. How do the existing Medicare pathways for reimbursement limit patient access to innovation that promise to improve treatment decisions and patient outcomes and what can be done to improve payment pathways?

Response:

While CMS has recognized the value and the complex nature of FDA cleared AI, the agency's reimbursement decisions have not uniformly and consistently ensured appropriate levels of payment for these products. This inconsistent, unpredictable approach has the potential to disincentivize innovation and stifle adoption and access to AI technologies across our health care system – especially in rural and underserved communities.

Given this, we support a solution that ensures a predictable and consistent approach by CMS – an approach that recognizes the costs of AI used in clinical patient care and reimburses quantitative or qualitative AI analysis with a temporary and separate payment until more data can be evaluated on AI's overall benefit to patients. We believe more data will demonstrate AI's ability to increase access to healthcare and improve patient outcomes.

**The Honorable Anna Eshoo**

**1.** I'm concerned about vulnerable patients – particularly children – not benefiting from advancements in AI technology for medical imaging. Few medical devices using AI specify whether they've been tested or trained on pediatric populations. a) Please explain why AI is such a critical tool for improving medical imaging.

Response:

Artificial intelligence has become a significant tool in the rising demand for medical imaging, helping drive an increase in radiologist productivity and enabling more precise and tailored clinical decisions for patients. AI-powered workflow solutions free up clinical staff to focus more on the patient by taking over repetitive tasks and increase diagnostic precision in the assessment of medical images. Imaging exams can be accelerated by utilizing AI to optimize patient positioning and image quality, thus decreasing the overall duration of the exam, especially critical for pediatric patients.

**b)** What should Congress be doing to make sure children are benefiting from the AI revolution in medical imaging? What measures have you instituted to ensure human oversight of AI technology?

Response:

Siemens Healthineers recognizes that medical imaging of children differs from adults, with different disease types, physiology and behavior all having a direct impact on diagnostic image quality. We collaborate with an extensive network of world-class clinicians, where we combine our research and development Research & Development (R&D) capabilities with the clinical expertise of the healthcare provider. This includes human clinical validation of data used to train our AI algorithms. The results of this collaborative process are powerful, clinically proven AI companions for decision-making that help to provide better patient care at lower cost. Humans and artificial intelligence have vastly different abilities. We believe that the future of medicine lies in combining the strengths of these capabilities.

As a leader in the development of AI algorithms, Siemens Healthineers is committed to building algorithms only with training data that is clinically relevant to ensure it is accurate and reflective of the patient population it is serving, in this case children. Further, we regularly update algorithms with new, curated data to ensure continued accuracy. Finally, we educate our users about the underlying technology, test datasets, and quality assurance to allow traceability and transparency for the clinician – so they fully understand the intended use of the AI algorithm.

2. Several large companies currently represent most of the market for AI used in medical imaging. Siemens Healthineers is one of those companies. a) How does Siemens Healthineers work with other companies to ensure medical data, such as Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) scans, can be reviewed in different systems?  
b) How are your systems interoperable with others in the industry?

Response:

Siemens Healthineers works very diligently to develop dedicated AI medical imaging solutions that can process patient clinical data from both Siemens Healthineers and non-Siemens Healthineers CT or MRI imaging scanners, including submitting AI algorithms for FDA approval that have been validated on non-Siemens Healthineers imaging platforms. We achieve this interoperability by adhering to industry established technical standards, like Digital Imaging and Communications in Medicine (DICOM) and Integrating the Healthcare Enterprise (IHE) to ensure these critical AI tools are accessible to all clinicians regardless of their imaging environment.

3. I introduced the *CREATE AI Act* (H.R. 5077) to give medical researchers in all sectors of society, including academia, small businesses, nonprofits, and government agencies equitable access to resources needed to develop AI technology. In no industry is equitable access to innovative technologies as important as the health care industry, where the lives of patients are on the line every day. a) Do you support this bill?

Response:

As a best practice with every Siemens Healthineers AI algorithm developed, equitable access to care starts with ensuring that the patient is at the center of AI innovation, from inception to implementation. We believe this starts with building algorithms only with data that we have validated to ensure it is accurate and reflects the patient population it is serving. Additionally, we vow our AI solutions will be measured against the highest scientific standards. It is also critical that AI developers educate their users about the underlying technology, test datasets, and quality assurance to allow traceability and transparency.

Finally, for all communities and populations to have access to innovative technologies, especially rural and underserved communities, it is crucial that CMS creates a consistent and predictable reimbursement pathway for FDA cleared AI analytical algorithms.

Transparency for patients and clinicians alike, privacy protections, reimbursement, and data that is free from bias and prejudice are core components in building trust and ensuring equitable access to care for all.

Siemens Healthineers is grateful for all of Ranking Member Eshoo's focus on the challenges and opportunities of AI in healthcare. The introduction of the *CREATE AI Act* (H.R. 5077), is just another example of her fostering positive public policy discussion around a critical issue and we look forward to reviewing the details of the proposed legislation and how it aligns with our tenets for equitable AI in healthcare.

**The Honorable Nanette Barragán**

1. Latinos are at greater risk of dementia and certain types of cancer compared to non-Hispanic white people. Early detection is critical to increase success of treatments or slow progression of these diseases. Can you explain how improving Medicare reimbursement of AI innovations, such as the utilization of AI in medical imaging, could help achieve health equity in early detection of diseases such as Alzheimer's and cancer?

Response:

Artificial intelligence and medical imaging play a critical role in early detection of diseases like Alzheimer's and dementia. At Siemens Healthineers, we have developed specific MRI Brain AI algorithms to detect changes in brain volume, an early indication of potential neurodegenerative disease. Providing patient access to this tool is critical to assisting in early detection. This can be enabled by CMS establishing a predictable and consistent reimbursement approach to such AI tools, recognizing the costs of these AI tools used in clinical patient care and reimbursing the quantitative or qualitative AI analysis with a temporary and separate payment until more data can be evaluated on AI's overall benefit to the patient. We believe this will encourage more providers to invest in such AI tools, especially in rural and underserved communities, and thus increase overall accessibility of AI innovations to patients.