Statement for the Record

of

The AI Healthcare Coalition for the

Senate Finance Committee

“Artificial Intelligence and Health Care: Promise and Pitfalls”

February 8, 2024

The AI Healthcare Coalition appreciates the opportunity to submit a statement regarding the Senate Finance Committee hearing on “Artificial Intelligence and Health Care: Promise and Pitfalls.”

Founded in 2019, the AI Healthcare Coalition convenes healthcare AI innovators and stakeholders to advocate for patient access to safe, ethically-developed healthcare AI. Our members are AI innovators who have or are in the process of developing AI services (or devices) that require U.S. Food & Drug Administration (FDA) oversight and market authorization. Our founding membership includes the first-ever autonomous AI innovator to obtain FDA authorization, as well as innovators who have obtained the first-ever Medicare reimbursement for their respective AI services. At the AI Healthcare Coalition’s inception in 2019, we developed ethical principles for healthcare AI systems derived from the bioethical principles non-maleficence, agency, and accountability.¹

The AI Healthcare Coalition thanks the committee for its leadership and commitment to ensuring access to FDA-authorized, rigorously validated healthcare AI services. We offer below our specific recommendations to the committee:

I. Congress should create permanent Medicare payment pathways for AI services.

The single greatest impediment for patient access to FDA-authorized AI services is the lack of permanent health insurer payment and coverage for such services. In the context of the federal healthcare programs, while the Centers for Medicare & Medicaid Services (CMS) has made intermediate, service-specific policies to allow for payment of AI services in certain limited circumstances, in general, the existing Medicare payment methodologies (e.g. the Medicare Physician Fee Schedule (PFS), Outpatient Prospective Payment System (OPPS), and Inpatient Prospective Payment System (IPPS)) do not lend themselves to payment for AI healthcare services. \(^2\) Given the increasing number of AI services receiving FDA authorization, and the promise of these technologies to improve patient care and address workforce shortages, clear and permanent payment pathways are needed.

The Medicare PFS is particularly challenging for AI innovators seeking to commercialize. CMS has made clear in its annual PFS rulemaking over the past several years that the agency considers most AI services to be a physician office “indirect practice expense (PE),” akin to a continuing overhead cost like a computer system or rent for office space. However many, if not most, AI services are provided to patients on a per-patient, per-service basis, which is best accounted for by a per-use payment, the same way that other medical services are valued and paid. In prior iterations of the PFS, CMS has discussed the potential need for a comprehensive update to PE data inputs, and possibly the PE methodology as a whole. CMS has expressed its belief that, ideally, comprehensive PE data inputs and a different PE calculation methodology would better account for the use of AI or machine learning (ML) technology, among other innovations.

There are also issues in the Medicare OPPS and IPPS that need to be addressed. Those payment systems have pathways for certain non-traditional technologies, namely, the New Technology Ambulatory Payment Classification or “New Tech APC” payment for certain outpatient services, and the New Technology Add-on Payment or “NTAP” payment for certain inpatient hospital services. While these programs are aimed at payment for innovative technologies, the New Tech APC and NTAP payment pathways were not created expressly for healthcare AI services and each has its own challenges. For example, AI innovators cite barriers created by the time limited nature of these payments, a lack of clear, consistent transition to permanent payment, and complexities concerning what a “new” service is for purposes of obtaining payment as a new technology. Collectively, the complexity of applying for and maintaining these payments presents a barrier for AI innovators seeking to ensure patient access to their services.

As more AI services are rigorously validated and FDA-authorized, clear reimbursement pathways are needed to ensure that Medicare beneficiaries and clinicians can access these services. Notably, AI services are diverse and varied, spanning multiple medical specialties and incorporating modalities that vary in their use of algorithmic design and ML. Some services may have clinical labor, non-clinical labor, and/or telehealth components. We believe strongly that this is the most acute challenge facing the deployment of FDA-authorized, rigorously validated AI services for patients.

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\(^2\) CMS has approved national Medicare payment for some AI services. For example, in 2021, CMS finalized the first-ever national payment rate for a fully autonomous AI service (CPT® 92229) to diagnose diabetic retinopathy in the primary care setting. CMS has also provided national payment rates for AI services in the specialty areas of cardiology and neurology.
II. **Congress should address outdated statutes to ensure access to FDA-authorized AI services.**

As more AI services become part of the clinical workflow and are adopted by clinicians, some statutory barriers should be addressed. These laws were created before the widespread use of AI in the clinical setting, and require amendment by Congress now to be brought up to date and allow for the use of safe, FDA-authorized AI services. Some examples include:

- **Section 5102(b) of the Deficit Reduction Act (DRA).** Congress enacted Section 5102(b), also known as the “OPPS cap” in 2007. The law was created to address concerns regarding rapid growth in federal spending on imaging services, particularly for advanced imaging modalities—such as computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine—as compared to growth in spending among less advanced imaging modalities, such as x-ray or ultrasound. AI services were not contemplated at the time of enactment as within the scope of the OPPS cap. Recently, CMS has begun to add AI services which analyze and provide diagnostic interpretations of images to the OPPS cap list. These services are not imaging services as contemplated by Congress when Section 5102(b) was enacted. AI healthcare services should not be on the OPPS cap list and Section 5102(b) should be amended to exclude such services.

- **The Mammography Quality Standards Act (MQSA).** The MQSA was enacted in 1994 and requires that all mammography facilities (except facilities of the Department of Veterans Affairs (VA)) be accredited by an approved accreditation body and certified by the FDA (or an approved State certification agency). The MQSA requires that “mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography.” There is a concern that this language precludes the use of AI analysis to interpret breast imaging for the identification of cancer, which is a front line use case for AI. When Congress passed the MQSA in 1994, the possibility of FDA-authorized, AI-enabled mammogram interpretation was not contemplated, and the existing statutory language hinders the development of AI technology that would advance Congress’ goal in passing the MQSA of high quality care for patients. To ensure patient access to advanced breast cancer detection technology, Congress should review and consider changes to the MQSA that will allow for the adoption of AI to enhance screening and early detection.

- **Glaucoma Screening.** Section 1861(uu) of the Social Security Act (SSA) requires that glaucoma screening be furnished by “by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician’s professional service...”. Like in many other parts of the SSA, this requirement precludes the use of fully autonomous AI services to perform an essential Medicare benefit – in this case, glaucoma screening. Congress should amend the SSA to allow for the use of rigorously validated, FDA-authorized autonomous AI services for glaucoma screening and the provision of other healthcare services.
III. Congress should provide ample resources to the FDA to continue its oversight of AI services.

The FDA has done significant work to evaluate and, in certain instances, approve AI/ML-enabled medical devices, and to date has approved over 500 AI applications.\(^3\) The FDA has also released numerous guidance documents concerning AI/ML oversight, including the *AI/ML-Based Software as a Medical Device (SaMD) Action Plan*, the *Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD*, and the *Clinical Decision Support Final Guidance*. The agency recently solicited comment on two additional guidance papers: the *AI/ML for Drug Development Discussion Paper* and the *Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions*.

As Congress considers additional regulatory frameworks for healthcare AI, we urge the Committee to recognize that some AI healthcare applications require FDA approval and continuing oversight—including review of the potential for bias and data set diversity—and others do not. AI services that fall within the scope of a “medical device” per FDA’s regulations and guidance are already subject to FDA review and market authorization, which is lengthy process that requires the same rigor of review as a traditional medical device application.

With respect to improvements in the regulatory frameworks that the FDA has for FDA-regulated AI/ML-enabled medical devices, we urge CMS to provide resources that enable the FDA to engage in collaborative, ongoing dialogue with AI developers, and to conduct reviews in an expeditious manner. For example, empowering the FDA with resources that facilitate the FDA pre-submission process and to engage collaboratively with external stakeholders and submitting parties.

Congress should fully fund initiatives at the FDA Digital Health Center for Excellence to develop policies for AI innovation, and the Center for Devices and Radiological Health (CDRH) to review AI/ML-enabled medical device market authorization applications. In addition, CMS should ensure that efforts to coordinate the AI activities of CMS and FDA are fully funded. We also support H.R.1691, the *Ensuring Patient Access to Critical Breakthrough Products Act of 2023*, which passed out of the House Energy & Commerce Subcommittee on Health recently and would provide coverage to innovative healthcare AI services.

IV. Congress should avoid undue regulatory burden and duplication that would inhibit American innovation.

It is paramount that Congress does not impose duplicative, industry-agnostic laws and regulations that are overly burdensome for American AI innovation. The development, use, and commercialization of AI is and will be a global endeavor, and it is imperative to create legal and regulatory constraints that put American AI innovator companies in a position where they cannot compete.

Like we have seen in Congress’ recent activity to address supply chain disruptions, once a market becomes untenable for manufacturing and production, it is very difficult to bring essential capabilities back to U.S. soil. Ensuring that we have the capabilities here at home to provide the

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best care—through AI, tech capabilities, and common-sense approaches to AI safety and ethics—is essential to American competitiveness in global AI innovation.

We caution against other regions’ industry agnostic, top-down approach to AI regulation, as we have seen some AI innovator companies cease operations in regions where such approaches have been implemented. AI innovation and deployment is a global endeavor, and our U.S. companies should be set up for successful development and provision of safe, trustworthy AI.

We appreciate the opportunity to express our views and look forward to working with the committee to ensure that patients and providers have access to FDA-authorized, rigorously validated healthcare AI. If you have any questions about this statement, please contact our Executive Director, Cybil Roehrenbeck, JD, at cybil.roehrenbeck@ai-coalition.org.