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Statement of

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Introduction

Chair Rodgers, Ranking Member Pallone, and distinguished Members of the Committee, thank you for the opportunity to testify today in support of the Department of Health and Human Services' (HHS) efforts to promote the fair, appropriate, valid, effective, and safe use of artificial intelligence (AI) and machine learning (ML) in health care, public health, and human services.

My name is Micky Tripathi, and I have been the National Coordinator for Health Information Technology since January 2021. I have over 20 years of industry experience across the health information technology (IT) landscape, working for private sector non-profit and for-profit organizations focused on health data interoperability, population health management, and data analytics. My organization, the HHS Office of the National Coordinator for Health Information Technology (ONC),[1] is at the forefront of the federal government's health IT efforts and supports the entire health system to advance the adoption of health IT and secure, nationwide, standards-based health information exchange.

In addition to my formal title as National Coordinator for Health Information Technology, I have been tasked by Secretary Becerra to help coordinate HHS's efforts pertaining to AI, including under the recently issued *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence[2](EO 14110)*.

The United States health care delivery system has undergone profound change in the use of digital technologies over the past decade, spurred by the HTECH Act and the 21st Century Cures Act. ONC-certified health IT, such as electronic health records (EHRs), which support an array of clinical and administrative activities, are now used by 97% of hospitals and almost 80% of ambulatory practices across the country.[3] Embedded clinical decision support (CDS) technologies – such as drug-drug interaction alerts and cardiac risk calculators – have been routinely used for many years by health care practitioners to help inform decisions about patient care, and recent advances in the availability and sophistication of AI/ML capabilities are rapidly expanding the depth and breadth of decision support technologies in health care.

In recent years, AI has become a part of our everyday lives. Advances in the same basic technology that can predict what movie you might want to watch, what song you might want to listen to, or what item you might want to buy online, can help to predict the onset of diseases, forecast costs of care, and recommend treatment options for your doctors, nurses, and pharmacists. The President's executive order underscores that to achieve these benefits, there needs to be appropriate protections related to AI in critical fields, including health care, human services, and public health. This includes holding those developing and deploying AI accountable to standards and practices that protect against unlawful discrimination and abuse. To execute on the EO, HHS is taking a multi-faceted approach to promote the safe and effective uses of AI in health care, human services, and public health.

In this written testimony, I will describe the following:

I)   The current state of AI within health care, human services, and public health
II)   HHS's actions to date in AI
III)   HHS's planned path forward pursuant to EO 14110

1. Current state of AI within health care, human services, and public health

In recent years, AI has become a part of our everyday lives. Health AI in particular has experienced explosive growth over the past five years. There have been significant increases in venture capital and private health AI investments, with some studies estimating a more than 40% compound annual growth rate and projections to reach approximately $45 billion by 2026.[4] And generative AI – algorithms that create new content based on analysis of large amounts of data – is projected to grow faster in health care than any other industry, with a compound annual growth rate of 85% through 2027.[5]

Basic algorithms—step by step instructions (rules) to perform a task or solve a problem—have been widely used in the health care sector for decades, especially once they became computerized. Historically, such algorithms have been simple "fixed-rules", or recipes based on clinical guidelines from medical experts and evidence drawn from research such as clinical trials and observational studies. For example, clinicians may use simple algorithms such as "if a person's cardiovascular risk score is above 15%, then they should get a moderate-to high-intensity statin" or "if a woman is between the ages of 45 and 54 and if she is of average risk of breast cancer, then she should get a mammogram every year."[6]

Advances in AI and ML capabilities are "super-charging" such algorithms by enabling them to go beyond such generalized fixed rules drawn from large numbers of patients to become more "predictive" by analyzing or "learning" from real data and tailoring their output to the characteristics of an individual patient. This makes predictive AI powerful tools because they can, at least in theory, be used to predict anything about which the technology collects data—whether an image looks like a tumor, whether a patient is likely to develop a specific disease, or whether a patient is likely to show up for their next appointment—to name a few. In addition to informing diagnostic and treatment decisions in the exam room, advances in AI and ML have fueled the increased use of predictive models in what is often known as the "back office" of the health care system, such as medical appointments scheduling, prior authorizations, and health care operations.[7]

Harnessing AI's potential

From monitoring patients, to recommending treatments and supporting population health management, AI-based technologies have the potential to drive innovation, increase market competition and vastly improve care for patients and populations. At HHS, we are particularly excited about the potential for AI-enabled technologies in a number of areas, including:

- Improving clinical outcomes by providing high value decision support and identifying and mitigating against errors;
- Accelerating scientific breakthroughs that ultimately increase quality and quantity of life;
- Reducing clinician burnout by allowing for greater time spent on patient care while reducing low value administrative costs from the health care system; and,
- Empowering patients through improved health and human services benefits delivery and plain language explanations and engagement of health information.

Mitigating against AI's risks

While predictive AI models have enormous potential to improve many aspects of health care, they also present several potential risks that could lead to adverse impacts or outcomes.[8] Some researchers have found that AI/ML-driven predictive technology has the potential to impact patient safety or introduce or propagate bias, which may result in discrimination or increased costs, all depending on how the model was designed, implemented, and used.[9]

These risks may be magnified because of predictive AI's potential to "learn" rapidly from real data and generate predictions for the care of millions of patients. If the analysis methods used by the algorithm are flawed or not robust, or the data used to "train" the model does not reflect the characteristics of the patient population at a particular health care setting, the model could go awry and draw conclusions or make recommendations that are ineffective, discriminatory, or unsafe.

Even well-designed AI/ML algorithms and models can be inaccurate or unreliable due to factors including differences in local patient characteristics than the model was based on due to variation in patient demographics (such as gender, race, or age composition), subtle shifts in the data over time, differences in health care practitioner or patient behavior, or shifts in data capture and management practices. These issues can degrade the predictive capabilities of algorithms and undermine the potential benefits from such tools in health care, human services, and public health. We have already seen, for example, a population health management model discovered to have unintended racial bias implications leading to the re-release of the model.[10,11,12]

More generally, many factors can present risks to the benefits of a model, such as how the model was designed and developed, the quality of the data used to build the model, and how the model is applied and used. A holistic perspective of those risks includes those that amplify implicit and structural biases; magnify ethical and social concerns related to data collection and use; reinforce common, non-evidence-based practices; bake-in existing inexplicable differences in health outcomes; perpetuate information asymmetries (i.e., "black box") regarding what goes into a model and how it performs; and make recommendations that are ineffective or unsafe. As this list suggests, risks to beneficial use of AI in health care can stem not only from poor or naïve model design, but also from a lack of or inconsistent governance of data, or policies and controls for how data are acquired, managed, and used.[13]

2. HHS actions to date in AI

HHS has worked for many years to utilize AI to advance its mission across numerous arenas, including research and discovery, drug and device safety, health care delivery, human services delivery, and public health. HHS prioritizes the development of AI across common enterprise mission areas and continues to lead in identifying opportunities for AI solutions, mitigating risks appropriately, using a shared framework of federal and HHS guidance.

Specific examples of HHS AI-related activities to date include the following:

- The Food and Drug Administration (FDA) has authorized more than 690 AI-enabled devices to improve medical diagnosis and treatment and expand access to care for patients, including cardiac ultrasound software that uses AI to guide users; an AI-based device that assists clinicians in detecting lesions (such as polyps or suspected tumors) in the colon in real time during a colonoscopy; a diagnostic aid for Autism Spectrum Disorder; and an AI-based device to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.[14] The FDA is also exploring how AI will impact the regulatory review process of drugs, biological

products, and medical devices (including software as a medical device). The agency recently issued and is seeking comment on new draft guidance and hosting workshops to solicit feedback.[15]

- Additionally, the growing adoption of new software tools and digital platforms that incorporate ML to meet patient needs also highlights the importance of promoting an internationally harmonized approach to Pre-determined Change Control Plans (PCCPs) for AI/ML-enabled devices. Recently, FDA released draft guidance related to PCCPs to ensure the AI/ML-enabled medical devices can be safely, effectively, and rapidly modified, updated, and improved in response to new data. In October, FDA, with Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) jointly published Guiding Principles for PCCPs for Machine Learning-Enabled Medical Devices.

- FDA has established the Digital Health Center of Excellence (DHCoE) and has successfully recruited experts who have worked in the industry developing AI-based products and are very familiar with the challenges faced by developers entering the field of medical device regulation. DHCoE staff has a diverse set of digital health industry experience and includes people with public health and patient advocacy experience, which is critical to understanding the challenges patients face when using and understanding AI technologies.[16]

- The National Institutes of Health (NIH) is utilizing AI to research priority areas, including cancer, Alzheimer's disease, and mental illness investing at least $200M in FY2023 (approximately $175M in FY2022) in the use of large data sets on topics such as helping researchers understand how to diagnose individuals with autism-spectrum disorders. NIH also issued a Notice of Funding Opportunities (NOFO) to develop AI/ML tools and resources to support the NIH Brain Initiative and issued a Notice of Special Interest (NOSI) to help improve the usability of NIH-supported data for AI/ML analytics.

- NIH recently announced the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program that will establish mutually beneficial and coordinated partnerships to increase the participation and representation of researchers and communities currently underrepresented in the development of AI/ML models and enhance the capabilities of this emerging technology, beginning with EHR data.

- ONC proposed a rule in April 2023 to increase algorithm transparency and adopt risk management approaches to AI-based technologies to support a dynamic and high-quality market for predictive AI in electronic health records used by 97% of hospitals and almost 80% of physician offices across the country (*additional details below*).[17]

- The Office for Civil Rights (OCR) proposed a rule in August 2022 under Section 1557 of the Affordable Care Act that would prohibit discrimination in certain health programs and activities through the use of clinical algorithms in decision-making.

- The Agency for Healthcare Research and Quality (AHRQ) conducted an evidence review to summarize research on racial and ethnic bias in health care algorithms and approaches to mitigate bias and reduce disparities.

- The Centers for Medicare & Medicaid Services (CMS) is requiring Medicare Advantage (MA) organizations to ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as opposed to using an algorithm or software that does not account for an individual's circumstances. These requirements become effective on January 1, 2024, and CMS will then begin taking enforcements actions against Medicare Advantage organizations that do not comply with the new utilization management requirements. Separately, the Center for Medicare and Medicaid Innovation conducted an AI Health Outcomes Challenge

from 2018-2021 to accelerate the development of AI tools-such as deep learning and neural networks-for predicting patient health outcomes for Medicare beneficiaries.

- The Centers for Disease Control and Prevention (CDC) is developing an AI strategy and exploring how AI and Natural Language Processing methods can augment existing methods to improve the timeliness and enhance public health's ability to estimate U.S. suicide fatalities and other important sentinel events. CDC also uses AI to aid in the response to disease outbreaks and combatting the opioid epidemic (e.g., identifying opioid use vs misuse in EHRs and vital records).
- The Administration for Strategic Preparedness and Response currently leverages ML and AI tools to improve COVID-19 data collection and analysis, forecasting, and vaccine access and distribution.
- The Administration for Children and Families conducted a study focused on emerging issues and needs associated with AI in the health and human services sectors, resulting in the published report titled, *Options and Opportunities to Address and Mitigate the Existing and Potential Risks, as well as Promote Benefits, Associated with AI and Other Advanced Analytic Methods.*[18]

Importantly, throughout these and other activities, HHS is committed to the concept of "health equity by design," where health equity considerations are identified and incorporated from the inception and throughout the technology design, build, and implementation process. The EO 14091 emphasizes the incorporation of equity principles in AI-enabled technologies used in the health and human services sector.[19]

Additional details on ONC draft rule:

My office – ONC – has proposals for algorithmic transparency in our Health Data, Technology, and Interoperability HTI-1 Proposed Rule. This proposed rule, which ONC released in April 2023 and is working on finalizing, includes proposals designed to enable improved information transparency on the quality of predictive AI models to support their responsible and widespread use in health care. If finalized, these proposals would improve transparency regarding how a predictive AI model is designed, developed, trained, evaluated, and how it should be used. Greater transparency could serve as the tipping point for the vast potential of ML and related technologies in health care while also ensuring their fair, appropriate, valid, effective, and safe (FAVES) use.[20] These proposals would also enhance trustworthiness – through transparency on how certified health IT developers manage potential risks and govern predictive AI-based and other algorithms that are supported by their certified health IT (e.g., EHRs). The proposed rule would also establish an industry-wide baseline of information that will enable users to determine the quality of predictive AI models. Further, as EHR systems are used by the vast majority of hospitals and physician offices today, are a major source of data for AI-based models, and are a vehicle by which such models influence day-to-day decision-making that directly affects patient lives, we believe that these proposals could provide a prudent and critical set of useful benchmarks and guard-rails to allow AI innovation in health care to proceed responsibly.

3. HHS's planned path forward pursuant to EO 14110

HHS is prioritizing five activities relating to our work on AI:

1. Develop resources and policies to enable the safe, responsible adoption and use and manage risks of AI in health care, public health, and human services.
2. Advance quality and safety of AI in health through assurance standards and quality management processes.
3. Leverage grantmaking and contracting to advance the development and responsible use of AI across the health and human services delivery value chain.
4. Provide public education across the health care ecosystem and constituents – from individuals to organizations and states – on AI development and use in health and human services delivery.
5. Evaluate and deploy AI capabilities across HHS to drive process innovation and modernization.

Taken together, these objectives will enable HHS to fully mobilize its components to seamlessly integrate with and meaningfully contribute to a whole-of-government-and-industry approach to improving quality, efficiency, trustworthiness, access, and outcomes in health and human services through the safe, ethical, and responsible use of AI.

Further in line with EO 14110, HHS intends to develop a strategic plan within the next year that includes policies and frameworks on responsible deployment and use of AI and AI-enabled technologies for research and discovery, drug and device safety, health care delivery and financing, and public health. Additional details on how HHS intends to meet these objectives is included below:

1. *Develop resources and policies to enable the safe, responsible adoption and use and manage risks of AI in health care, public health, and human services*

   a. Given HHS's role as provider, researcher and regulator of health and human services, HHS seeks to strengthen AI resources and policy for the health sector (such as best practice guidance documents, frameworks and guidelines, standards, or regulation). The HHS workgroups will enhance collaboration with all relevant stakeholders (e.g., industry, states, and consumers). HHS is currently reviewing how AI fits into current regulatory frameworks and is also exploring areas where additional statutory authority may be necessary to implement regulation as appropriate. With input from industry and in partnership with other Federal partners HHS will work to determine what issues to prioritize and how to approach them.

2. *Advance quality and safety of AI in health through assurance standards and quality management processes.*

   a. The proliferation of AI has magnified existing concerns about the ethical and social implications of underlying data practices (collection, management, and use). AI poses unique challenges and risks when applied to the delivery of health and human services. HHS seeks to explore mechanisms to reduce the AI associated risks to patients and consumers, such as through quality and assurance testing and through monitoring for AI-related safety events. In the next twelve to eighteen months, HHS intends to develop a comprehensive approach to quality assurance that could be supported through an AI safety program.

b. HHS is already co-leading planning and development of critical components of the National Artificial Intelligence Research Resource (NAIRR) and looks forward to continuing to be a major contributor to the NAIRR.[21]

3. *Leverage grantmaking and contracting to advance the development and responsible use of AI across the health and human services delivery value chain.*

   a. As the largest grantmaking agency in the federal government, HHS evaluates and manages thousands of projects that invest in research and deliver services in support of our mission. As a steward of federal funds, HHS will encourage grant recipients to consider AI's utility and prioritize and enable programs, grants, and research that use AI in trustworthy ways to realize mission impact more efficiently or effectively. Specifically, these efforts include advancing biomedicine through AI-enabled insights into large datasets, predictive analytics in public health surveillance and responses, and the use of cognitive technologies to identify new approaches to health and behavioral conditions with complex multifactorial causality. HHS will also deploy AI in the grantmaking process itself, for example, to facilitate risk-based grant review in order to optimize the allocation of resources and to reduce opportunities for waste, fraud, and abuse of federal funds.

   b. HHS seeks to further empower organizations making advancement in AI technology applicable to health and human services through grants, contracts, and other funding opportunities. In the next twelve to eighteen months, HHS envisions accelerating its grants and contract allocations relating to AI (e.g., AI-enabled research) and the launch of multiple AI-related challenge grants. We are creating a cross-departmental approach to funding AI (e.g., how is AI tied to funding across public health) and identifying priority gaps and opportunities. We also seek to better understand and scale existing effective approaches to funding AI across HHS.

4. *Provide public education across the healthcare ecosystem and constituents – from individuals to organizations and states – on AI development and use in health and human services delivery.*

   a. HHS will explore ways to support all of its stakeholders in growing their literacy on safe and responsible use of AI, while also ensuring they have access to the resources and tools to ensure equity and minimize the digital divide. In the next twelve to eighteen months, HHS aspires to develop and identify useful content for myriad stakeholders to consume and learn from, engage in an AI public education campaign, and accelerate and strengthen connections between stakeholders for information sharing (e.g., connecting more and less advanced state governments on AI deployment and use).

   b. HHS collaborates with partners in private industry, academia, and various state, local, tribal, and territorial governments to advance common interests across shared missions in administering essential human services and health programs. HHS will engage with these partners to identify opportunities for trustworthy AI applications that advance health and human services, including streamlining processes that span the Department and its partners, reducing costly or inefficient resources allocated to low-value, repetitive tasks,

and providing enhanced experiences and services for program beneficiaries and the American public.

    c.   HHS will also engage with partners to prioritize needs and opportunities for AI advancements that enable better outcomes in research, public health and safety, social services, disease prevention, and wellness. HHS will develop toolkits in collaboration with AI developers for regulated firms to develop metrics, methods, and systems for continuous verification, and evaluate the need for development of an assurance lab project for algorithm testing, validation, and performance evaluation. HHS will also support development and dissemination of AI curricula for provider training (e.g., nursing and medical school, residency).

    5.   *Evaluate and deploy AI capabilities across HHS to drive process innovation and modernization.*

    a.   At HHS, we seek to lead by example in the safe and responsible use of AI by significantly increasing its use for both mission delivery and internal operations. In the next twelve to eighteen months, HHS aspires to significantly increase internal experimentation along with responsible use of AI to both advance HHS internal operations (e.g., back-office functions) and support mission delivery. This includes administrative functions (e.g., notice of funding opportunity notifications, acquisitions and contracting), IT system modernization and cybersecurity, and human capital (e.g., hiring and upskilling AI workforce).

Conclusion

As illustrated by my testimony today, AI is touching all equities at HHS, and this represents a shared responsibility across many partners, including AI technology developers, customers, users, providers, data scientists, engineers, researchers, patients, and government.

Trustworthy, safe, and responsible use of AI technologies will accelerate HHS' ability to meet evolving needs as both a leader and responsive partner in innovations across health and human services. AI will be critical to HHS in achieving its mission and vision, as well as positioning HHS to address the health and human services challenges of tomorrow. HHS will continue its leadership at the vanguard of health and human services innovation to meet the changing needs of the American people in regard to AI.

As we do so, we will continue to keep Congress informed of our progress. Chair Rodgers, Ranking Member Pallone, and Members of the Committee, thank you for the opportunity to testify. I look forward to responding to any questions you may have.

Endnotes

[1] More information about the history and creation of ONC available at https://www.healthit.gov/topic/about-onc.

[2] United States, Executive Office of the President [Joseph Biden]. Executive Order 14110: Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. Oct. 30, 2023, https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/.

[3] Office of the National Coordinator for Health Information Technology. National Trends in Hospital and Physician Adoption of Electronic Health Records, Health IT Quick-Stat #61; *Office-based Physician Electronic Health Record Adoption*, https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption.

[4] Boston Consulting Group. Medtech's Generative AI Opportunity, 2023, https://www.bcg.com/publications/2023/generative-ai-in-medtech.

[5] Id.

[6] ONC, Health IT Buzz Blog, AI & ML Blog Series: *Two Sides of the AI/ML Coin in Health Care* (October 2022): https://www.healthit.gov/buzz-blog/blog-series-artificial-intelligence-machine-learning/ai-ml-in-health-care.

[7] See *e.g.,* Michele Samorani, Shannon L. Harris, Linda Goler Blount, Haibing Lu, Michael A. Santoro (2021) Overbooked and Overlooked: Machine Learning and Racial Bias in Medical Appointment Scheduling. Manufacturing & Service Operations Management 0(0), https://pubsonline.informs.org/doi/10.1287/msom.2021.0999.

[8] *See e.g*., Wong A, OtlesE, Donnelly JP, Krumm A, McCullough J, DeTroyer-Cooley O, et al. External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. JAMA Internal Medicine. 2021;181(8):1065-70.

[9] *See e.g*., Vyas DA, Eisenstein LG, Jones DS. Hidden in plain sight—reconsidering the use of race correction in clinical algorithms. Mass Medical Soc; 2020. P. 874-82; Delgado C, Baweja M, Crews DC, EneanyaND, GadegbekuCA, Inker LA, et al. A unifying approach for GFR estimation: recommendations of the NKF-ASN task force on reassessing the inclusion of race in diagnosing kidney disease. American Journal of Kidney Diseases. 2022;79(2):268-88. E1.

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[11] Knaus, William A., et al. "The APACHE III prognostic system: risk prediction of hospital mortality for critically III hospitalized adults." Chest 100.6 (1991): 1619-1636.

[12] Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019;366(6464):447-53.

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[14] FDA, Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (2023), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.

[15] FDA, https://www.federalregister.gov/documents/2023/05/11/2023-09985/using-artificial-intelligence-and-machine-learning-in-the-development-of-drug-and-biological.

[16] FDA, Digital Health Center of Excellence, https://www.fda.gov/medical-devices/digital-health-center-excellence

[17] See U.S. Department of Health and Human Services, ONC, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, available at: https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and; ONC, Health IT Buzz Blog, AI & ML Blog Series: *Increasing the Transparency and Trustworthiness of AI in Health Care* (April 2023), https://www.healthit.gov/buzz-blog/health-innovation/transparent-and-trustworthy-ai-in-health-care.

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[19] United States, Executive Office of the President [Joseph Biden]. Executive Order 14110: Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. Oct. 30, 2023, https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/

[20] ONC, Health IT Buzz Blog, AI & ML Blog Series: *Getting the Best out of Algorithms in Health Care* (June 2022), https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/getting-the-best-out-of-algorithms-in-health-care.

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