ConnectedHealthInitiative

July 7, 2023

Office of Science and Technology Policy
Eisenhower Executive Office Building
725 17th Street NW
Washington, District of Columbia 20502

RE: Comments of the Connected Health Initiative to the White House's Office of Science and Technology Policy on *Request for Information; National Priorities for Artificial Intelligence* (88 FR 34194; OSTP-TECH-2023-0007)

The Connected Health Initiative (CHI) appreciates the opportunity to provide input to the Office of Science and Technology Policy (OSTP) on national priorities to inform the development of a National Artificial Intelligence (AI) Strategy.[1] CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of thought leaders from across the connected health ecosystem. We aim to realize an environment where Americans can improve their health through policies that allow connected health technologies to enhance health outcomes and reduce costs.

AI is an evolving constellation of technologies that enable computers to simulate elements of human thinking, such as learning and reasoning. An encompassing term, AI entails a range of approaches and technologies, such as machine learning (ML), where algorithms use data, learn from it, and apply their newly learned lessons to make informed decisions, and deep learning, where an algorithm based on the way neurons and synapses in the brain change as they are exposed to new inputs allows for independent or assisted decision-making. AI-driven tools are having, and will continue to have, substantial direct and indirect effects on Americans in how they manage their health. Some forms of AI are already being used to improve American consumers' lives today – for example, AI is used to accomplish backend administrative functions for healthcare providers. Moving forward, AI has incredible potential to advance the Quadruple Aim; for example, healthcare treatments and patient outcomes stand poised to improve disease prevention and conditions, as well as efficiently and effectively treat diseases through automated analysis of x-rays and other medical imaging. From a governance perspective, AI solutions will derive greater insights from infrastructure and support proactive interventions and more effective decision making across a range of contexts.

Nonetheless, AI's growing use raises a variety of challenges, and some new and unique considerations, for policymakers as well as those making AI operational in healthcare. CHI appreciates OSTP's exploration of policies to provide reliable guidance to

[1] 88 FR 34194.

stakeholders to reassure end users that AI systems are legal, effective, ethical, safe, and otherwise trustworthy.

As part of its commitment to responsibly advance AI in healthcare, CHI assembled a Health AI Task Force consisting of a range of innovators and experts, which developed a number of recommendations for policymakers. **Notably, CHI has developed a comprehensive set of health AI policy recommendations (available at https://bit.ly/3m9ZBLv and appended to this comment[2]) that we urge OSTP to consider.**

We also encourage OSTP to consider the following additional resources CHI has developed as it moves forward with the National AI Strategy:

- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*,[3] a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5);
- CHI's *Good Machine Learning Practices for FDA-Regulated AI*, a proposed risk-based approach to benefit the Food and Drug Administration (FDA) as it addresses both locked and continuously-learning AI systems that meet the definition of a medical device (https://bit.ly/2YaYljk); and
- CHI's *Why AI? Considerations for Use of Artificial Intelligence in States' Medicaid and CHIP Programs*, which maps CHI's Health AI Policy Principles to the challenges and opportunities faced at the state level (https://bit.ly/2Y2FJle).

Further, CHI strongly requests OSTP support a coordinated effort across both executive and independent agencies through the National AI Strategy. Already, numerous regulatory agencies, some cross-sectoral and others sector-specific, are considering or advancing regulatory proposals that would take starkly different approaches to AI accountability. Some of these proposals are poised to put significant hurdles in place for the development and use of health AI through one-size-fits-all approaches that have nominal public benefit at best, such as the Department of Health and Human Services (HHS) Office of Civil Rights' proposed approach to preventing discriminatory outcomes in healthcare;[4] and HHS' Office of the National Coordinator for Health IT (ONC) proposal to impose new requirements on clinical decision support AI already regulated by FDA,[5] both of which are leading examples of sector-specific misalignment with other leading Administration efforts, such as that of the National Institute of Standards and

[2] Also included with this comment as **Appendix A**.

[3] Also included with this comment as **Appendix B**.

[4] Nondiscrimination in Health Programs and Activities, 87 FR 47824 (Aug. 4, 2022); CHI's detailed views on this HHS OCR proposal are included in this comment as **Appendix C**.

[5] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 FR 23746 (Apr. 18, 2023); CHI's detailed views on this HHS ONC proposal are included in this comment as **Appendix D**.

Technology (NIST).[6] In some other cases, such proposals are being developed based on speculative and undemonstrated harms.[7] OSTP, along with other cross-sectoral subject matter expert agencies in the federal government such as NIST, should take immediate steps to ensure a harmonized and informed approach to AI governance.

Many entities, both public and private, are actively engaging in efforts to create and enforce AI accountability frameworks, which may lead to the creation of trusted audits/assessments/certifications. While this work continues to mature and converge, we strongly urge OSTP to align with NIST's efforts to develop a voluntary artificial intelligence risk management framework (AI RMF), which aims to help designers, developers, users, and evaluators of AI systems evolve in knowledge, awareness, and best practices to better manage risks across the AI lifecycle.[8] NIST's AI RMF is best positioned to guide federal government efforts in addressing AI due to NIST's expertise and its collaborative and open approach to developing the AI RMF, similar to NIST's Cybersecurity Framework.[9] And it is in the public's best interest that a scaled, risk-based approach serve as a basis for both executive and independent agencies' approach to AI risk management and governance; and that OSTP take active steps to bring federal agencies into alignment with this approach.

[6] https://www.nist.gov/itl/ai-risk-management-framework.

[7] Trade Regulation Rule on Commercial Surveillance and Data Security, 87 FR 51273 (Aug. 22, 2022); CHI views provided to the Federal Trade Commission in response to its Advanced Notice of Proposed Rulemaking are available at https://www.regulations.gov/comment/FTC-2022-0053-1089.

[8] https://www.nist.gov/itl/ai-risk-management-framework.

[9] https://www.nist.gov/cyberframework.

CHI appreciates OSTP's consideration of the above (and appended) views, and we urge OSTP to contact the undersigned with any questions or ways that we can assist moving forward.

Sincerely,

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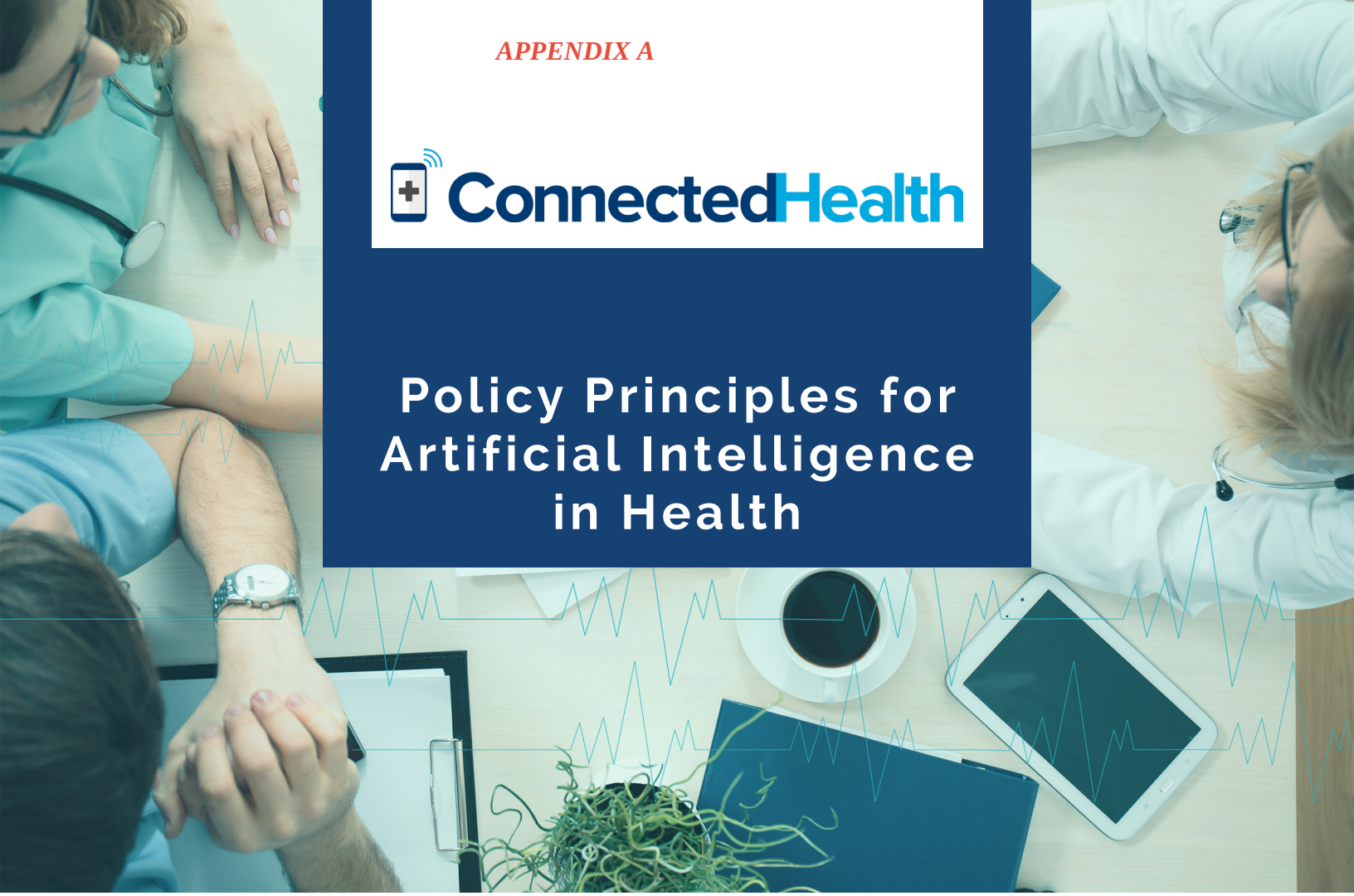
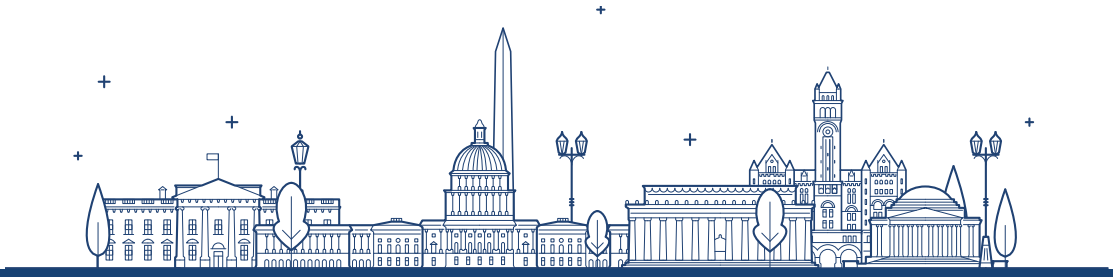
APPENDIX A

ConnectedHealth

Policy Principles for Artificial Intelligence in Health





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Policy Principles for AI in Health

Today, there are already many examples of AI systems, powered by streams of data and advanced algorithms, improving healthcare by preventing hospitalizations, reducing complications, decreasing administrative burdens, and improving patient engagement. AI systems offer the promise to rapidly accelerate and scale such results and drive a fundamental transformation of the current disease-based system to one that supports prevention and health maintenance. Nonetheless, AI in healthcare has the potential to raise a variety of unique considerations for U.S. policymakers.

Many organizations are taking steps to proactively address adoption and integration of AI into health care and how it should be approached by clinicians, technologists, patients and consumers, policymakers, and other stakeholders, such as the Partnership for AI, Xavier Health, the American Medical Association, and the Association for the Advancement of Medical Instrumentation and BSI. Building on these important efforts, the Connected Health Initiative's (CHI) Health AI Task Force is taking the next step to address the role of AI in healthcare.

First, AI systems deployed in healthcare must advance the "quadruple aim" by improving population health; improving patient health outcomes and satisfaction; increasing value by lowering overall costs; and improving clinician and healthcare team well-being. Second, AI systems should:

- Enhance access to health care.
- Empower patients and consumers to manage and optimize their health.
- Facilitate and strengthen the relationship and communication that individuals have with their health care team.
- Reduce administrative and cognitive burdens for patients and their health care team.

To guide policymakers, we recommend the following principles to guide action:

- **National Health AI Strategy:** Many of the policy issues raised below involve significant work and changes that will impact a range of stakeholders. The cultural, workforce training and education, data access, and technology-related changes will require strong guidance and coordination. Given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as steward of significant amounts of patient data, a federal healthcare AI strategy incorporating guidance on the issues below will be vital to achieving the promise that AI offers to patients and the healthcare sector. Other countries have begun to take similar steps (e.g., The UK's Initial Code of Conduct for Data Driven Care and Technology) and it is critical that U.S. policymakers collaborate with provider organizations, other civil society organizations, and private sector stakeholders to begin similar work.

- **Research:** Policy frameworks should support and facilitate research and development of AI in healthcare by prioritizing and providing sufficient funding while also ensuring adequate incentives (e.g., streamlined availability of data to developers, tax credits) are in place to encourage private and non-profit sector research. Clinical validation and transparency research should be prioritized and involve collaboration among all affected stakeholders who must responsibly address the ethical, social, economic, and legal implications that may result from AI applications in healthcare. Further, public funding and incentives should be conditioned on promoting the medical commons in order to advance shared knowledge, access, and innovation.
- **Quality Assurance and Oversight:** Policy frameworks should utilize risk-based approaches to ensure that the use of AI in healthcare aligns with recognized standards of safety, efficacy, and equity. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. Policy frameworks addressing liability should ensure the appropriate distribution and mitigation of risk and liability. Specifically, those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. Some recommended guidelines include:
    - Ensuring AI in healthcare is safe, efficacious, and equitable.
    - Ensuring algorithms, datasets, and decisions are auditable and when applied to medical care (such as screening, diagnosis, or treatment) are clinically validated and explainable.
    - AI developers should consistently utilize rigorous procedures and must be able to document their methods and results.
    - Those developing, offering, or testing healthcare AI systems should be required to provide truthful and easy to understand representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI solution.
    - Adverse events should be timely reported to relevant oversight bodies for appropriate investigation and action.

- **Thoughtful Design:** Policy frameworks should require design of AI systems in health care that are informed by real-world workflow, human-centered design and usability principles, and end-user needs. Also, AI systems should help patients, providers, and other care team members overcome the current fragmentation and dysfunctions of the healthcare system. AI systems solutions should facilitate a transition to changes in care delivery that advance the quadruple aim. The design, development, and success of AI in healthcare should leverage collaboration and dialogue between caregivers, AI technology developers, and other healthcare stakeholders in order to have all perspectives reflected in AI solutions.
- **Access and Affordability:** Policy frameworks should ensure AI systems in health care are accessible and affordable. Significant resources may be required to scale systems in health care and policy-makers must take steps to remedy the uneven distribution of resources and access. There are varied applications of AI systems in health care such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI system with an eye toward ensuring value. While AI systems should help transition to value-based delivery models by providing essential population health tools and providing enhanced scalability and patient support, in the interim payment policies must incentivize a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.
- **Ethics:** Given the longstanding, deeply rooted, and well-developed body of medical and biomedical ethics, it will be critical to promote many of the existing and emerging ethical norms of the medical community for broader adherence by technologists, innovators, computer scientists, and those who use such systems. Healthcare AI will only succeed if it is used ethically to protect patients and consumers. Policy frameworks should:
    - Ensure AI in healthcare is safe, efficacious, and equitable.
    - Ensure that healthcare AI solutions align with all relevant ethical obligations, from design to development to use.
    - Encourage the development of new ethical guidelines to address emerging issues with the use of AI in healthcare, as needed.
    - Ensure consistency with international conventions on human rights.
    - Ensure that AI for health is inclusive such that AI solutions beneficial to patients are developed across socioeconomic, age, gender, geographic origin, and other groupings.
    - Reflect that AI for health tools may reveal extremely sensitive and private information about a patient and ensure that laws protect such information from being used to discriminate against patients.

- **Modernized Privacy and Security Frameworks:** While the types of data items analyzed by AI and other technologies are not new, this analysis provides greater potential utility of those data items to other individuals, entities, and machines. Thus, there are many new uses for, and ways to analyze, the collected data. This raises privacy issues and questions surrounding consent to use data in a particular way (e.g., research, commercial product/service development). It also offers the potential for more powerful and granular access controls for patients. Accordingly, any policy framework should address the topics of privacy, consent, and modern technological capabilities as a part of the policy development process. Policy frameworks must be scalable and assure that an individual's health information is properly protected, while also allowing the flow of health information. This information is necessary to provide and promote high-quality healthcare and to protect the public's health and well-being. There are specific uses of data that require additional policy safeguards, i.e., genomic information. Given that one individual's DNA includes potentially identifying information about even distant relatives of that individual, a separate and more detailed approach may be necessary for genomic privacy. Further, enhanced protection from discrimination based on pre-existing conditions or genomic information may be needed for patients. Finally, with proper protections in place, policy frameworks should also promote data access, including open access to appropriate machine-readable public data, development of a culture of securely sharing data with external partners, and explicit communication of allowable use with periodic review of informed consent.
- **Collaboration and Interoperability:** Policy frameworks should enable eased data access and use through creating a culture of cooperation, trust, and openness among policymakers, health AI technology developers and users, and the public.
- **Workforce Issues and AI in Healthcare:** The United States faces significant demands on the healthcare system and safety net programs due to an aging population and a wave of retirements among practicing care workers. And lower birth rates mean that fewer young people are entering the workforce. Successful creation and deployment of AI-enabled technologies which help care providers meet the needs of all patients will be an essential part of addressing this projected shortage of care workers. Policymakers and stakeholders will need to work together to create the appropriate balance between human care and decision-making and augmented capabilities from AI-enabled technologies and tools.
- **Bias:** The bias inherent in all data as well as errors will remain one of the more pressing issues with AI systems that utilize machine learning techniques in particular. In developing and using healthcare AI solutions, these data provenance and bias issues must be addressed. Policy frameworks should:
    - Require the identification, disclosure, and mitigation of bias while encouraging access to databases and promoting inclusion and diversity.
    - Ensure that data bias does not cause harm to patients or consumers.

- **Education:** Policy frameworks should support education for the advancement of AI in healthcare, promote examples that demonstrate the success of AI in healthcare, and encourage stakeholder engagements to keep frameworks responsive to emerging opportunities and challenges.
    - Patients and consumers should be educated as to the use of AI in the care they are receiving.
    - Academic/medical education should include curriculum that will advance health care providers' understanding of and ability to use health AI solutions. Ongoing continuing education should also advance understanding of the safe and effective use of AI in healthcare delivery.

ConnectedHealth

Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

OCTOBER 2021

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Executive Summary

Today, the most well-known FDA-approved applications of artificial intelligence and machine learning (AI/ML) technology in healthcare are diagnostic tools that help clinicians read and interpret images to predict, detect, and monitor a number of diseases, including diabetic retinopathy and lung cancer. In the future, the use of AI/ML technology in both operational and clinical settings promises to enable a more proactive approach to healthcare that promotes investments in preventative care that can result in fewer hospitalizations, fewer doctor visits, and fewer treatments. Across use cases, AI/ML technology is helping, and must increasingly help, the healthcare industry move away from a reactive disease treatment approach to a population health management approach that lowers costs and improves care.

The immense potential of AI/ML technology in healthcare may never be fully acheived, however, unless AI/ML technologies first earn the trust of healthcare professionals and patients. The cornerstone of building trust in AI/ML technologies is to enhance transparency – providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic. The more understandable the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.

The recommendations in this Connected Health Initiative (CHI) AI Task Force report, informed by a public roundtable CHI held to address AI/ML transparency and extensive consultations with stakeholders from across the digital health ecosystem, represent a holistic approach to creating and maintaining the trust of both healthcare professionals and patients. The Task Force set out the foundational steps AI/ML tool developers must take to build transparency into their products, but it also outlines the important roles that clinicians, healthcare providers, regulators, academic medical institutions, and accrediting organizations must play.

The medical and technology communities have a shared responsibility to provide caregivers and patients (as well as other stakeholders) with an assurance of quality through truthful representations clearly indicating the AI/ML's intended uses and risks that would be reasonably understood by those intended and expected to use the AI/ML. Uptake will depend on the buy-in of clinicians who first develop trust in AI/ML software as a medical device (SaMD) through use and experience, establishing confidence as it is adopted into practice. Once adopted, clinicians can then work with their patients to explain their use of SaMD AI/ML and inspire the same trust and confidence from the patients in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The foundation of any successful use of AI/ML technologies in healthcare depends on the trust of healthcare professionals and patients, and we believe these recommendations present a clear path toward earning that trust.

About the Connected Health Initiative

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. We aim to realize an environment where Americans can improve their health through policies that allow for connected health technologies to enhance health outcomes and reduce costs. Having members who are developers and users of connected health technologies across a wide range of use cases, CHI serves as an active advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement and payment, privacy and security, effectiveness, and quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence and machine learning (AI/ML) in care delivery.

In 2019, CHI formed a Task Force focused on policy challenges and opportunities related to the use of AI/ML in healthcare. CHI's AI/ML Task Force already developed a set of health AI/ML policy principles addressing how policy frameworks should adopt the role of AI/ML in healthcare.[1] A cornerstone of these principles is the idea of requiring those developing, offering, or testing healthcare AI/ML systems to provide truthful representations clearly indicating the intended use and risks that would be reasonably understood by those intended and expected to use the AI/ML solution. Such steps will provide much-needed quality assurances to caregivers and patients (as well as other stakeholders) and assist in resolving data issues that arise when an algorithm is fed bad data that can skew its learning and introduce bias. CHI's AI Task Force later developed detailed Good Machine Learning Practices for FDA-regulated AI,[2] which reflect and elaborate on this priority. The recommendations in this paper build on those deliverables.

Numerous CHI Steering Committee members and other key stakeholders from throughout the healthcare value chain participate in this Task Force and share a commitment to realizing the value of AI/ML in healthcare while protecting patient safety and advancing the quadruple aim. The recommendations in this paper find basis in an evaluation by the Task Force of the healthcare ecosystem's implementation of AI/ML to date, challenges and opportunities reflected by federal policymakers, and the existing and emerging issues created by AI's deployment. This report is also informed by a CHI public roundtable held in April 2021 on how to improve AI/ML transparency for caregivers and patients based on their needs and concerns, during which a wide range of stakeholders contributed to a discussion exploring novel approaches to transparency of AI/ML taken today.

For more information, please visit www.connectedhi.com.

1 https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.
2 https://bit.ly/3B6nslm.

Artificial Intelligence's Role in a Successful Healthcare Ecosystem Requires Transparency

Responsible implementation of AI/ML in healthcare leads to improved medical outcomes and overall increased cost savings

Today, there are many important operational and clinical AI/ML solutions in use and many more in development.[3] Some of the most well-known applications of AI/ML in healthcare that have received market clearance from the FDA are diagnostic tools that help clinicians read and interpret images. For example, AI/ML image analysis software can assist clinicians in predicting, detecting, and monitoring a number of diseases, including diabetic retinopathy, lung cancer, prostate cancer, and skin cancer. Such AI/ML uses are generally intended to be used to assist human clinicians in providing more efficient and accurate results, rather than autonomously diagnosing disease.

Separately, research projects within and outside of clinical settings continue to further explore AI's potential to revolutionize healthcare. For example, an AI/ML system developed by researchers at Northwestern University's Feinberg School of Medicine correctly identifies small lung cancer tumors nearly 95 percent of the time, while radiologists undertaking the same task unassisted are correct only 65 percent of the time.[4] Researchers at Carnegie Mellon developed a miniature mobile robot called HeartLander that uses machine learning algorithms to make treating ventricular fibrillation (VF)—a deadly type of cardiac arrhythmia that requires cardioversion and then, if the patient survives, surgical removal of faulty heart tissue—far safer and less invasive.[5]

As a recent research paper discussing challenges related to deployment of AI/ML technologies into the clinical setting stated, "the success of a deep learning model does not rest solely on its accuracy."[6]The researchers noted that clinician "experiences with the system, and the socio-environmental factors that impacted system performance" must be evaulated and addressed for these systems to function in the clinical setting with the accuracy rates illustrated in the lab setting.[7] Clearly, if the challenges of integrating AI/ML tools into clinical workflow can be overcome, AI/ML can support clinicians in a wide range of other areas. Its potential to reshape the healthcare landscape is profound, especially in the improvements it can bring to any process within healthcare operation and delivery.

Medical devices and systems that use AI/ML also represent a real opportunity to drive down healthcare costs for consumers, practitioners, and healthcare businesses alike. It is estimated that AI/ML applications can cut annual U.S. healthcare costs by $150 billion by 2026.[8] Most of these cost reductions stem from changing the healthcare model from a reactive to a proactive approach, focusing on health management rather than disease treatment. This focus on using AI/ML as an investment in

3 The FDA now publicly lists AI/ML medical devices cleared for marketing in United States, and includes their intended uses. *See* https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.
4 https://www.nature.com/articles/d41586-020-03157-9
5 https://onlinelibrary.wiley.com/doi/10.1002/rcs.2297
6 Emma Beede et al, A Human-Centered Evaluation of a Deep Learning System Deployed in Clinics for the Detection of Diabetic Retinopathy, CHI Conference on Human Factors in Computing Systems (April 2020) available at https://dl.acm.org/doi/fullHtml/10.1145/3313831.3376718.
7 *Id.*
8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7325854/.

preventative care can result in fewer hospitalizations, fewer doctor visits, fewer treatments, and thus fewer side effects. AI-based technology will have an important role in helping people stay healthy via remote monitoring technologies and coaching and will ensure earlier diagnosis, tailored treatments, and more efficient follow-ups.[9]

For example, AI/ML image analysis technologies can reduce medical expenses in several ways. For one, AI/ML systems can be very helpful in augmenting a clinician's analysis and treatment decisions more quickly. AI/ML technologies enable clinicians to provide the same, accurate service in a fraction of the time, increasing the volume of patients without increasing time spent treating them.[10] Second, a patient whose disease is diagnosed early will pay less to treat or cure the disease than one who catches it later. The longer a disease goes undiagnosed, the more damage it causes and more resources it takes to treat, assuming it remains treatable at all. Wearable technologies that use AI, such as remote monitoring technologies, increase access to healthcare and increase engagement in treatment plans by, for example, analyzing user health data in real time and notifying wearers or their healthcare providers (or both) of potential health issues.

By introducing new, accurate, and timely data streams for human clinicians' review, AI/ML medical tools and systems that use wearable technologies can enable practitioners to come up with care and treatment options without having to see a patient in person as much, reducing administrative and in-office visit resource expenditures, and, during outbreaks of communicable diseases, at lower risk of infection to both provider and patient. The use of such technologies will also enhance patient engagement in their own care plans. This same concept also applies to laboratory technologies that use AI/ML systems, where the work hours currently required for repetitive and routine tasks could see drastic reductions, significantly cutting labor costs.[11]

Increased efficiency, precision, and affordability are just some of the benefits that AI/ML can offer the healthcare community and those they serve, but realizing these benefits will depend on the buy-in of the provider and patient communities as well as support for responsible deployments from policymakers. CHI's AI/ML Task Force released detailed policy principles,[12] as well as proposed good machine learning practices for AI/ML meeting the definition of a medical device,[13] to address these challenges. Notably, CHI's AI/ML Task Force has acknowledged that without its processes being understandable by humans and transparency (providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic), particularly for patients and caregivers, AI/ML cannot most effectively improve healthcare. Namely, those developing, offering, or testing healthcare AI/ML systems must provide truthful and understandable representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI/ML software as a medical device (SaMD) solution.

9 *Id.*
10 *See* McPhail et al, Stage at diagnosis and early mortality from cancer in England (Br J Cancer 2015), doi: 10.1038/bjc.2015.49.
11 Rong, et al, "Artificial Intelligence in Healthcare: Review and Prediction Case Studies," Engineering, doi: 10.1016/j.eng.2019.08.015 at Sec. 2.2.
12 https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.
13 https://bit.ly/3B6nslm.

How Can Transparency into Healthcare AI/ML Solutions be Advanced?

While evidence of healthcare AI's potential for widespread benefit continues to build, that potential can never be realized without healthcare professionals and patients understanding and trusting AI/ML solutions. The more transparent the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.[14] Transparency for healthcare AI's intended uses must happen at several levels, disseminating tailored messaging to specific audiences that require insights into the AI/ML solution to make informed decisions. Building the trust that must be a foundation for the responsible deployment of AI/ML is a shared responsibility amongst developers, providers, and regulators.

Providing transparency into health AI/ML must start with the developers of the AI/ML tools. Then, uptake of AI/ML will need to be built on the buy-in of clinicians who first develop trust in AI/ML SaMD through use and experience, establishing confidence as it is adopted into practice. Once adopted, the provider can then work with his or her patients to explain their use of SaMD AI/ML and inspire the same trust and confidence by the patient in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The CHI AI/ML Task Force's recommendations for enhancing transparency for health AI/ML include:

Developers of AI/ML SaMD should:

- Prioritize making healthcare AI/ML solutions reasonably safe, efficacious, and equitable from the earliest stages of design, considering the perspectives of both patients and providers, leveraging and where necessary tweaking medical AI/ML guidelines on research and ethics,[15] leading standards,[16] and other resources as appropriate.
- Employ algorithms that produce repeatable results and, when feasible, are auditable, and make decisions that, when applied to medical care (such as screening, diagnosis, or treatment), are clinically validated and where possible understandable using rigorous procedures with documented methods and results, fostering efficacy through continuous monitoring.
- Rigorously identify, disclose, and mitigate biases in datasets used to train algorithms.
- Utilize risk-scaled privacy protection mechanisms for patients' data to account for the fact that the analysis by health AI/ML tools provides greater potential utility of those data items to other individuals, entities, and machines, providing many new uses for, and ways to analyze, the collected data, as well as correspondingly stronger incentives for malefactors to attempt to obtain access unlawfully. Specific uses of data that require additional safeguards (such as genomic

14 https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bsi/nsb/innovation/mhra-ai-paper-2019.pdf

15 *E.g.*, World Health Organization, 'Ethics & Governance of Artificial Intelligence for Health' (2021), *available at* https://www.who.int/publications/i/item/9789240029200.

16 *E.g.*, Consumer Technology Association, 'The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)' (2021), *available at* https://shop.cta.tech/collections/standards/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090.

information) may necessitate a tailored approach or enhanced protections from discrimination (e.g., pre-existing conditions or genomic information may be needed for patients).

- Comply with all applicable legal and regulatory requirements.
- Develop a tailored communications and engagement plan that gives patients and providers representative of the AI/ML tool's user group a reasonably justifiable level of confidence in healthcare AI's efficacy. Such communications should enable these patients and providers to visualize the AI, and to receive direct and clear information about how their health data are being collected and used (while also avoiding information overload) and how biases in data that exacerbate disparities in healthcare are being mitigated. Reflecting that the division of labor between the developers of AI-enabled tools and the clinician or patient is critical, clearly explain intended uses, including whether a tool might include the restriction that it is not for diagnostic use or for informational purposes only, as well as risks.

Providers should:

- Develop their own risk-based and tailored communications and engagement plan that enables them to explain to patients the development of the AI/ML application, its maintainnace, its performance, and how it aligns with the latest best practices and regulatory requirements to improve patient safety using easily understood and standardized formats. Providers should also acknowledge that "best practices" are dynamic and prone to obsolescence.
- Offer further detail for patients in additional resources that explain the clinical testing of AI/ML applications and the confirmation of the results by clinical experts.

The Food and Drug Administration (FDA) should:

- Leverage its successful approach to authorizing medical device AI[17] that has already safely brought health AI/ML innovations to patients and providers to develop a comprehensive regulatory approach to AI/ML that meets the definition of a medical device. The FDA can accomplish this by, for example, progressing its Software Precertification Pilot[18] to a full program available to all developers of SaMD AI, FDA can also update its rules and processes to realize its envisioned total product lifecycle (TPLC) regulatory approach, facilitating a potentially rapid cycle of product improvement and allowing these devices to continually improve while providing effective safeguards. This new approach should leverage CHI's Good Machine Learning Practices to address both locked and continuously learning AI.
- Evolve its requirements on reporting type and frequency so that such requirements can be adapted and scaled based on relevant factors such as risk, extent, and magnitude of

17 Software as a Medical Device (SaMD): Clinical Evaluation: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm524904.pdf; Deciding When to Submit a 510(k) for a Software Change to an Existing Device: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514737.pdf.

18 Pre-Cert Program Version 1.0 Working Model: https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf.

modifications, and the demonstrated reliability of the AI (e.g., quality control plans for updates).[19] Initially, the FDA should finalize guidance on SaMD pre-specifications and algorithm change protocol inputs that FDA should periodically receive.

- Develop methods to efficiently communicate when FDA has authorized a product developed with or that utilizes AI/ML, along with information on how it was developed, is maintained and performs, and aligns with the latest best practices and regulatory requirements that ensure patient safety using easily understood (e.g., infographics) and standardized formats. For example, where approval is required for the deployment of new solutions in the market, the FDA should provide information describing the datasets used to train the AI/ML software and what efforts are being taken to align with ethical standards and to mitigate data biases. This work should build on the recently released database of AI-enabled devices legally marketed in the United States from the FDA's Digital Health Center of Excellence.[20]
- Serve as a coordinator and convenor of other U.S. federal agencies to ensure a harmonized approach to health AI/ML transparency across government.
- Build on its leadership to date within the International Medical Device Regulatory Forum (IMDRF), promote its approach to SaMD AI/ML to improve approaches to transparency internationally.
- Host recurring public events, in partnership with health AI/ML developers, patients, and providers, that feature the FDA Digital Health Center of Excellence's latest approaches and thinking, as well as demonstrations of AI/ML in healthcare today.

The Centers for Medicare and Medicaid Services (CMS) should**:**

- Continue to develop its understanding of medical AI/ML definitions, present-day and future AI/ML solutions, how AI/ML is changing the practice of medicine, and the future of AI/ML medical coding.
- Develop Medicare support mechanisms for the use of AI/ML by providers based on clinical validation, alignment with clinical decision-making processes familiar to providers, and high-quality clinical evidence.
- Build on support provided in the Medicare system for the use of health AI,[21] develop easy to understand resources for Medicare beneficiaries that capture how AI/ML is being used in the Medicare system and what it means to patients. CMS should leverage its Advisory Panel on Outreach and Education[22] to develop this messaging.

19 As the FDA has noted, new reporting mechanisms for a scalable AI/ML medical device reporting structure "may require additional statutory authority to implement fully". Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback (Apr. 10, 2021) at 15. *Available at* https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf.

20 https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices. This FDA list currently provides key information such as submission number, device and company name, and date of marketing authorization of the device (510(k) clearance, granting of De Novo, or PMA approval).

21 For example, CMS already provides payment for CPT code 92229 (point-of-care diabetic retinopathy automated analysis and provides a diagnostic report using AI).

22 https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.

The Federal Trade Commission (FTC) should:

- Support ways to mitigate biases or other unfair outcomes from healthcare AI,[23] and, where appropriate, enforce against violations of key laws such as Section 5 of the FTC Act, which prohibits unfair or deceptive practices, where appropriate.

Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards should:

- Develop medical standard of care and ethical guidelines to address emerging issues with the use of SaMD AI/ML in healthcare needed to advance the quadruple aim.
- Develop and disseminate guidance and education on the responsible deployment of SaMD AI, both generally and for specialty-specific uses.

Academic and Medical Education Institutions should:

- Develop and include curriculum that will advance understanding of and ability to use healthcare AI/ML solutions, which should be assisted by inclusion of non-clinicians, such as data scientists and engineers, as instructors. Ongoing training and continuing education should also advance understanding of the safe and effective use of AI/ML in healthcare delivery, addressing both its capabilities and limitations.
- Develop curriculum to advance understanding of data science research to help inform ethical bodies such as Institutional Review Boards (IRBs) that are reviewing protocols of clinical trials of AI-enabled medical devices.

23 https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai

Conclusion

CHI is pleased to present its recommendations on AI/ML transparency for the consideration of the healthcare ecosystem, policymakers, and others. We are committed to continued engagement with the digital health community writ large to realize the both the responsible deployment of AI/ML across healthcare and its immensely positive societal benefit.

ConnectedHealthInitiative

April 14, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue Southwest
Washington, District of Columbia 20201

Melanie Fontes Rainer
Director
U.S. Department of Health and Human Services
Office for Civil Rights
200 Independence Avenue Southwest
Washington, District of Columbia 20201

The Connected Health Initiative (CHI) represents a diverse coalition of stakeholders that spans the healthcare and technology sectors, all of whom support the expanded use of connected health technologies in healthcare. We write to provide further consensus recommendations on the Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) proposed rule on Section 1557 of the Affordable Care Act (ACA), specifically its proposal to update § 92.210 to "make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557" without clarification on how to detect and mitigate potential algorithmic bias.[1] **Below, we share our concerns with proposals poised to impact the use of artificial intelligence (AI) in healthcare and urge for the withdrawal of the technology-specific proposal addressing covered entities' use of algorithms in its 1557 nondiscrimination rules. Alternatively. Alternatively, should OCR nonetheless choose to retain AI-specific provisions in its new 1557 nondiscrimination rules, we offer several ways that these AI-specific provisions in the 1557 nondiscrimination rules should be revised to protect patient safety and equity while supporting innovation in healthcare AI.**

CHI is a not-for-profit that seeks to advance policies that will provide the infrastructure and policy environment to support, as well as incent, the use of cutting-edge digital health products and services in both the prevention and treatment of disease. CHI's AI Task Force has developed a set of health AI policy principles to help guide policymakers to effectively address the role of AI in healthcare.[2] Evidence demonstrates that digital health improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement. Leveraging wide ranges of datasets, including patient-generated health data, with AI tools holds incredible promise for equitably advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. To achieve this potential, government policies must be put in place to support building infrastructure and preparing and training personnel, as well as developing, testing, validating, and maintaining AI systems to ensure value. AI tools are also critical in meeting the Administration's priorities, such as reducing disparities. CHI shares the Administration's commitment to advancing health equity in this regard.[3]

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[1] 87 FR 47884.

[2] Connected Health Initiative, Policy Principles for Artificial Intelligence in Health, available at https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf

[3] https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/16/executive-order-on-further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

We appreciate HHS' efforts to date to responsibly bring the benefits of AI to patients in a way that advances health equities and benefits all providers and patients. For example, the Centers for Medicare and Medicaid Services have taken a number of important steps to make AI's benefits available to more caregivers and patients, including updating its Medicare Physician Fee Schedule rules to provide national payment rates for AI's responsible use in addressing specific use cases, such as in diabetic retinopathy, and integrating AI into value-based care, specifically in various Quality Payment Program Merit-based Incentive Payment System quality measures.

In its proposed rule, OCR proposes to make explicit that covered entities are prohibited from discriminating, through the use of clinical algorithms, on the basis of race, color, national origin, sex, age, or disability under Section 1557, and requests input on the appropriate scope and specificity of such a requirement. While we share HHS' goal of advancing the use of beneficial algorithms by covered entities, share concerns with potential discriminatory outcomes resulting from the use of health AI tools and services, and support the intent of the 1557 rule as a whole, HHS' proposals targeting AI raise a number of concerns, including:

- HHS' evaluation of various use cases demonstrating its concerns with health AI-related discriminatory outcomes does not adequately differentiate root causes for the outcomes it seeks to avoid.
- HHS' proposal to explicitly address an emerging technology area (AI) does not appear to consider ongoing developments in standardization, and further raises the risk of technology terms and capabilities evolving more quickly than regulations can be updated.
- Our community is working to develop a consensus standard on how to validate that biases are being identified and appropriately mitigated, and to establish an adequate infrastructure of test beds for making such standards operational. For example, providers, technology developers, governments, and others continue to address how to make AI data sets appropriately representative of the populations/communities AI tools are intended to serve and benefit.
- HHS' proposal appears to omit that providers rely on a health AI manufacturer's intended uses, whether the AI meets the definition of a medical device or not, and that its proposal would force covered entities to police their own supply chains for AI tools and services, despite realities that would make such efforts impracticable (for example, it is often infeasible to require a covered entity to audit AI and/or the datasets used to train AI they purchase). Further, the additional steps that covered entities would need to take to comply with HHS' proposed requirement are likely to contribute to providers' already strained workload and further contribute to burnout.
- HHS' proposal does not account for the fact that some algorithms are specifically designed to identify and/or consider specific patient characteristics when assisting decision-making (*e.g.*, an algorithm intended to identify certain groups of patients susceptible to a condition or that may benefit from a particular therapy).
- HHS' proposals affecting the use of AI do not adequately consider the role of transparent communication of intended uses and related risks, and of patient consent, with respect to the appropriate use of AI tools and services by covered entities.
- Under HHS' proposal, covered entities could face liability for discriminatory outcomes realized after using an AI tool for some time, presenting a significant incentive to avoid

using AI tools altogether, which may not align with health AI-related liability distributions for other risks (*e.g.*, patient safety).

- Machine translation tools are widely relied upon by providers, and serve as a critical tool in providing timely and efficacious care (particularly in the real-time communication context), and continue to be improved upon. HHS proposes to require a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of a limited English proficiency individual, when accuracy is essential, or when the source documents or materials contain complex, non-literal, or technical language. HHS' rationale for such a proposal lacks a sufficient evidence base of machine translation tools being blanket categorized as not fit for purpose and could effectively force any covered entity using machine translation tools to have to further provide for a human translator's review in all circumstances.
- Implementing the proposed 1557 regulations for AI will require significant efforts to build capacity within HHS to appropriately conduct fact-specific analyses of allegations of discrimination, and to work with the covered entity to achieve compliance.

To be clear, we share HHS' concerns about health AI and the impact of harmful biases, and are committed to advancing solutions to ensure that such harms are identified and mitigated. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. We urge HHS to collaborate with all stakeholders to develop and operationalize frameworks that utilize risk-based approaches to align healthcare AI uses with consensus benchmarks for safety, efficacy, and equity. Moreover, we also urge HHS to collaborate with stakeholders to ensure the appropriate distribution and mitigation of risk and liability by supporting those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. HHS' proposed 1557 regulatory updates for AI bias, as drafted, would derail the progress made through public-private partnerships and standardization activities, and significantly disincent covered entities' use of AI, ultimately robbing patients of the benefits of AI.

We urge OCR to build on and defer to the leading work of other federal actors with deep expertise in AI and bias risk mitigation, and to leverage these agencies' expertise to build its capacity to address AI-related concerns (*e.g.,* training and staffing, enhanced public-private partnership activities, etc.). OCR must ensure that its AI-specific proposals in the 1557 rule build on these leading efforts, deferring to them where possible in order to avoid imposing new liability on providers with no connected public benefit. OCR's technology-neutral 1557 regulations already enable it to work with these agencies, building on their expertise, to enforce its regulations to address discriminatory outcomes that may be related to algorithms. These other federal efforts include:

- **The Food & Drug Administration (FDA)** oversees market entry for AI-based software as a medical device (SaMD) across a wide range of conditions, and provides guidance on avoiding bias in automated decision-making (*e.g.*, the avoidance of automation bias in the context of clinical decision support[4]). FDA continues to leverage total product lifecycle oversight to further the potential that AI has to deliver safe and effective

[4] https://www.fda.gov/media/109618/download.

software functionality that improves patients' quality of care.[5] Even more recently, FDA has proposed new guidance addressing what information should be included in a Predetermined Change Control Plan that may be provided in a marketing submission for machine learning-enabled device software functions.[6]

- **The Federal Trade Commission** prohibits unfair or deceptive practices, including in the context of the sale or use of racially-biased algorithms used in healthcare.[7]
- **The Centers for Medicare and Medicaid Services (CMS)** continues to develop means to advance equity through its policies, both in the context of fee-for-service and value-based care.[8]
- **The Agency for Healthcare Research and Quality (AHRQ)** leads in reviewing, collecting, and sharing leading health and clinical evidence, including in the context of AI.[9] AHRQ's efforts have demonstrated that reliance on a quality- and safety-focused approach to risk management results in advancement of the Quadruple Aim.
- **The United States Preventive Services Task Force (USPSTF)** has developed guidance aimed at mitigating bias harms (*e.g.*, for addressing racism in preventative services[10]), which promotes a responsibility to consider direct and indirect harms in preventative care, and to manage those risks based on how likely, frequent, and severe they are.
- **The Office of the National Coordinator for Health IT** continues to collaborate with the healthcare community to develop standards for the seamless exchange of health data points for inclusion in electronic health records.[11] Even more recently, ONC has proposed new requirements for "decision support interventions" in the ONC Health IT Certification Program.[12]

Indeed, CHI agrees that higher-risk health AI should, per sound risk management practices, have a human being engaged in an oversight role. This approach would be consistent with the FDA's (described infra), and the CHI community has been forthright in supporting such measures in its health AI policy principles and subsequent detailed recommendations on good

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[5] https://www.fda.gov/media/122535/download; https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial.

[7] *E.g.*, https://www.ftc.gov/business-guidance/blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai.

[8] https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.

[9] E.g., https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/protocol.

[10] https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/addressing-racism-preventive-services-technical%20brief.pdf.

[11] https://confluence.hl7.org/display/FAST/FHIR+at+Scale+Taskforce+%28FAST%29+Home.

[12] https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/oncs-new-proposed-rule-the-next-step-to-advancing-the-care-continuum-through-technology-and-interoperability.

machine learning practices for AI medical devices as well as CHI's health AI transparency recommendations.[13]

Accordingly, CHI strongly urges HHS to withdraw its technology-specific proposal addressing covered entities' use of algorithms in its 1557 nondiscrimination rules. OCR can address such instances of bias and related discriminatory outcomes through the application of its 1557 rules across use cases that may involve new technology capabilities and means, including AI, in a technology-neutral manner to providers' activities that are in scope. OCR should explore how general 1557 regulatory language may be relied upon to address its concerns with health AI and discriminatory outcomes in a technology neutral manner. OCR should then, as a next step, undertake further consultations and evaluation of existing and ongoing research and best practices, in collaboration with other agencies and the broader healthcare community, to (1) gain understanding of the state of health AI technologies and deployments, including technical and legal realities of health technology supply chains, (2) ensure that its proposals impacting health AI and liability for discriminatory outcomes do not disincent the development and use of beneficial AI tools in healthcare, and (3) avoid misaligning liabilities for health AI-related discriminatory outcomes with the distribution of risks and liabilities related to other issues. Such a process would enable OCR to partner with our community to advance standardization and testing efforts that will mitigate AI bias harms, and contribute to the appropriate distribution and mitigation of risk and liability (*i.e.*, those in the value chain with the knowledge and ability to minimize and mitigate risks should have the appropriate incentives to do so). Such a consultation would also enable OCR and others to fully understand the affect of its AI-related proposals on covered entities' practical ability to use AI tools and services, particularly those with limited resources, and other priorities such as the need to reduce provider burnout.

If OCR nonetheless decides to retain AI-specific provisions in its new 1557 nondiscrimination rules, we strongly encourage the following steps be taken:

- ***Scope the Application of OCR's AI-Specific Provisions to Map to OCR's Goals.*** OCR's definition of AI, in its rules, should be tailored so that the rules map to the outcomes it seeks. In its present proposal, OCR would apply to "clinical algorithms" which OCR states are "tools used to guide health care decision-making and can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models." With no definition of "clinical algorithm" currently existing in federal regulation, application of the rules will be difficult for covered entities and could result in the application of the rules to use cases not intended by OCR. Indeed, in practice this sweeping definition could encompass nearly any technology used by a covered entity. An automated calendar tool that identifies the next available appointment for a patient or a tool that predicts when a doctor's office will need to order additional supplies are arguably within scope, even though the likelihood and severity of discrimination harm stemming from these tools is low. OCR's rule should limit the definition of covered algorithm to those that exclude human oversight and should not include technology simply used to support, inform, or facilitate decision-making. Rather than place liability on covered entities for any discriminatory algorithm, the proposed rules should be modified to impose liability where the clinical algorithm is not subject to human review or judgment to minimize the risk of over-reliance on such tools in a way that results in discrimination. If the provider's independent judgment, coupled with the use of the clinical algorithm, results in discrimination, the other provisions in Section

[13] Connected Health Initiative, Policy Principles for Artificial Intelligence in Health, available at https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf

1557 would apply and would prohibit this behavior, and the latest proposed rules' steps to reinstate and clarify what type of discrimination is unlawful would ensure that the prohibition against discrimination is meaningful.

Further, a key way to resolve definition/scope ambiguities, and to build on sister agency expertise, is to exempt uses of health AI from the scope of its rules already authorized and overseen by the FDA, as the FDA takes steps to address the biases with which OCR is concerned. OCR must recognize that application of 1557 nondiscrimination rules would present overlapping regulatory burdens in competition with expert federal partners already addressing AI bias, strongly disincenting the uptake or continued use of any AI across healthcare practices. In turn, this would adversely affectadversely America's unserved and underserved communities most acutely, undermining OCR's motivations in introducing AI-specific provisions into the 1557 regulations.

- ***Clarify Reliance on an Actual Knowledge Standard.*** OCR's nondiscrimination rules should align with an actual knowledge standard of liability. Providers, and others in a healthcare value chain, should only be expected to take reasonable steps to mitigate disparities in algorithms they have developed or have knowledge of. Such an approach would reflect the need for appropriate risk distribution throughout healthcare value chains, and that those in the value chain with the ability to minimize and mitigate risks based on their knowledge have appropriate incentives to do so. Therefore, we strongly encourage OCR to ensure that its rules do not assess individual liability for the performance of algorithms they did not design or know or have reason to know that the algorithm produced discriminatory results.
- ***Take Measures to Enable Pro-Patient Uses of Machine Translation Tools.*** OCR should reviser its proposals specifically addressing machine translation to reflect the wide benefits that administrative AI functions (*e.g.,* machine translation tools) provide today across healthcare contexts, particularly in real-time communications, and clarify that a mandate for review by a human interpreter does not apply to real-time communications (whether in-person or via video). As proposed, OCR's requirements on machine translation would result in the widespread abandonment of machine translation tools across covered entities, ultimately harming patient care, increasing healthcare costs, and adding to provider burdens. OCR's rules affecting machine translation must be predicated on a compliance analysis, weighing the net impacts of removing machine translation tools from the care continuum entirely in assessing the reasonableness of a covered entity's activities in using such machine translation tools under its proposed factors.

- ***Provide a Reasonable Pathway to Compliance.*** The deployer of AI-enabled technology is best positioned to understand the context and environment in which a clinical algorithm is used, and best able to manage other guardrails such as appropriate human review or judgment. In order to facilitate deployers obtaining appropriate information and assurances about the algorithms, we encourage OCR to further explore whether a HIPAA business associate-like approach could most effectively help address OCR's concerns, where entities subject to Section 1557 of the ACA would contractually require AI developers to provide assurances that the clinical algorithm does not discriminate, that appropriate steps were taken to mitigate risk of discrimination, and that the inputs of the algorithm were representative of the community in which the clinical algorithm would be used. If OCR is principally interested in creating accountability with AI developers, it could incorporate a model where entities subject to Section 1557 are

required to implement contractual terms with providers or a safe harbor from liability if terms are in place. If the HHS proposed rule were to enter into effect in its current form, covered entities are likely to create this contractual flow-down structure as a means of mitigating risk.

Further, OCR should provide a reasonable enforcement discretion period (one year) before any enforcement of AI-specific provisions would take place to enable process changes needed to comply with the rules. During such a period, we urge OCR to engage in proactive outreach and education to the healthcare community affected by its rules. And whether or not OCR does move forward with AI-specific provisions in the 1557 nondiscrimination rules, the CHI community requests OCR's assistance in understanding compliance with 1557 rules and emerging technologies, including but not limited to AI and machine learning. CHI members, and the healthcare community writ large, would benefit from compliance assistance, and we welcome the opportunity to collaborate in creating resources to address this need.

We appreciate HHS' consideration of our input on its proposals and encourage thoughtful consideration of our input. As a community, we stand ready to assist further in any way that we can.

Sincerely,

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ConnectedHealthInitiative

June 20, 2023

Department of Health and Human Services
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Washington, District of Columbia 20201

RE: Comments of the Connected Health Initiative to the Office of the National Coordinator for Health Information Technology on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (HHS-ONC-2023-0007; 88 FR 23746)

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule to implement the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology developers under the ONC Health IT Certification Program.[1]

I. Introduction and Statement of Interest

CHI is the leading effort, driven by consensus that spans the healthcare ecosystem, to drive policies that enable the responsible deployment and use of digital health tools throughout the continuum of care to improve individual patient outcomes, reduce costs, augment population health, and streamline the clinician experience. For more information, see www.connectedhi.com.

The effectiveness of the technology tools needed to improve patient outcomes, advance precision medicine and population health, and save costs is dependent in large part on the availability of massive data sets. The free and secure flow of information, and interoperability, are central to improving outcomes for all patients, and CHI is committed to advancing health data interoperability throughout the continuum of care. Further, CHI is committed to advancing the responsible development and use of artificial intelligence (AI) in healthcare and appreciates ONC's efforts to advance efficacious and accountable AI. Building on our community's consensus, we provide detailed views on a range of ONC's proposals below.

[1] 88 FR 23746.

II. CHI Views on ONC's Proposed Updates to its Information Blocking Rules

A truly interoperable healthcare ecosystem must be inclusive and welcoming of data from a range of sources through open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats, with interoperability facilitated by APIs, supports real-time analytics and alerting capabilities and the use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement.

While ONC has completed its initial tranche of information blocking rules (which it is now proposing to update), HHS' Office of the Inspector General (OIG) has to date failed to advance the companion civil monetary penalty (CMP) enforcement rules for ONC's information blocking rules, meaning that no enforcement of the rules can occur. While ONC's rules have been in place for several years, the lack of possibility of enforcement makes it difficult to operationalize ONC information blocking rules. We urge ONC to take all steps practicable to help OIG advance its CMP rules as soon as possible.

CHI offers the following recommendations to ONC in response to its proposed updates to its information blocking rules:

- CHI reiterates its support for ONC's efforts to prevent illegal information blocking and to facilitate greater data access throughout the care continuum. We generally support ONC efforts to resolve ambiguities in its requirements, and to align its information blocking requirements with the certified capabilities of health IT vendors (i.e., the U.S. Core Data for Interoperability [USCDI] and APIs).
- CHI welcomes clarifications proposed by ONC to its definition of "health IT developer of certified health IT," which will provide greater certainty as to who its rules apply to and when. Relatedly, we urge ONC to clarify whether organizations that classify themselves as "frameworks" (and not "exchanges") are subject to the information blocking rules.
- With respect to proposed modifications to its information blocking exceptions:
    - Infeasibility Exception: CHI appreciates ONC's proposed clarifications to its Infeasibility Exception, which would make certain that an uncontrollable event specified in § 171.204(a)(1) is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception. However, CHI notes that the third party seeking modification use condition of the Infeasibility Exception is concerning because it may provide Certified Health IT vendors with a catchall claim that avenues of access are "infeasible" despite the control they have over their own services (if, for example, a patient seeks access to their data via a HIN, the actor may claim that a third party seeking "modification use (i.e., patient matching based queries)" of the EHI could, through that use, pose

specific threats to the confidentiality of data on its system (i.e., unspecified claims that a patient matching algorithms is not sufficient). We request that ONC tailor its proposed clarifications to tailor this exception to avoid its overbroad application in such a manner.

- Manner Exhausted Condition: CHI appreciates ONC's rationale for its proposed updates to the Manner Exhausted Condition, which describes ONC's intent to find a balance between the interests of actors and requestors that may not be fully leveraging open consensus standards or other industry standards and supports the information blocking rules advancing reliance on interoperable standards. However, as proposed, § 171.204(a)(4) does not sufficiently address the excepting language "unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request," and the section requires additional clarity regarding the current methods utilized by the actor. For example, it is not clear whether an actor is using a HIN to exchange data with other providers can reject an individual access request on the basis of technical infeasibility.
- TEFCA Manner Exception Condition: CHI appreciates ONC's rationale offered for adding a TEFCA condition to the information blocking rules' Manner Exception. However, CHI believes that limiting the ability of organizations to negotiate the manner of their access (e.g., to a certified EHR's SMART on FHIR Population API endpoints), whether those manners are TEFCA mechanisms or otherwise, is important because TEFCA is not yet fully launched and TEFCA-related challenges cannot be fully understood yet. TEFCA participation will be driven by many different use cases, and its utility may vary across those use cases. Instead of introducing a Manner Exception for TEFCA at this time, ONC should closely monitor TEFCA deployments for utility, completeness, timeliness, ease of access, security, privacy, transparency, and consumer participation. Such an exception should only be finalized if real-world experience demonstrates that the problems shows that the exception ONC proposes (or some modified version of it based) is required,

  Further, we are concerned that this TEFCA exception could be used to elect out of participating in Individual Access Services (IAS) in a national network capacity. While responding to individual requests via TEFCA is required, Qualified Health Information Networks (QHINs) are not obligated to support the initiation of IAS. Some could use this exception to connect to a QHIN (or elect to become a QHIN themselves) and not offer IAS, thus creating pockets of bad access, poor QHIN-to-QHIN exchange, and unnecessary friction for individuals requesting access to their own data.

- CHI continues to support requiring the adoption of FHIR Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides.

- CHI notes that innovative developers have made, and continue to make, strides in providing the segmentation of data and sharing of information consistent with patient preferences and applicable laws. Data segmentation is critical to providing patient data privacy and security, meeting patient expectations and attaining informed consent, and in managing data flows in light of legal and contractual requirements. CHI welcomes ONC's partnership in advancing effective segmentation practices that will avoid improper sharing or withholding of a medical record due to misunderstandings about requirements on EHRs, including in the context of illegal information blocking.
- We also emphasize that it is crucial for ONC to ensure that its interoperability rule is as aligned as possible with the interoperability rules being developed by the HHS Centers for Medicare and Medicaid Innovation (CMS). Should the rules diverge, stakeholders may be put into a position where they are forced to violate one rule (e.g., meet the requirements of the CMS interoperability rule but face ambiguities as to whether the requirements of an exception to ONC information blocking is being satisfied). CHI acknowledges ONC's (and CMS') efforts to coordinate and supports those efforts.

  For example, there is still some uncertainty about the liabilities in releasing information to patients with respect to Health Insurance Portability and Accountability Act of 1996 (HIPAA) Hand Federal Trade Commission requirements. While it must be expected that a HIPAA breach may occur in a post-info blocking world, additional language is requested to advance the ecosystem's understanding of safeguards, best practices and exceptions may be deemed acceptable. We continue to experience confusion among healthcare professionals, clinical and IT staff, administrative and back-office personnel, compliance officers, consultants, attorneys, records release professionals, and technology vendors on implementing ONC's information blocking regulations. This lack of clarity contributes, in some instances, to oversharing information or, conversely, blocking information when entities are paralyzed by confusion. ONC-developed webinars and FAQs, while helpful, are not yet sufficiently communicating what can and cannot be done for all the segments and individuals needed to orchestrate optimal implementation of ONC's rules.

III. CHI Views on Various ONC Health IT Certification Program Updates

CHI generally appreciates ONC's continued curation of health IT certification program requirements, and offers the following views and specific inputs on ONC's proposals:

- CHI generally supports ONC's API conditions and maintenance of certification provisions. We appreciate ONC's efforts to address excessive fees charged by EHR vendors to connect their products with other health IT systems, health information exchanges, and third-party applications. ONC's proposal fee policy attempts to address most scenarios, but the resulting framework is complex and

has limited usefulness. In previous comments, CHI has suggested a more practical approach that includes a tiered fee structure for APIs,[2] which we urge consideration of in this matter.

- CHI supports ONC's proposal to provide USCDI v3 as a new baseline, and for the proposed January 1, 2025, expiration of UCSDI v1 (after which any Health IT Modules seeking certification for criteria would need to be capable of exchanging data classes and elements in USCDI v3). CHI reiterates its support for the USCDI's proposed Version 3's Data Classes, which build on the data classes referenced by the 2015 Edition Common Clinical Data Set (CCDS) definition and includes Clinical Notes and Provenance. CHI further supports USCDI expansion, consistent with technology and competitive neutrality principles, to include social determinants of health (SDOH) with scaled security and privacy risk management practices that recognize the sensitivity of SDOH data that may be shared or disclosed. This includes incorporating SDOH data that considers social and environmental factors of patients' lives outside of the healthcare system in the USCDI with adequate safeguards, which requires ONC to coordinate with the HHS' Office for Civil Rights, standards development organizations, and other affected stakeholders, which we support and encourage

  We urge ONC (and CMS) to collaborate to gather and share SDOH data, and to support the responsible leveraging of SDOH data. However, It is essential that we protect sensitive personal health information—as both a foundation for health equity but also to mitigate the risk of negative impacts to individuals resulting from the disclosure of their information. To that end, CHI urges ONC to move forward with the granular data segmentation policies concurrently with adopting USCDI v3. In many instances, it will be inappropriate to share all USCDI v3 elements unless granular segmentation is enabled to protect privacy related to sensitive data elements, in accordance with patient preference, state and federal law and regulation.

- CHI generally supports ONC's proposed adoption of additional standards for electronic case reporting.
- CHI supports ONC's proposed addition of new "Insights Condition" reporting under its Condition and Maintenance of Certification requirements, which would cover four areas of interoperability, including individuals' access to EHI, public health information exchange, clinical care information exchange, and standards adoption and conformance. Using data from the certified health IT system, ONC would generate metrics using numerator/denominator calculations based on the certified health IT's supplied data points, which will provide new insights into the functional interoperability of EHRs.

  At the same time, we urge ONC to reduce provider administrative/reporting burdens. We encourage ONC to work with CMS to advance the joint agency

[2] [cite to previous CHI info blocking comments]

goals of gaining insight into interoperability and reducing provider reporting burdens by allowing provider reporting to be accomplished through a yes/no attestation to meeting Performing Interoperability Objectives, instead of requiring the reporting of a numerator/denominator, which would be complemented or supplemented by EHR developer-reported Insights Conditions data.

- CHI generally supports ONC's proposed revisions to "standardized API for patient and population services" certification criterion, including the adoption of FHIR US Core IG STU version 5.0.1 and adoption of Substitutable Medical Applications, Reusable Technologies (SMART) Application Launch Framework Implementation Guide Release 2.0.0.
    - ONC proposes to align with new technical requirements in SMART v2 and the authorization and authentication requirement in § 170.315(g)(10)(v)(A)(1)(i) by requiring ''authorize-post'' capability." The authorization code flow with a POST request is supported by the specifications,[3] however, the specification indicates that support for the POST method is optional, stating that "authorization server MUST support the use of the HTTP 'GET' method [RFC2616] for the authorization endpoint and MAY support the use of the 'POST' method as well." We recognize that there are risks to the use of GET requests, including URL length limits when the request contains many scope values. However, we recommend that the rule requires the use of Pushed Authorization Requests[4] as a standard mechanism to resolve known issues with GET requests.
    - ONC proposes adoption of the SMART v2 Guide. The SMART v2 Guide section 3.0.2.3[5] describes an experimental mechanism to enable fine-grained resource constraints which uses filter queries as a component of OAuth scopes. OAuth implementations are generally dependent upon an enumerated list of scope values used for authorization. Implementing changes to support complex filter queries in addition to enumerated scopes is non-trivial. The IETf OAuth Working Group recently addressed the need for finer-grained authorization controls with the publication of RFC 9396 Rich Authorization Requests.[6] We recommend that the ONC does not adopt the complex filter syntax as described in the SMART v2 Guide due to its experimental status. Instead, we recommend that ONC examines the viability of OAuth Rich Authorization Requests in RFC9396 as a standard mechanism to achieve fine grained authorization. We support the requirement to use PKCE[7] as a security control in all

[3] RFC 6749, Section 3.1 https://datatracker.ietf.org/doc/html/rfc6749#section-3.1.
[4] PAR, RFC 9126 https://www.rfc-editor.org/rfc/rfc9126.html.
[5] http://hl7.org/fhir/smart-app-launch/STU2/scopes-and-launch-context.html#finer-grained-resource-constraints-using-search-parameters.
[6] RFC 9396, https://www.rfc-editor.org/rfc/rfc9396.
[7] RFC 7636, https://www.rfc-editor.org/rfc/rfc7636.

deployments of OAuth to mitigate the risk of authorization code interception attacks.

- CHI supports ONC's proposed updates to enable certified health IT users to restrict data from use/disclosure in response to a patient request per the HIPAA Privacy Rule's right to request a restriction on uses and disclosures.
- CHI supports ONC's efforts to advance real world testing requirements, and to establish herEHR Reporting Program per sectioher002(c) of the Cures Act. Across these new measures, we urge ONC to minimize administrative burdens.

a. CHI Views and Recommendations on ONC's Decision Support Intervention (DSI) Proposals

CHI appreciates ONC's support for AI's growing role in improving healthcare. AI is an evolving constellation of technologies that enable computers to simulate elements of human thinking, such as learning and reasoning. An encompassing term, AI entails a range of approaches and technologies, such as machine learning (ML), where algorithms use data, learn from it, and apply their newly-learned lessons to make informed decisions, and deep learning, where an algorithm based on the way neurons and synapses in the brain change as they are exposed to new inputs allows for independent or assisted decision-making. AI-driven tools are having, and will continue to have, substantial direct and indirect effects on Americans in how they manage their health. Some forms of AI are already being used to improve American consumers' lives today; for example, AI is used to accomplish backend administrative functions for healthcare providers. Moving forward, AI has incredible potential to advance the Quadruple Aim; for example, healthcare treatments and patient outcomes stand poised to improve disease prevention and conditions, as well as efficiently and effectively treat diseases through automated analysis of x-rays and other medical imaging. Nonetheless, AI's growing use raises a variety of challenges, and some new and unique considerations, for policymakers as well as those making AI operational in healthcare. CHI appreciates ONC's exploration of policies to provide reliable guidance to stakeholders to reassure end-users that AI systems are legal, effective, ethical, safe, and otherwise trustworthy.

As part of its commitment to responsibly advance AI in healthcare, CHI has developed a number of resources for policymakers, linked below. We encourage ONC to align its next steps with each of these resources:

- CHI's *Health AI Policy Principles*,[8] a set of recommendations on the wide range of areas that should be addressed by policymakers examining AI's use in healthcare (available at https://bit.ly/3m9ZBLv);
- CHI's Position Paper, *Why AI? Considerations for Use of Artificial Intelligence in States' Medicaid and CHIP Programs*, which maps CHI's Health AI Policy

[8] Also included as **Appendix A**.

Principles to the challenges and opportunities faced at the state level (https://bit.ly/2Y2FJle);

- CHI's *Good Machine Learning Practices for FDA-Regulated AI*, a proposed risk-based approach to benefit the Food and Drug Administration (FDA) as it addresses both locked and continuously-learning AI systems that meet the definition of a medical device (https://bit.ly/2YaYljk); and
- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*,[9] a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5).

Consistent with CHI's shared goal of ensuring that health AI recommendations are fair, appropriate, valid, effective, and safe (FAVES), health AI developers, whether subject to this ONC rule or not, to (1) proactively take steps to address and mitigate disparities; (2) protect patient privacy, and the security and integrity of patients' data; and (3) leverage robust and constant feedback loops throughout a health AI offering's lifecycle to track and mitigate real-world issues that may arise. A comprehensive approach to responsible health AI development, deployment, and curation will include consideration of intended and reasonably expected use(s), evidence of safety, efficacy, level of automation, and conditions of deployment. Health AI's adoption will be best facilitated by as much information about clinical limitations, risks, and liability being available and understood throughout the value chain. CHI agrees that trustworthy AI requires transparency. ONC can advance these shared goals by supporting the appropriate distribution and mitigation of risk and liability by providing that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so, and by enhancing communications about DSI intended uses, risks, and benefits to patients as well as providers.

CHI strongly urges for a coordinated effort across both executive and independent agencies. Already, aside from ONC, numerous regulatory agencies—some cross-sectoral and others sector-specific—are considering or advancing regulatory proposals that would take starkly different approaches to AI accountability. Some of these proposals are poised to put significant hurdles in place for the development and use of AI through one-size-fits-all approaches that have nominal public benefit at best, such as the Department of Health and Human Services Office of Civil Rights' proposed approach to preventing discriminatory outcomes in healthcare,[10] on which CHI has detailed its views publicly (and we encourage ONC's consideration of these viewpoints as a leading example of sector-specific misalignment with other leading Administration efforts, such as that of the National Institute of Standards and Technology [NIST][11]). In some cases, such proposals are being developed based on speculative and

[9] Also included as **Appendix B**.

[10] Nondiscrimination in Health Programs and Activities, 87 FR 47824 (Aug. 4, 2022); CHI's Connected Health Initiative detailed views on this HHS OCR proposal are included in this comment as **Appendix A**.

[11] https://www.nist.gov/itl/ai-risk-management-framework.

undemonstrated harms.[12] ONC, along with other cross-sectoral subject matter expert agencies in the federal government such as NIST, should take immediate steps to ensure a harmonized and informed approach to AI governance. Further, as part of effort to advance a coordinated federal approach to health AI, ONC should also leverage CPT Appendix S (*AI taxonomy for medical services & procedures*)[13] to advance common terminology.

ONC proposes to introduce new requirements for developers of certified health IT with Health IT Modules aimed at providing transparency for predictive DSIs, in addition to establishing decision support configuration requirements and intervention risk management practices. Because so many approaches to leveraging different kinds of data are in development, CHI urges ONC's full consideration of the impact that new regulations will have on specific health AI datasets or models. With so much AI in development and the range of technologies within the field far from mature, we urge ONC to take steps to ensure that its DSI mandates do not have unintended consequences (e.g., locking in certain DSI capabilities and creating an artificial ceiling for innovation in the space, or contributing to information overload in reporting requirements mandating reporting that may not be effective or useful to accomplishing).

In addition, CHI recognizes the considerable steps that will be needed for DSI developer and developers of certified health IT to comply with ONC's new DSI requirements. Collecting information from third party developers of DSIs, displaying that information to their users, and implementing a DSI risk management framework may carry significant compliance costs for developers and DSI users. CHI urges ONC to minimize these costs and consider other unintended burdens. As one example, it appeher that EHR companies may need to request that third party developers provide them with access to proprietary information about products usedherth their EHR, placing them in the role of enforcing DSI requirements on other companies, and effectively incenting them to decline to enable or interface with third party DSIs or limit patients from doing so to avoid liability. Transparency is very important in DSI use; however, CHI would be concerned if DSI development stagnates due to unclear or unworkable regulation.

Should ONC move forward with its DSI proposal, we request that:

- ONC's DSI definition clearly match ONC's stated policy intent to surface DSI information on AI-based tools used for predictive purposes to provide increased transparency to DSI users and focus its initial policies on AI tools that leverage data managed or controlled by developers of certified health IT.
- ONC utilize a scaled risk management approach to DSI, which would subject low-risk applications to less stringent requirements compared to high-risk applications.

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[12] Trade Regulation Rule on Commercial Surveillance and Data Security, 87 FR 51273 (Aug. 22, 2022); CHI views provided to the Federal Trade Commission in response to its Advanced Notice of Proposed Rulemaking are included in this comment as **Appendix B**.

[13] https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

- ONC clearly provide that public disclosures per the DSI requirements do not include intellectual property or trade secrets.
- ONC mitigate the burdens related to overlapping regulation of health AI by the FDA.
- DSI requirements be limited in scope to apply only to features and attributes that have been shown to successfully function in real-world deployments, e.g., ONCs real-world DSI testing requirements; similarly, we urge ONC to extend DSI data review user experience (UX) requirements to those that have been demonstrated to work in practice. Taking these steps will avoid negatively impacting new and innovative health AI technologies in design or concept phases.

In the short term, we urge ONC to focus on continued dialogue with our community to understand capabilities and the effects ONC's proposals will have on the development and use of health AI. Further, we urge ONC, along with other federal agencies addressing health AI, to undertake an education and outreach campaign to help providers, patients, and developers (and others affected by health AI policies) understand the capabilities of health AI today and contribute to their responsible development and deployment.

IV. Conclusion

CHI appreciates the opportunity to submit its comments, highlighted in this letter, and attached in full, to ONC. We look forward to assisting ONC in realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

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