ConnectedHealthInitiative

September 11, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

RE: ***Connected Health Initiative Comments on the Center for Medicare and Medicaid Services'*** **Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction** ***(CMS-1786-P; 88 FR 49552)***

Dear Administrator Brooks-LaSure:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare and Medicaid Services (CMS) on its proposed changes to the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2024.[1]

I. Introduction & Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to connected health technologies that improve health outcomes and reduce costs. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

[1] 88 Fed Reg 49552.

CHI engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, CHI is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG), an initiative bringing together a diverse cross-section of nationally recognized experts who identify barriers to digital medicine adoption and propose comprehensive solutions revolving around coding, payment, coverage, and more.[2]

II. Connected Health's Integral Role in the Future of Medicare

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called 'telehealth," "mHealth," "store and forward," "remote patient monitoring," "remote physiologic monitoring," "communication technology-based services," or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device (SaMD), mobile medical apps, and cloud-based portals and dashboards, can fundamentally improve and transform American healthcare.[3] Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, there was low utilization of digital health innovations prior to the COVID-19 public health emergency, despite the ability to drastically improve beneficiary outcomes as well as to generate immense cost savings.

Further, CMS should seek to enable the use of health data and patient-generated health data (PGHD) through AI. There are various applications of AI systems in healthcare 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 systems with an eye toward ensuring value. 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.

The need for rapid and permanent modernization of Medicare incentives is more imperative considering the impacts of the COVID-19 crisis on the United States. With the public health emergency (PHE) now expired, it is clear that remote monitoring tools have proven effective in preventing hospital admissions and improving recovery from

[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group

[3] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

the COVID-19 virus. Building on the PHE experience, and in light of the Congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, CMS' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

CMS' support for remote monitoring capabilities represents a game-changing shift of the Medicare system that recognizes the value of the wide range of asynchronous technologies, and which will contribute to a more connected continuum of care that leverages PGHD in a timely way to mitigate disparities while improving outcomes and reducing Medicare costs. CHI continues to find enthusiasm throughout the healthcare continuum for CMS' leadership in providing support for these critical services. The ability to monitor data enables a wide range of medical specialty use cases that rely on medical device data to monitor physiologic and therapeutic parameters. CHI continues to work with CMS to ensure that all Medicare beneficiaries can leverage remote monitoring tools to improve their care while making the most efficient use of the system's resources. Remote monitoring tools must play a central role in CMS' efforts to make its OPPS more efficient and effective. We strongly encourage CMS to fully support the use of remote monitoring (both physiologic and therapeutic) through its OPPS policies.

And while CMS has, across numerous payment rules, made important pro-digital health updates, the pace of uptake for digital health innovations in the Medicare system continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient. It is essential that the OPPS and ASC leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs.

III. Connected Health Initiative Views on Various CMS Proposed OPPS ASC Policies

CHI provides the following specific input on a variety of CMS' proposals impacting digital health interests in its draft CY2024 OPPS rule:

- **Mental Health Services:** CHI continues to support CMS permitting mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes as covered outpatient department services payable under the OPPS, and to create OPPS-specific coding for these services. We encourage CMS to responsibly expand the availability of critical mental health services already demonstrated to improve patient outcomes while reducing costs. CHI supports CMS' proposed clarifications on remote mental health HCPCS codes and its creation of C79XX, which builds on its finalizing HCPCS codes for mental health services furnished by hospital staff to beneficiaries in their homes through communications technology in the CY2023 OPPS rule.

  However, CHI also continues to oppose CMS requirements for in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, with exceptions to the in-person visit requirement allowed to be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed per clinical needs on a case-by-case basis. Requirements for in-person service in order to receive remote mental health services directly undermines the goal of making such services more widely available and places America's most vulnerable beneficiaries at risk during a pandemic. Further, the requirement would place special restrictions on mental health services without any evidence to justify the stricter treatment of telemental health services. CHI strongly encourages CMS to discard its proposed in-person restrictions from its rules for telemental health entirely. Should CMS elect to retain such restrictions, we support similarly retaining the ability for exceptions to the in-person visit requirement allowed to be made based on beneficiary circumstances. CHI therefore supports CMS' proposal to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025,

  Further, CHI encourages CMS to permit audio-only interactive telecommunications systems to be used to furnish mental health services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology. Such flexibilities are appropriate and reflect allowances made for telemental health in other CMS payment rules.

- **Virtual Outpatient Therapy, Diabetes Self-Management Training, and Medical Nutrition Therapy:** Building on our views above, CHI supports CMS' proposal to continue to make payment for outpatient therapy (physical therapy,

occupational therapy, and speech-language pathology) services, Diabetes Self-Management Training, and Medical Nutrition Therapy when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024.

- **Quality Measures for Various Digital Health Use Cases:** CHI supports CMS' support of digital health services in quality measures across several contexts:
    - CHI encourages CMS to adopt measures that advance value and protect against overuse and fraud, while avoiding overburdensome requirements to alleviate provider burnout. CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.
    - CHI urges CMS to continue to prioritize maternal health, a key use case for digital health,[4] in the OPPS. CMS' strategy for rural emergency hospitals (REHs) and maternal health must directly address the need for using advanced technology (telehealth, RPM, and other communications-based technology services) as well as efficacious SaMD, in improving rural maternal and infant care. These technologies, when deployed responsibly, will greatly further CMS' goals. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.
    - CHI appreciates CMS' continued focus on quality measures for mental health, including in the context of telehealth and telemedicine. We share CMS' views on the many benefits of mental health services offered via or augmented by digital health tools and services. As noted above, CMS should discard its in-person requirements for such services. CMS should recognize that digital health tools offer much more efficient means of monitoring claims and quality when deployed responsibly, and align where possible with quality measures adopted in other key Medicare payment rules (e.g., the Quality Payment Program). CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. CMS should further acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.

[4] https://www.himss.org/resources/developing-digital-tech-enabled-maternal-health-roundtable-report.

- CHI similarly appreciates CMS' continued focus on quality measures for equity. Across the country, disparities in healthcare are sizable and growing, caused by barriers that exist at all levels, exacerbated by the ongoing COVID-19 public health emergency.[5] We strongly encourage CMS to provide support for digital health tools' crucial role in mitigating and eliminating disparities across the American healthcare system and within the home health context. Thanks to CMS' expanded support, reliance on digital health tools increased during the now-expired COVID-19 PHE. Use of these tools allowed many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions while also providing routine care to Americans to safely observe public health protocols during the COVID-19 pandemic. CMS should leverage every opportunity for permanent policy changes that will incent the responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

  CHI generally supports the development of health equity measures, and suggests that the OPPS may benefit from aligning with the health equity measures created for MIPS Value Pathways (MVPs). Health equity measures across Medicare should reflects the need for feasibility and flexibility for providers. CMS is encouraged to adopt measures that advance value and protect against overuse and fraud, while avoiding overburdensome requirements to alleviate provider burnout. CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.

- **Virtual Supervision:** CHI appreciates CMS' discussion of virtual direct supervision in the draft CY2024 OPPS. We support CMS' proposal to revise § 410.27(a)(1)(iv)(B)(1) to expand the practitioners who may supervise cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) services to include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), specifically the inclusion of virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 (and the same for NPs, PAs, and CNSs who are eligible to supervise these services in CY 2024). CMS took important steps to responsibly utilize technology

[5] For example, the Centers for Disease Control and Prevention has noted inadequate reporting on racial disparities in coronavirus patients, which experts believe has hampered the public health response in underserved communities. *See* https://appropriations.house.gov/events/hearings/covid-19-response-0.

for purposes of medical supervision during the PHE, revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. CHI strongly urges CMS to permit remote supervision as widely as practicable on a permanent basis to help Medicare providers and beneficiaries realize the widely-recognized efficiencies of remote work being realized across countless other sectors of the economy.

CHI reiterates that it does not share CMS' concern (expressed in, for example, previous PFS proposed rules) that virtual supervision inherently gives rise to patient safety issues. Numerous clinical staff and auxiliary personnel perform a wide range of tasks easily supervised virtually. Further, such staff categorically do not perform "complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures" that CMS has described in the past to explain its concerns with virtual direct supervision. Non-physician practitioners (NPPs), to the extent that they assist with such procedures, are subject to higher standards, certifications, and oversight. Again, CHI strongly encourages CMS to move away from any policies that discriminate against virtual modalities without evidence.

- **Expanded Support for Remote Monitoring:** CMS should ensure that critical access hospitals (CAHs) and REHs are able to provide services via the most appropriate and accessible modality, whether live voice/video or asynchronous modalities including remote monitoring. CAHs and REHs, at the front lines of care for America's most underserved populations, need the ability to monitor key PGHD metrics. CAHs and REHs should enjoy the same fee-for-service carve out that Federally-Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) already enjoy for Chronic Care Management (CCM), Transitional Care Management (TCM), and Behavioral Health Integration (BHI) services.

  Further, CMS must act to support the use of RPM and RTM by CAHs and REHs. Further, we note that CMS has proposed to provide new support for RPM and RTM to FQHCs and RHCs, and request that the OPPS rules provide similar support for CAHs and REHs.

- **Artificial Intelligence/Software as a Service (SaaS):** Leveraging health data, including social determinants of health (SDOH) and PGHD with AI tools (and software as a service [SaaS] AI applications) holds incredible promise for advancing value-based care in 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 systems to ensure value.

  As part of its commitment to responsibly advancing AI in healthcare, CHI assembled a Health AI Task Force, which has produced a number of resources

for policymakers considering the role of AI in healthcare.[6] We strongly urge CMS to review these CHI AI Task Force deliverables and consider ways to align with them.

CHI is immensely appreciative of CMS' efforts to responsibly bring AI to the Medicare system in a way that will benefit all providers and patients. Already, CMS' support for the use of AI in the OPPS represents a precedential development in advancing the system through the responsible uptake of AI, which CHI supports. We encourage CMS' expanded support of AI tools in the OPPS, consistent with our views on AI's efficacious deployment. We therefore generally support CMS' further proposed supportive actions of AI, including proposed OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2024.

In its proposed CY2024 OPPS rule, CMS has also posed a range of questions related to the potential of patient and workforce safety as a measurement topic area in the Hospital OQR Program. We appreciate CMS' posing of questions that raise the use of innovative technologies, including software algorithms and AI in health, and its efforts to better understand the resource costs for services involving their use. We are encouraged by CMS' leadership in exploring medical AI definitions, present and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding. We urge CMS to pose these questions in a standalone Request for Information that is not tied to an annual payment rule.

There have been further health AI developments on which we strongly encourage CMS to build on, and which speak to its questions posed about mitigating AI risks, improving safety, and facilitating quality measurement. For example:

- The CHI's AI Task Force's health AI policy principles, a comprehensive set of principles based on a consensus of the digital health community.[7]
- **The CHI's AI Task Force released *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*,[8] the digital health community's consensus recommendations addressing how to create health AI tools and maintain the trust in them of both healthcare professionals and patients.** This new set of recommendations builds on the Task Force's previously released general health AI policy

[6] The CHI Health AI Task Force's deliverables are accessible at https://connectedhi.com/resources/.

[7] The CHI's AI Task Force's health AI policy principles are appended to this comment as **Appendix A**.

[8] The CHI's AI Task Force's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem* is appended to this comment as **Appendix B**.

recommendations and recommended good machine learning practices for FDA-regulated AI.

- **The CPT® Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various AI applications. The Panel intended the Appendix to be consulted for code change applications to describe work associated with the use of AI-enabled medical services and/or procedures.** This taxonomy provides guidance for classifying various AI applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative, or autonomous, and its adoption represents a significant step forward in the evolution of CPT® coding.

CY2024 offers an excellent opportunity for continued CMS leadership and for timely and impactful policy changes to further support the responsible deployment of AI to benefit all Medicare beneficiaries and to reduce disparities. In its CY2024 Medicare rulemakings, we strongly urge CMS to:

- Rely on the CPT® Editorial Panel's new Appendix S to harmonize CMS' definitions and understanding of health AI and the CHI AI Task Force's released general health AI policy recommendations as a baseline for payment policy decisions impacting AI's use in Medicare.
- Continue to support and expand responsible payment (aligning, where possible, with valuation recommendations of the Relative Value Scale Update Committee) for AI tools that will drive greater access to innovative AI mechanisms for Medicare beneficiaries. CMS should adopt national rates for the payment of AI services and shift away from contractor pricing that encourages disparate approaches among Medicare Administrative Contractors.
- Recognize that AI (either standing alone or used in a system) is appropriately paid for as a direct PE. AI software is not simple off-the-shelf software and cannot not be properly categorized as an indirect PE. Like medical equipment and medical supplies, SaMD is a device as defined by FDA regardless of whether it is loaded onto and used on general purpose platforms or used as dedicated ancillary medical devices.
- Continue to engage in dialogue with the digital health community to inform new steps forward towards an expanded and nationally harmonized approach to AI's use in Medicare.

We commit to continued collaboration with CMS to realize the benefits of AI tools in Medicare equitably and welcome the opportunity to meet with you to discuss the above

IV. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with CMS and other stakeholders towards realizing the most successful OPPS and ASC possible.

Sincerely,

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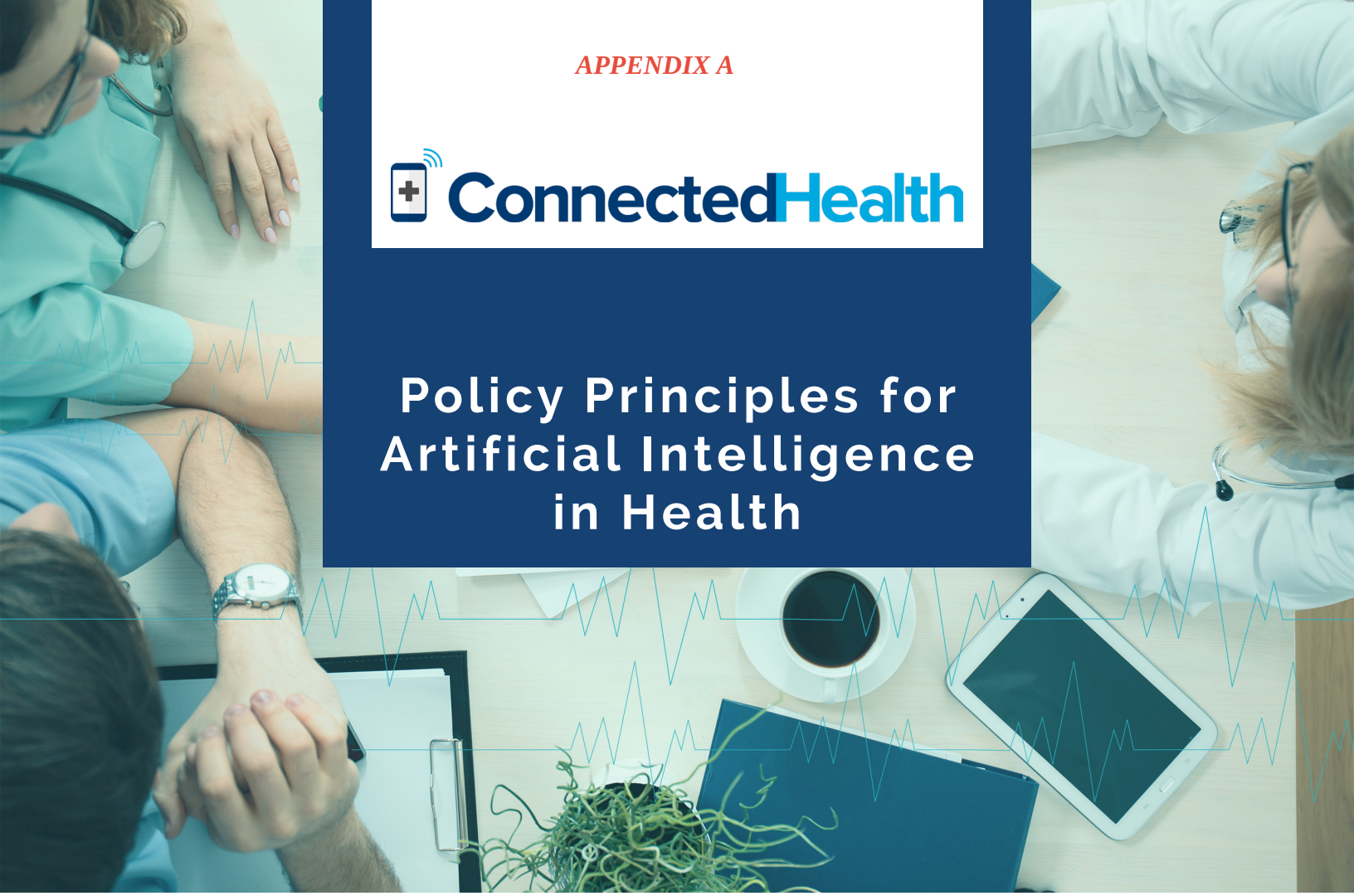
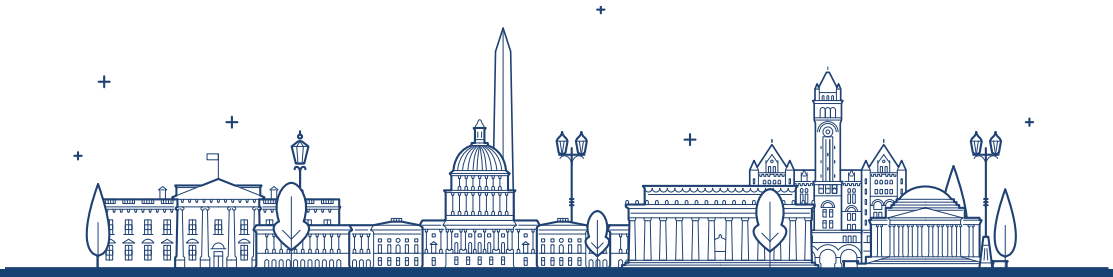
APPENDIX A

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:Ensuring 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.

APPENDIX B

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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.