April 3, 2020

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St. SW
Washington, District of Columbia 20201

RE: *Comments of the Connected Health Initiative on the Draft 2020-2025 Federal Health IT Strategic Plan*

Dear National Coordinator Rucker:

The Connected Health Initiative (CHI) writes to provide input on the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) draft *2020-2025 Federal Health IT Strategic Plan* (Draft Plan).[1]

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

CHI is a long-time active advocate for the increased use of innovative technology in the delivery of healthcare and engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, Morgan Reed, executive director of CHI and president of its convening organization ACT | The App Association, is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group. The DMPAG is an initiative bringing together a 15 nationally recognized experts to identify barriers to digital medicine adoption and propose comprehensive solutions regarding coding, payment, coverage, and more.[2]

---

[1] https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan.

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

Connected Health is an initiative of ACT | The App Association

1401 K Street NW Suite 501
Washington, DC 20005

202.331.2130
www.connectedhi.com

@connectedhealth
/ConnectedHealthInitiative

CHI is also a board member of Xcertia, a collaborative effort to develop and disseminate mHealth app guidelines that can drive the value mHealth apps bring to the market. These guidelines also seek to increase the confidence that physicians and consumers can have in mHealth apps and their ability to help people achieve their health and wellness goals.[3]

CHI supports ONC's efforts to reduce administrative burdens in healthcare by (1) Promoting Health and Wellness; (2) Enhancing the Delivery and Experience of Care; (3) Building a Secure, Data-Driven Culture to Accelerate Research and Innovation; and (4) Connecting Healthcare and Health Data through an Interoperable Health IT Infrastructure.

CHI also supports ONC moving forward with new rules to address illegal information blocking. The new health data interoperability and information blocking rules from ONC and Centers for Medicare and Medicaid Services (CMS) are postive steps towards a new era in healthcare where patients are finally put in control of their health information and unleash the app economy's innovation and efficiencies to healthcare. We would like to thank Secretary Alex Azar, Deputy Secretary Eric Hargan, CMS Administrator Seema Verma, and National Coordinator of Health IT Don Rucker for their collaborative and thoughtful approach to developing these rules and consideration of all stakeholder voices. CHI continues to review these rules in detail and looks forward to working with ONC and CMS about further implementation.

CHI urges onc to link this Draft Plan to the important steps recently taken by CMS in the Physician Fee Schedule (PFS) to responsibly advance the use of digital health tools. CHI has worked with CMS to advance these changes, and any steps ONC takes to in the 2020-2025 Federal Health IT Strategic Plan should build on the important changes, which include standalone support for the use of remote patient monitoring and advancing the use of digital health innovations in the Quality Payment Program's Merit-based Incentive Payment System (MIPS) rules, among others.

---

[3] http://www.xcertia.org/

The range of innovative connected health tools available today (and those in development), across patient conditions, offer key health IT functionalities that enable greater engagement in prevention and treatment as well as improved outcomes. Further, a diversity of application program interfaces (APIs) are emerging to assist in bringing patient-generated health data (PGHD) into the continuum of care. CHI stresses that not all of these are necessarily well integrated with electronic health records (EHRs). While certified EHR technology (CEHRT) will be required to support APIs, many vendors will enable "read only" access, allowing for data to only flow out of the EHR rather than both in and out, reducing the utility of the EHR technology. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards—creating "special effort" to develop applications and undue burden and costs for our members.

Many CHI members develop unique applications that benefit both providers and patients. However, misplaced CEHRT incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently (e.g., across all Quality Payment Program [QPP] components). For instance, the QPP MIPS Promoting Interoperability (PI) component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT. ONC's EHR Reporting Program should provide providers, third-party application developers, and other CEHRT users information on EHRs' ability to capture, incorporate, and leverage PGHD. For instance, providers and our members would both benefit from understanding if and how an EHR can be utilized to bring PGHD into clinical decision support (CDS) systems. CEHRT developers could report on their products' ability to capture structured PGHD and incorporate it into their systems' CDS logic; the ability of CEHRT to consume PGHD via an API (along with any applicable API costs); and precautions taken to secure interoperability with the API.

Furthermore, we urge ONC, along with all of HHS, to consider shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach permitting the use of non-CEHRT across the entire MIPS program. ONC and CMS should also seek to minimize administrative burdens (e.g., lengthy documentation and reporting program requirements) on Medicare caregivers. As such, ONC should work with CMS to leverage EHR data generated as a byproduct of Performing Interoperability (PI) participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS' "Support Electronic Referral Loops by Receiving and Incorporating Health Information" measure lumps summary of care records received and the reconciliation of clinical information into one process. Providers are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks providers with juggling the technical aspect of interoperability (i.e., digital document capture and incorporation) and the laborious process of reconciliation.

Instead, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the provider, whether the EHR was able to provide the provider with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. This type and level of information is far more meaningful and valuable to providers, CMS, and ONC, and should be supplied by the EHR developer. As part of its strategy, ONC should work with CMS to implement a "record once, reuse multiple times" approach, leveraging EHR-captured data for both ONC's EHR Reporting Program and CMS' EHR Reporting Programs (e.g., PI). To be clear, the intent is to reduce the reporting requirements on providers by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for provider reporting in programs like PI. This data would contribute to EHR performance measurement needs of both agencies.

CHI continues to support efforts to revise healthcare frameworks and programs (e.g., MIPS measures and objectives) to facilitate CEHRT program alignment with non-CEHRT use (e.g., remote monitoring technology, which can greatly improve patients' care and wellness). CHI strongly supports ONC's EHR Reporting Program as a method to enable competition and innovation to drive the development and flexible use of both CEHRT and non-CEHRT. CHI stresses that more must be done to reduce the over regulation of CEHRT to allow natural market forces to inform health IT development.

As a community, we continue to support ONC's efforts to utilize advanced technology to augment care for every patient. With the congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, ONC's efforts in continuing to advance the range of connected health innovations that will help American healthcare the improve outcomes and cost savings are essential.

As ONC builds its new EHR compliance program, we urge for a prioritization of technology developer awareness to encourage market participation by innovators. ONC should develop clear and easily accessible guidance on reporting requirements, and reinforce that CEHRT certification is a floor, rather than a ceiling, to ingenuity of the products and services offered to caregivers. As noted above, ONC's new CEHRT program reporting framework will be developed alongside the creation of the PI framework by CMS; we strongly encourage coordination and alignment across both programs; the communication of a clear relationship between both programs; and the utilization of data reported for one program to be used for another in all ways practicable in order to streamline compliance for all entities reporting into programs as well as for analysis by HHS of programmatic success.

Further, CHI appreciates ONC's efforts to address artificial intelligence in its Draft Plan. 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. CHI, through its Health AI Task Force, has taken a proactive approach to the role of AI in healthcare, and has adopted a set of policy principles (appended) that we urge ONC to align its 2020-2025 Federal Health IT Strategic Plan with.

<u>Based on the above, we offer the following on certain Strategies and Recommendations in the Draft Strategy:</u>

- Goal 1: Promote Health and Wellness

CHI fully supports ONC's proposed goal of empowering individuals, address patients' full range of health needs, promote healthy behaviors, and facilitate the improvement of health for individuals, families, and communities. ONC must advance data interoperability across the healthcare continuum to advance this goal, building on its important steps taken in, for example, new interoperability and information blocking rules (which notably provide a pathway for updating the U.S. Core Data Initiative). We urge this Plan to prioritize the development of private sector implementation guides to support this goal.

- Objective 2c: Reduce regulatory and administrative burden on providers

CHI notes its support for this Objective. Digital health innovations offer the ability to reduce burdens associated with prior authorization (PA), as opposed to the legacy approaches unfortunately still in use today (mail or fax). CHI specifically notes its support for the automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers.

CHI supports efforts to evaluate and address factors that lead to PA burden. It is important to note that process automation cannot fully relieve current practice burdens associated with PA. Broader policy reforms are needed to achieve meaningful reductions in the administrative hassles associated with PA. HHS' recommendations focus on how to make the actual PA process more efficient and less burdensome for the stakeholders involved, which is an admirable and essential component to PA reform. We believe that the industry should leverage technological advancements to reduce the overall volume of PAs by selectively targeting services and providers for PA and clinical documentation processes and eliminating low-value or problematic PA requirements. Examples of such efforts could include exploration of gold carding programs, clinical decision support mechanisms, regular review and adjustment of payers' PA lists, and other programs.

While prior authorization processes can be made more efficient through automation, they inherently can require patients and practices to take additional steps as compared to services without prior authorization. Refining the process and reducing the volume of PA is critical because even a fully automated process will result in administrative costs for providers and plans and can negatively impact care delivery. For example, a seamless electronic prior authorization process does not help a patient who suddenly cannot get a chronic medication they've taken successfully for years due to PA requirements under a new plan. As a result, prior authorization processes should only be applied to appropriate services, patients and clinicians.

- Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

CHI agrees that technology and analytic advancements like machine learning and AI forecasting have the potential to transform patient care and improve health, and that these tools will become essential in the future to support the individualized care of patients and communities. CHI urges for the responsible deployment of AI tools in healthcare that further the Quadruple Aim, as described in CHI's 'Policy Principles for AI in Health,' appended to this document.

Notably, CHI recommends that ONC utilize risk-based approaches to ensure an environment where 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. 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.*

- Objective 4a: Advance the development and use of health IT capabilities

CHI generally agrees with ONC's proposed Objective 4a, but has concerns with ONC's proposal to "support provider adoption and use of health IT by requiring health IT use to participate in federal programs, investing in health IT, and making resources available to support adoption and use." As we discuss above, ONC will more effectively reach this goal by providing the most flexibility to users of digital health tools possible, rather than requiring "use of Health IT" to participate in federal programs. HHS can take a meaningful step in this direction by enabling Merit-based Incentive Payment System (MIPS) participants to use non-CEHRT to accomplish MIPS goals.

- Objective 4d: Promote secure health information that protects patient privacy

CHI generally supports the proposed Objective 4d and urges for the advancement of both patient privacy and patient access. CHI believes that a new Objective should be added to provide patients with a basic level of privacy and app transparency through health apps attest that patient data is accessed, exchanged, and used in a responsible way through use of:
- *Industry-recognized development guidance;*
- *Transparency statements and best practices; and*
- *A model notice to patients.*

Pursuant to this new Objective, an EHR vendor's API would be required to document three "yes/no" attestations from any consumer-facing app aligned with the above. For example, an app developer could attest to: (1) conformance to Xcertia's Privacy Guidelines; (2) the Federal Trade Commission's (FTC) Mobile Health App Developers: FTC Best Practices; and (3) adopting and implementing ONC's Model Privacy Notice. These could be viewed as value-add services as proposed by ONC. The app could be acknowledged or listed by the health IT developer in some special manner (e.g., in an "app store," "verified app" list). We would urge EHR vendors to also publicize the app developers' attestations; ONC could also require a vendor to do so as a prerequisite to product certification.

- **Proposed** Objective: Responsibly scale up artificial intelligence tools to advance value and innovation throughout the care continuum

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 offers 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. For example, AI-driven digital therapeutics that deliver clinically-backed interventions to treat patients where they are, saving the patient, provider and others throughout the healthcare value chain immense time and expense.

We urge ONC to, when considering the value of AI in healthcare, to view the proposition through the lens of the "quadruple aim" framework. Built on the Institute for Healthcare Improvement's "triple aim,"[4] a widely accepted compass to optimize health system performance,[5] the quadruple aim focuses on four key areas where health systems need to be improved and acknowledges concerns of key stakeholders. The four areas are (1) enhancing population health; (2) improving patient experience, satisfaction, and health outcomes; (3) better clinician and healthcare team experience and satisfaction; and (4) lowered overall costs of healthcare.

> ***Improving Population Health Management:*** *AI-enabled tools offer great promise in overcoming the challenges faced by clinicians, health systems, health plans, and public health officials working to advance population health management and public health. AI-enabled tools, for example, can process massive and disparate data sources to provide public health officials, health care systems, and providers essential and actionable data rapidly related to assist with more timely and accurate population level disease surveillance and assessments of disparities and health care resource distribution.*
>
> *Population health[6] management has long been viewed as the essential ingredient to improve overall health outcomes and arrest rising health care costs. Population health management involves aggregation and analysis of huge amounts of data from divergent sources, something that can be potentially*

---

[4] http://www.ihi.org/engage/initiatives/tripleaim/pages/default.aspx.

[5] Thomas Bodenheimer, MD and Christine Sinsky, MDFrom Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider, Ann Fam Med November/December 2014 vol. 12 no. 6 573-576.

[6] Defined as "an approach [that] focuses on interrelated conditions and factors that influence the health of populations over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and well-being of those populations." Kindig, D. and Stoddart, G. What Is Population Health? American Journal of Public Health, 93, 380-383 (2003).

streamlined through robust and powerful AI systems. AI-powered tools can collect patient generated health data and deliver clinically-backed interventions to treat patients where they are.

As more systems are created and deployed, the opportunity for AI to help improve healthcare outcomes is significant, with estimates suggesting outcomes could be improved by 30-40 percent.[7]

Improving Patient Experience, Satisfaction, and Outcomes: *One of the more significant critiques of healthcare systems around the world is that they fail in many respects to meet patients' expectations around access to care, ease of use, and care continuity and coordination.*

All too often, patients are forced to make multiple visits, shuffling between a general practitioner and a specialist. With the ability to replicate specialist-level expertise at the frontlines of care, AI-enabled tools will reduce paperwork burdens, center care around where the patient is located, and enhance the ability to manage and understand how to sustain health or manage a disease. Services that increasingly can be enhanced and improved with AI systems will provide patients and their health care teams with timely, essential information, and ongoing support that is not currently available.

With people over the age of 65 representing an increasing percentage of the population, AI systems will be essential for human caregivers and clinicians to extend their reach and coverage of an ever-growing population of patients.

Improving Clinician and Healthcare Team Experience and Satisfaction:
Among clinicians and the extended health care team, the growing administrative and paperwork demands coupled with compounding rates of new medical knowledge and data generation are driving records levels of burn-out and dissatisfaction. AI-enabled tools can and should be deployed to drastically improve clinician and healthcare team satisfaction using tools that help clinicians and the health care team to more quickly screen, diagnose, treat, and monitor effectively patients and remove time-consuming and often mundane tasks.

---

[7] Nicole Lewis, Artificial Intelligence to play key role in population health, Medical Economics (2017) (available at http://www.medicaleconomics.com/medical-economics-blog/artificial-intelligence-play-key-role-population-health).

Reducing Healthcare Costs: *Countries around the world struggle with both rising costs and absolute costs of providing healthcare to their citizens. Nations spend between roughly 6 percent and 18 percent of their gross domestic product (GDP) and many have seen the share of GDP devoted to healthcare costs sharply rise over the last three decades.[8] The situation is unsustainable, and, in many countries, the problem will only get more acute as populations age and average life expectancy continues to rise. A huge amount of data is available today for collection and utilization in timely prevention and treatment decisions that would result in massive cost savings, but that data currently usable, but can be found in electronic health record (EHR) systems.*

Healthcare experts see enormous promise in AI to more accurately capture and leverage the range of health data available, with estimates suggesting AI applications can create $150 billion in annual savings for the United States healthcare economy by 2026.[9] This savings estimate includes only the top 10 AI scenarios, such as assisted surgery, virtual nursing assistants, and administrative workflow assistance, etc.

On a worldwide basis, healthcare administrative costs (e.g., billing) are a continuing challenge. The administrative costs of the U. S. health care system are estimated to be 31 percent of total healthcare expenditures.[10] AI's potential to help us address spiraling costs in healthcare is very real, and it is already showing returns today.

These are all areas where we are already seeing the potential AI systems have to positively impact the current healthcare system. We therefore urge ONC to create a new Goal in the Framework to focus on responsibly developing and scaling up AI tools to advance value and innovation throughout the care continuum, mapped to the quadruple aim described above. In the alternative, we call on ONC to integrate a priority for advancing the quadruple aim by responsibly developing and scaling up AI tools to advance value and innovation throughout the care continuum across its existing Goals and Objectives.

---

[8] Henry J Kaiser Family Foundation, Snapshots: Health Care Spending in the United States & Selected OECD Countries (2011); Bradley Sayer and Cynthia Cox, How does health spending in the U.S. compare to other countries?, Kaiser Family Foundation (2018).

[9] Accenture, Artificial Intelligence: Healthcare's New Nervous System (2017).

[10] http://www.pnhp.org/publications/nejmadmin.pdf.

***

CHI appreciates the opportunity to submit comments to ONC and its Draft Strategy, and we look forward to the opportunity to further work with ONC and other stakeholders to realize a digital health innovation-enabled care continuum that minimizes burdens on caregivers.

Sincerely,

Brian Scarpelli
Senior Global Policy Counsel
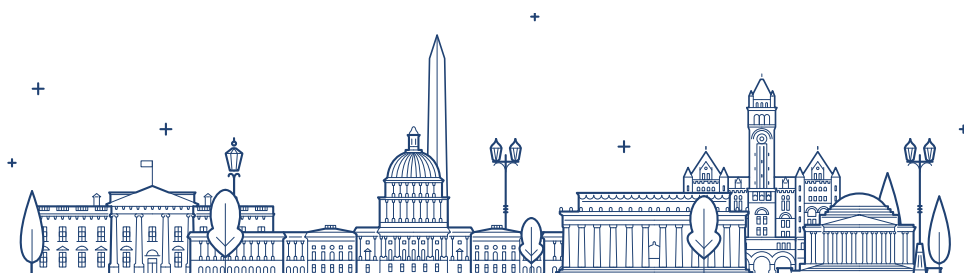
Alexandra McLeod
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005
p: +1 517-507-1446
e: bscarpelli@actonline.org

The Connected Health Initiative (CHI), an initiative of ACT | The App Association, is the leading multistakeholder spanning the connected health ecosystem seeking to effect policy changes that encourage the responsible use of digital health innovations throughout the continuum of care, supporting an environment in which patients and consumers can see improvements in their health. CHI is driven by the its Steering Committee, which consists of the American Medical Association, Apple, Bose Corporation, Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, The Omega Question, Otsuka Pharmaceutical, Podimetrics, Proteus Digital Health, Rimidi, Roche, Spekt, United Health Group, the University of California-Davis, the University of Mississippi Medical Center (UMMC) Center for Telehealth, the University of New Orleans, and the University of Virginia Center for Telehealth.

For more information, see www.connectedhi.com.

ConnectedHealth

Policy Principles for Artificial Intelligence in Health

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.