ConnectedHealthInitiative

February 23, 2025

Dr. Thomas Keane
Assistant Secretary for Technology Policy
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CHI Response to Assistant Secretary for Technology Policy Request for Information on Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (90 FR 60108)

Dear Assistant Secretary Keane:

The Connected Health Initiative (CHI)[1] shares your commitment to supporting the necessary expanded use of digital and connected health technologies. A growing evidence base continues to demonstrate that the responsible use of safe and effective digital health solutions produces better patient outcomes, reduces costs, augments population health management, and improves the healthcare workforce experience. Digital health tools, increasingly powered by artificial intelligence (AI), leverage patient-generated health data (PGHD) and include cloud-enabled solutions, to reduce administrative burden, support medical and clinical decision-making, and chronic and acute care management. The use of these tools is also vital in supporting unserved and underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions.

The Connected Health Initiative (CHI) is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected technologies to advance outcomes and reduce costs. We advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, to accomplish responsible pro-digital health policy and law changes 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 intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

[1] www.connectedhi.com.

Leveraging the tremendous potential of AI is critical to accomplishing the Administration's goals of empowering the American people with personalized solutions; equipping healthcare providers with better and timely data about the patients they serve and improving health outcomes; and shifting the paradigm for health care to a system that fosters prevention, wellness, and chronic disease management. Many AI use cases, ranging from solving administrative/backend efficiencies to supportive clinical decisions, have already demonstrated their capacity to advance the Quadruple Aim.

We are encouraged to see the Department of Health and Human Services (HHS) continue to investigate these goals, including with its request for information regarding accelerating the adoption of artificial intelligence as part of clinical care. HHS is well-positioned to leverage its existing authority to ensure that its policies propel the American healthcare system forward through its safe, effective, and responsible uptake of AI. We encourage you to set policy aligned with the following principles:

- **A Shared Responsibility for Quality and Efficacy:** Across HHS, adopt a risk-based approach to healthcare AI that tailors risk mitigation to the potential harms of intended and expected uses. Responsibility for managing risks should be appropriately shared among developers, vendors, and providers based on their knowledge of, and ability to address, those risks in alignment with leading standards such as ISO/IEC 42001. HHS should prevent the improper or unfair shifting of liability to those who rely on AI technologies in good faith to care for patients so as to encourage innovation and adoption without introducing new risks for critical health AI value chains. CHI's *Health AI Roles and Interdependencies Framework*,[2] which describes the health AI value chain, defining actors and describing roles for ensuring safety and efficacy as well as the interdependencies between these actors and mapping these roles to functions in the National Institute of Standards and Technology's AI Risk Management Framework, can inform policy decisions regarding AI liability.
- **Transparency and Explainability:** In alignment with existing standards and best practices for making appropriate information public, provide clear, risk-based communications that inform all healthcare stakeholders about relevant data requirements, intended uses, limitations, target populations, bias mitigation, and applications of AI tools. These communications should disclose sufficient detail to help providers assess when a tool is appropriate for individual patients, clarify whether the tool augments or automates clinical workflows, and specify compliance with all applicable legal and regulatory requirements. Transparency is a prerequisite for AI adoption.
- **Access and Affordability:** Prioritize measures that will ensure digital health technologies and AI systems in health care are accessible and affordable across research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must

[2] https://connectedhi.com/wp-content/uploads/2025/03/CHI-Health-AI-Roles.pdf

be in place to invest in building health AI infrastructure; preparing personnel and training; and appropriately incenting the responsible uptake and consistent use of AI tools demonstrated to advance the Quadruple Aim. Notably, CMS should modernize the way AI software is categorized and supported, including AI enabled non-medical device technologies, and provide support in Medicare for AI tools to improve Medicare beneficiaries' experience and care (as well as working with states to achieve a harmonized expansion of similar support for AI in Medicaid). Further, CMS should make overdue modernizations to key disease prevention programs (e.g., diabetes prevention) and support preventative healthcare by fully leveraging digital health technologies tools, such as patient-facing wearables and AI-enabled services. AI can play a central role in the transition to value-based care by providing essential population health tools and providing enhanced scalability and patient support.

- **Interoperability:** Ease data access and improve interoperability, while protecting data privacy and security, to foster cooperation, trust, and openness among patients, providers, health AI technology developers, and researchers. A truly interoperable healthcare system is one that enables and engages patients across multiple privacy-preserving platforms using open APIs, enabling the secure integration of patient-generated health data into electronic health records. Interoperability rules under the 21st Century Cures Act should enable clinicians' access to medical records and patients to get their data and provide it to other organizations, including for research. The success of AI tools for precision medicine, population health, and clinical decision support, all of which are key tools in addressing chronic diseases, depends on accessible and interoperable data.
- **Ethics:** Given the longstanding, deeply rooted, and well-developed body of medical and biomedical ethics, it will be critical to preserve existing and emerging ethical norms developed by providers and healthcare professional organizations for broader adherence by technologists, innovators, computer scientists, and those who use such systems. From design, development, implementation, and to use, healthcare AI tools should reflect the practical, ethical, and operational realities of patient care.
- **Workforce:** The United States faces a stark, and growing, healthcare workforce shortage. Successful creation and deployment of AI-enabled technologies which help care providers streamline tasks and meet the needs of their patients will be an essential part of addressing this shortage. Policies should support user education and workforce development through AI upskilling and strengthen the clinician-patient relationship.
- **Education:** Support educational efforts to increase AI literacy in healthcare, highlight successful AI applications, and promote stakeholder engagement to keep policies responsive to new opportunities and challenges. Education should be developed by healthcare professional organizations in partnership with AI

developers. Educating the public about how AI is used in their care increases transparency, fosters trust, and enables patients to make informed decisions about their health.

- **Collaboration:** We strongly encourage you to leverage the public-private partnership framework to collaborate with providers, patients, industry, research institutions, and government agencies to advance the above and to more broadly drive safe and effective innovation in healthcare AI.

Further, CHI has worked with the broader community to develop, and strongly encourage the HHS strategy to align with, healthcare ecosystem-wide consensus recommendations on the use of AI in healthcare (each is appended to this comment):

- **CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem***, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf); and
- **CHI's *Health AI Roles & Interdependency Framework***, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf); and
- **CHI's *Value-Based Payment Reform: Leveraging SaaS Technologies for Care Model Innovation*,** a report offering leading recommendations for payment reforms to enable and incentivize the adoption of modern software and AI technologies and care model innovation (https://connectedhi.com/value-based-payment-reform-leveraging-saas-technologies-for-care-model-innovation/).

Building on the above, we also provide specific responses to the RFI's questions:

1. **What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?**

CHI has consistently identified several interconnected barriers that impede the private sector's ability to innovate and deploy AI in clinical care:

Regulatory Uncertainty and Fragmentation. The current regulatory landscape is fragmented across FDA, CMS, ONC, OCR, and state-level agencies, creating overlapping and sometimes conflicting obligations for AI developers and deployers. As a leading example, key stakeholders frequently lack clarity on whether their AI product is classified as a medical device, clinical decision support (CDS) software, or a non-regulated wellness tool. The lack of a unified, coherent framework makes investment planning and compliance difficult. CHI supports a coordinated framework, which there are examples of today, such as the coordinated CMS Advancing Chronic Care with Effective, Scalable

Solutions (ACCESS) Model and FDA Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot.

Reimbursement Gaps and Misaligned Incentives. Legacy fee-for-service payment models do not recognize or reward the value that AI-enabled tools deliver. There is currently no systematic mechanism for CMS to provide coverage and reimbursement for AI-powered clinical decision support, ambient documentation, or remote patient monitoring tools that improve outcomes and reduce costs. Without a viable reimbursement pathway, innovators cannot achieve the commercial sustainability needed to scale, and health systems lack the financial incentive to adopt these tools.

A significant barrier to medical AI innovation is CMS' outdated Medicare Part B Practice Expense (PE) payment methodology which CMS itself has acknowledged in stating that it hasn't updated the underlying data and methodology in over a decade. At the heart of the problem is CMS' interpretation that it cannot pay for software, including Software as a Medical Device (SaMD) or AI-based algorithmic solutions, under this framework. Despite issuing annual requests for public comment on the topic since 2018, which requested comments on everything from communications technologies and patient-generated health data to digital therapies and AI, CMS has taken little meaningful action to resolve the ambiguity. The fix lies in how PE costs are categorized: direct practice expenses, which are allocable and actually reimbursed, cover clinical staff, medical supplies, and medical equipment; while indirect expenses, which are largely non-allocable, cover administrative labor, office overhead, and "computer software." CMS has been treating software as the latter, but this is legally inconsistent. Notably, SaMD has been classified as a medical device under U.S. law since the Medical Device Amendments Act of 1976, is regulated by the FDA on par with hardware devices, and carries the same legal, regulatory, and financial burdens as any hardware medical device manufacturer. Categorizing it alongside generic office software and administrative overhead makes no sense under the law. CMS can and should act now to ensure that it categorizes SaMD as a medical device, not an administrative expense, and therefore treats it as an allocable direct practice expense within the current PE methodology.

Data Access, Quality, and Interoperability. AI models are only as good as the data on which they are trained and validated. Inadequate interoperability across electronic health record (EHR) systems, persistent information blocking, gaps in structured data availability, and lack of standardized real-world datasets impede both the development and post-market monitoring of AI tools. CHI has long advocated for enforcement of the ONC information blocking rules, adoption of HL7 FHIR-based APIs, and expanded access to high-quality, de-identified datasets to power AI development.

Privacy and Liability Uncertainty. The existing patchwork of federal and state privacy laws, including HIPAA, the FTC Act, and various state-level statutes, create compliance complexity for companies using patient data to train and validate AI models. The lack of a comprehensive national privacy law leaves significant gaps in coverage, particularly for

health data that falls outside HIPAA. Additionally, unclear liability frameworks for the use of AI discourage health system adoption and developer investment.

Workforce and Adoption Readiness. Health systems, particularly safety-net providers, rural facilities, and small practices, too often lack the IT infrastructure, data governance capabilities, and clinician training needed to effectively integrate AI tools.

2. **What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.**

CHI recommends the following priority changes:

Modernize CMS Reimbursement to Recognize Software AI-Enabled Care. CMS should establish new supports across its existing payment rules that enable AI-supported clinical services, building on the existing framework for Remote Physiologic/Therapeutic Monitoring (RPM and RTM), Chronic Care Management (CCM), and Transitional Care Management. Specifically, CMS should take further action to integrate AI-powered clinical decision support into clinical workflows, and for ambient AI documentation tools that reduce clinician burden, including through ensuring that SaMD is considered a direct PE (described above in CHI's answer to Question 1).

CHI notes that it is not required by law for CMS to exclude SaMD from its existing payment methodology. CMS has, in fact, previously included procedure-specific software as direct PE inputs, making it well within the agency's existing regulatory authority to properly categorize SaMD as direct PE "medical equipment" rather than generic "computer software" indirect PE. Moreover, because SaMD continuously evolves, requiring updates and upgrades to address cybersecurity threats, vulnerabilities, and improvements driven by real-world evidence, those ongoing costs are analogous to "medical supplies," another recognized direct PE category. Both the equipment and its upkeep should be accounted for accordingly.

SaMD-delivered services are also separable and distinct procedures in their own right, consistent with CMS' own rationale when it covered FFRCT CPT codes for augmentative software analysis. CPT coding has evolved to recognize this shift through the creation of a new AI taxonomy for CPT codes, classifying AI applications as assistive, augmentative, or autonomous.[3] Autonomous AI is increasingly performing work once done by physicians or clinical staff, which is already reflected in CPT code 92229 for autonomous retinal imaging,

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

analysis CMS must update its PE methodology to treat SaMD as medical equipment, just as it does for hardware devices.

Looking further ahead, AI raises deeper questions that go beyond straightforward categorization. When machines fully replace provider or clinical staff work, policymakers must address how Relative Value Units are updated to reflect that. And as digital therapeutics introduce entirely new mechanisms of action, driven not by chemicals or human intervention but by algorithms, entirely new frameworks may be needed. These are questions that may deserve dedicated attention through a standalone public Request for Information, an associated public meeting with national experts and relevant government officials, and a formal expert process to build the right framework for capturing machine-performed medical work. At the same time, these questions cannot sit unanswered for much longer.

Accelerate Value-Based Care Models that Reward AI Outcomes. CMS Innovation Center (CMMI) models are better positioned than fee-for-service to recognize and incentivize AI-driven improvements in care quality and cost. HHS should expand and codify payment models that allow participants to share in savings generated by AI tools. CHI continues to support the ACCESS Model and other Models that are enabling cost savings and high-quality prevention and treatments through leveraging digital health innovations.

Harmonize FDA Regulatory Framework for AI-Enabled Software. HHS should work with FDA to finalize a clear, stable categorization framework for AI-enabled device software functions consistent with the 21st Century Cures Act's clinical decision support provisions (21 U.S.C. § 360j(o)). CHI supports a risk-tiered approach that reserves stringent premarket review for high-risk functions while enabling lower-risk non-device AI tools to deploy under quality and transparency frameworks without full FDA clearance, and is appreciative of new FDA guidance that has provided greater clarity on CDS and general wellness devices.

Protect and Strengthen ASTP/ONC Interoperability and Information Blocking Rules. The Health IT Certification Program and the information blocking provisions of the 21st Century Cures Act should be strengthened to ensure that EHR systems make AI-enabling data securely available in standardized FHIR-based formats. CHI has supported the use of SMART on FHIR and CDS Hooks standards to enable AI applications to integrate seamlessly into clinical workflows.

Revisit OIG Safe Harbor Regulations to Enable Value-Based AI Arrangements. The OIG safe harbors under the Anti-Kickback Statute do not clearly protect arrangements in which health systems provide AI tools to clinicians at below-market cost in furtherance of value-based care. CHI urges OIG to clarify protections for AI tool dissemination in value-based care arrangements.

3. **For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance**

and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?

CHI has identified the following novel legal and implementation issues for non-medical device AI in clinical care:

Liability Allocation Across the AI Value Chain. CHI's Health AI Roles and Interdependency Framework (2024) describes a complex chain of AI/ML developers, health AI platform developers, digital health solution developers, deploying organizations, and clinical users, each of share the responsibility for AI safety and efficacy. HHS should work with Congress and, where possible, use its regulatory tools to clarify the appropriate allocation of responsibility across this chain based on knowledge and the ability to do something about known risks. HHS should also leverage the National AI Initiative and NIST's AI Risk Management Framework as organizing principles for this work.

Privacy Gaps Outside HIPAA. A significant share of health-relevant AI development uses data that falls outside HIPAA's scope, including data from wellness apps, wearables, and consumer health platforms. CHI has long supported the enactment of a comprehensive national privacy law and, absent such legislation, has urged HHS to use guidance to clarify the applicability of HIPAA to AI training and validation pipelines. HHS should also clarify the circumstances under which de-identification under 45 CFR Part 164.514 is sufficient to permit use of clinical data for AI model training.

Information Blocking and AI Tool Integration. Information blocking provisions that apply to health care providers, health IT developers, and health information networks should be clarified so that there is no question about whether the use of technical or contractual restrictions to prevent AI applications from accessing standardized EHR data constitutes information blocking, and that the Information Blocking Rule applies to practices that impede AI-enabled innovation.

Improving the Approach to Non-Medical Devices in Federal Health Programs. Under 42 U.S. Code § 1395y(a)(1)(A) of the Social Security Act, Medicare cannot pay for any item or service that is not "reasonable and necessary" for the diagnosis or treatment of illness or injury. Separately, under Section 201(h) of the Federal Food, Drug, and Cosmetic Act, products used for exactly those purposes (diagnosis, treatment, or improving the functioning of a malformed body member) are defined as regulated medical devices. Relatively recently, CMS has been using the term Software as a Service (SaaS) when discussing software-based clinical decision-making tools, but SaaS is a marketing term describing cloud-based administrative and non-medical computing and has no bearing on medical devices or clinical care. FDA has long regulated software that meets the Section 201(h) device definition, including CDS software intended to aid in diagnosis, treatment, or disease mitigation. FDA has also clearly delineated what constitutes "Non-Device CDS" functions like alerts, reminders, order sets, and documentation templates, which do not meet the device definition and fall outside FDA oversight. When CMS discusses software that supports clinical decision-making under Medicare Part B, it is talking about Device CDS or SaMD, making use of the term SaaS problematic. CMS should ensure that it does not conflate SaMD with SaaS, which may undermine the clarity that patients, providers, and innovators all need.

4. **For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care?**

CHI has identified several evaluation approaches CHI believes HHS should support:

Risk-Proportionate Evaluation. CHI supports a risk-tiered approach in which the rigor of evaluation is proportionate to the demonstrated harms. High-risk tools that autonomously influence treatment decisions may require clinical validation, while lower-risk tools can be validated through retrospective analysis and real-world performance monitoring.

Real-World Evidence and Post-Market Surveillance. CHI supports the use of EHR-derived real-world data, device logs, and patient-reported outcomes for post-deployment monitoring. HHS should develop standardized templates for AI model performance cards that capture key metrics including accuracy, sensitivity, specificity, and equity indicators.

Human-Centered and Workflow Integration Evaluation. CHI supports evaluation frameworks that examine not just algorithmic performance but human-AI interaction, including how clinician trust, alert fatigue, over-reliance, and workflow friction affect actual outcomes. The NIST AI RMF's emphasis on human factors provides a strong foundation for this work.

HHS Support Mechanisms. CHI supports HHS investment in evaluation infrastructure through grants and cooperative agreements with academic medical centers, federally

qualified health centers, and AI testing labs. CHI also supports the development of open, publicly accessible benchmark datasets and testing tools.

5. **How can HHS best support private sector activities (e.g., accreditation, certification, industry-driven testing, and credentialing) to promote innovative and effective AI use in clinical care?**

CHI strongly supports iprivate sector-led governance and certification mechanisms as a complement to government regulation. Key recommendations include:

Recognize and Incentivize Voluntary Certification Schemes. HHS should recognize voluntary AI certification programs developed by industry consortia, standards bodies, and professional societies as evidence of responsible AI practices. Participation in recognized certification schemes should be considered favorably in CMS coverage decisions and in compliance reviews.

Support the Development of Health AI Standards. CHI supports HHS collaboration with NIST, ISO, and IEC to develop health-specific AI standards that can underpin voluntary certification; and the incorporation by reference of those standards into goverance approaches where appropriate. The NIST AI RMF provides a useful cross-sector foundation that should guide HHS in developing a health sector profile that maps RMF functions to clinical AI use cases (CHI notes that its Roles & Interdependencies Framework has done this).

Establish a Recognized Testing and Evaluation Infrastructure. HHS should support the development of test beds and sandbox environments where AI developers can evaluate their tools against standardized benchmarks, including for data bias, robustness, and interoperability. These test beds should be accessible to small developers on affordable terms. CHI's AI Roles Framework notes that certification bodies and test beds have a specific responsibility to create transparent processes for AI conformity assessment.

Coordinate with Accrediting and Licensing Bodies. Medical specialty societies, state licensing boards, and hospital accreditation bodies (e.g., The Joint Commission) have an important role in, and significant influence over, clinical AI adoption. HHS should engage these bodies to develop clinical AI governance standards and to integrate AI competency into clinical training and credentialing.

Protect Against Market Fragmentation from State Requirements. While CHI supports state authority in healthcare regulation, proliferating and inconsistent state AI mandates create compliance burdens. HHS should provide model frameworks and guidance that states can adopt to minimize fragmentation, while preserving appropriate state innovation in healthcare governance.

6. **Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential?**

Areas of Demonstrated Success. AI-enabled RPM/RTM tools have demonstrated clear value in managing chronic conditions such as congestive heart failure, diabetes, and hypertension, reducing hospitalizations, improving medication adherence, and enabling more proactive clinical intervention. AI-powered ambient documentation tools have shown promising results in reducing clinician administrative burden and documentation time, directly addressing the clinician burnout crisis. AI-assisted diagnostic imaging tools, particularly in radiology, pathology, and ophthalmology, have demonstrated performance at or above human accuracy in well-defined, high-prevalence conditions.

Highest-Potential Novel Applications. CHI members and the broader health AI ecosystem have identified significant potential in AI-enabled population health management tools that synthesize multi-source data (EHR, RPM, SDOH) to identify high-risk patients and recommend targeted interventions; generative AI tools for care coordination and patient communication that reduce administrative burden while improving patient engagement; AI-powered predictive models for hospital readmission, deterioration, and sepsis that can be integrated into nursing workflows; and AI tools that enable precision medicine approaches, including pharmacogenomics and personalized treatment planning, in primary care settings.

7. **Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles?**

HHS should support the development of frameworks, data governance templates, and clinical integration playbooks that health systems can adopt to reduce barriers, and CMMI should consider including AI adoption support as a feature of future value-based care models. Based on CHI's engagement across the digital health ecosystem, the following stakeholders exercise the greatest influence on clinical AI adoption:

Chief Medical Officers (CMOs) and Chief Clinical Informatics Officers (CCIOs). Clinical leadership approval is typically a prerequisite for adoption of AI tools that touch clinical workflows. CMOs and CCIOs evaluate AI tools for clinical validity, workflow integration, and liability implications. HHS support and guidance that give these stakeholders confidence in AI tool quality will materially accelerate adoption.

Chief Information Officers (CIOs) and Chief Information Security Officers (CISOs). Technical and cybersecurity leadership control procurement decisions, integration timelines, and data governance. Interoperability barriers, including proprietary EHR APIs

and lack of FHIR compliance, are frequently cited as the primary technical bottlenecks in AI deployment.

Payers and Value-Based Care Coordinators. For health systems operating under value-based contracts, payer coverage and reimbursement decisions are major determinants of AI adoption. Tools that can demonstrate cost savings and quality improvements within CMS and commercial quality measurement frameworks are more likely to receive institutional investment.

Primary Administrative Hurdles. Key administrative barriers include: lengthy and complex procurement and contracting processes that are poorly suited to fast-moving AI technology; inadequate IT infrastructure and data governance in smaller and rural health systems; lack of staff training and change management support for AI deployment; legal uncertainty regarding liability for AI-assisted clinical decisions; and absence of reimbursement signals that justify the cost of AI tool implementation.

8. **Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking of tools.**

CHI has consistently advocated for health data interoperability as an enabler of both clinical care and digital health innovation. Key areas where enhanced interoperability would most benefit AI development and deployment include:

FHIR-Based API Standardization. Broad adoption of HL7 FHIR R4 and emerging R4B/R5 standards, including SMART on FHIR for application authorization and CDS Hooks for real-time clinical decision support integration, is fundamental to enabling AI tools to access the clinical data they need at the point of care. CHI has supported ONC's interoperability regulations and has urged aggressive enforcement of information blocking provisions to ensure that EHR vendors provide FHIR-compliant APIs that AI developers can use without prohibitive licensing restrictions.

Patient-Generated Health Data (PGHD) Integration. AI tools that can synthesize data from wearables, remote patient monitoring devices, and consumer health applications alongside EHR data have significantly greater clinical utility than those limited to EHR data alone. CHI has long advocated for standardized pathways to integrate PGHD into EHRs and population health platforms, including through standardized RPM device data formats and the USCDI+ data classes.

Benchmarking and Reference Datasets. HHS should invest in the development and maintenance of publicly accessible, de-identified clinical datasets that AI developers can use for model development and validation. Reference datasets for specific disease areas and care settings would enable more rigorous pre-deployment benchmarking. CHI also

supports the use of synthetic data generation techniques to expand dataset availability while preserving privacy.

HL7 FHIR for Real-World Evidence. CHI supports expanding the use of FHIR-structured data in regulatory submissions and post-market surveillance, enabling AI developers to use real-world evidence more efficiently in both FDA submissions and CMS coverage applications.

9. **What challenges within health care do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care? What concerns do they have?**

CHI's multistakeholder governance model includes patient and consumer advocates, and our policy positions consistently reflect patient perspectives alongside industry interests. CHI urges HHS to include meaningful patient and caregiver representation in all AI policy development processes, and to support appropriate patient-facing disclosures when AI tools are used in clinical decision-making. HHS should also support patient education initiatives that improve health AI literacy and enable patients to make informed decisions about the use of AI in their care. Based on CHI's engagement with patient stakeholders:

Patient Priorities for AI. Patients and caregivers most consistently seek AI applications that reduce administrative burdens such as prior authorization delays and billing complexity that impede access to care; improve care coordination and information sharing across providers, reducing the burden on patients to serve as their own health information couriers; enable earlier and more accurate diagnosis, particularly for rare diseases, complex chronic conditions, and mental health, by synthesizing multi-source clinical data; expand access to specialist-level care in underserved and rural communities through AI-enhanced telemedicine and primary care support; and facilitate more personalized treatment planning and medication management, including through AI-powered tools that integrate patient preferences, lifestyle factors, and social determinants.

Patient Concerns About AI. CHI recognizes that patients have legitimate and important concerns about AI in clinical care, including with respect to the privacy and security of sensitive health data used to train and operate AI systems; transparency as to when and how AI is influencing their clinical care; the human dimension of the clinical relationship if AI reduces clinician engagement; and errors and accountability gaps when AI contributes to clinical errors, particularly questions about who bears responsibility and how patients can seek redress.

10. **Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care? What does the literature say about impact, costs, benefits, and transfers?**

CHI recommends HHS prioritize the following AI research areas:

Implementation Science and Care Delivery Research. The most important gap in health AI research is not algorithmic performance but in how AI tools can be integrated into clinical workflows at scale, in disparate care settings, with sustainable outcomes. HHS/NIH should prioritize funding for implementation science research that examines the real-world conditions under which AI tools deliver clinical value, including the role of clinician training, organizational factors, and workflow design.

AI for Chronic Disease Management and Prevention. Given the chronic disease burden and associated cost drivers in U.S. healthcare, CHI recommends HHS prioritize AI research addressing both preventing and treating diabetes, cardiovascular disease, mental health, and substance use disorders, all areas where AI-enabled RPM, predictive analytics, and personalized intervention have demonstrated early promise.

Generative AI in Clinical Documentation and Care Coordination. HHS/NIH should fund research on the accuracy, safety, and liability implications of generative AI used in clinical note generation, care coordination, and patient communication.

Literature on Impact, Costs, and Benefits. Peer-reviewed literature documents significant clinical and economic value from specific categories of health AI. Studies of AI-enabled RPM programs for heart failure patients have documented reductions in 30-day readmission rates and associated cost savings. AI-assisted imaging tools in radiology and pathology have demonstrated improvements in diagnostic sensitivity for cancer screening. At the same time, researchers have noted challenges in attributing outcomes specifically to AI versus other care process improvements, and have highlighted the importance of rigorous study design, pre-registration of endpoints, and head-to-head comparisons with standard of care. HHS should invest in prospective comparative research that generates high-quality evidence on AI clinical and economic outcomes that can inform coverage decisions and clinical guidelines.

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CHI appreciates HHS's forward-looking approach to accelerating clinical AI adoption through this RFI. The responses provided above reflect CHI's long-standing consensus positions developed through years of multistakeholder engagement across developers, clinicians, patients, payers, and regulators. CHI stands ready to provide further input, engage in follow-on consultations, and work with HHS to translate these recommendations into actionable policy. We are committed to a future in which AI in clinical care is safe, effective, equitable, and accessible — driving better health outcomes for all Americans.

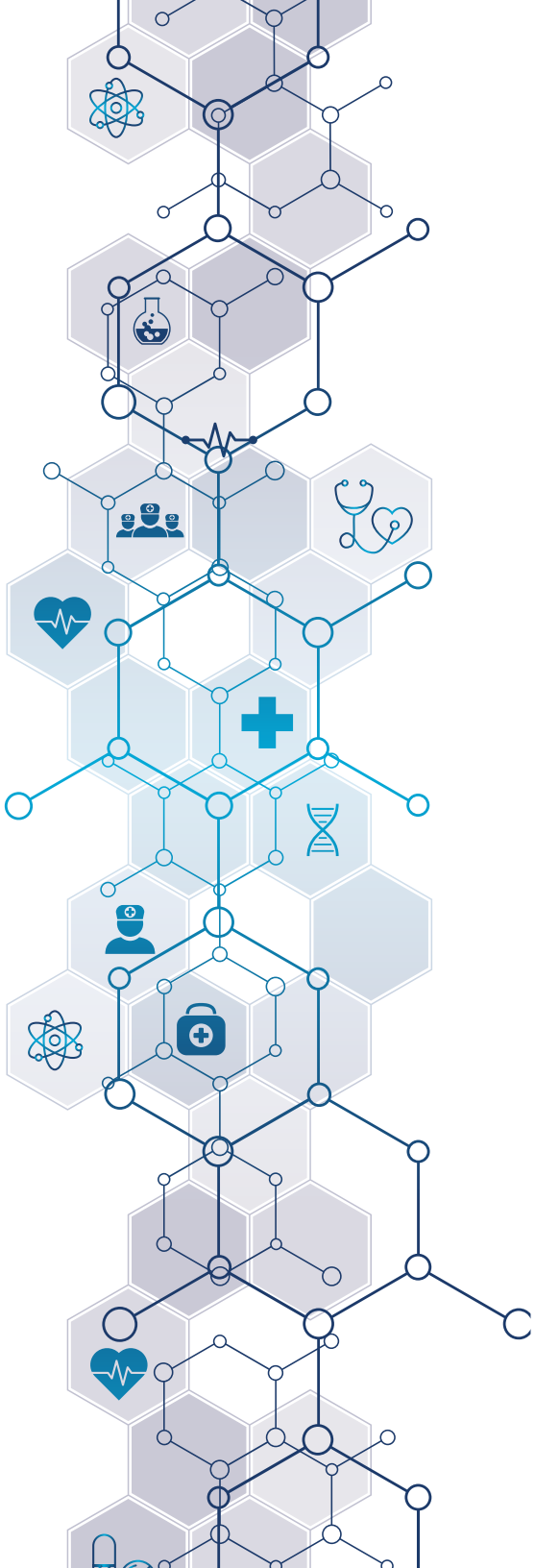
Sincerely,

Brian Scarpelli
Executive Director

Chapin Gregor
Policy Counsel

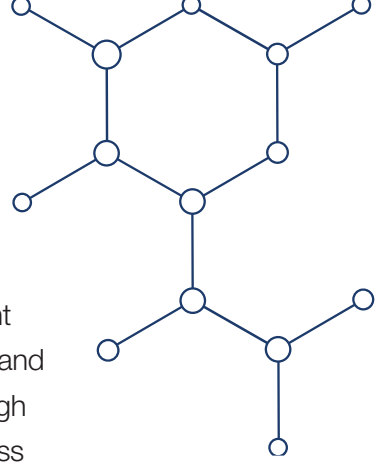
Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005

CHI Health AI Roles & Interdependency Framework



ConnectedHealthInitiative

Overview

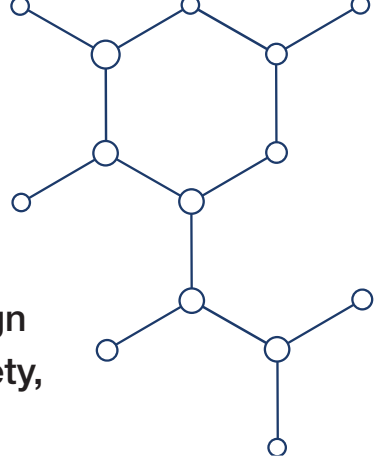


Artificial Intelligence (AI), especially generative AI, is already a powerful tool in healthcare, offering amazing potential to upgrade patient care by improving care outcomes and patient experiences, reducing healthcare provider burnout by simplifying administrative tasks, and helping to lower the total cost of care. One of the most helpful ways to see the value of AI in healthcare is to view the question through the lens of the "quadruple aim" framework. Built on the Institute for Healthcare Improvement's "triple aim," a widely accepted compass to optimize health system performance, the quadruple aim focuses on four key areas where health systems need to be improved, all of which AI is already, and will continue to, provide value across:

- Enhancing population health.
- Improving patient experience, satisfaction, and health outcomes.
- Augmenting clinician and healthcare team experience and satisfaction.
- Lowering overall costs of healthcare.

CHI has explored the ways in which AI is supporting each of the four aims of the quadruple aim in CHI's paper, Why Does Healthcare Need AI?

But this promising technology is not infallible, and as healthcare organizations seek opportunities to use AI, stakeholders are facing important questions about how various risks or limitations should be handled in the development, distribution, deployment, and end use chain. Many organizations involved in the creation or application of healthcare AI have started to develop Responsible AI programs aimed at managing these risks or limitations within their organization. But as we have learned from other new technologies in the past, stakeholders can benefit from a clear discussion around all the safety measures and other actions that are needed, and how those actions might be applied at different steps from creation to the operation of the tool by the end user. This discussion will help various stakeholders better determine accountability for responsible AI best practices across this chain of stakeholders.



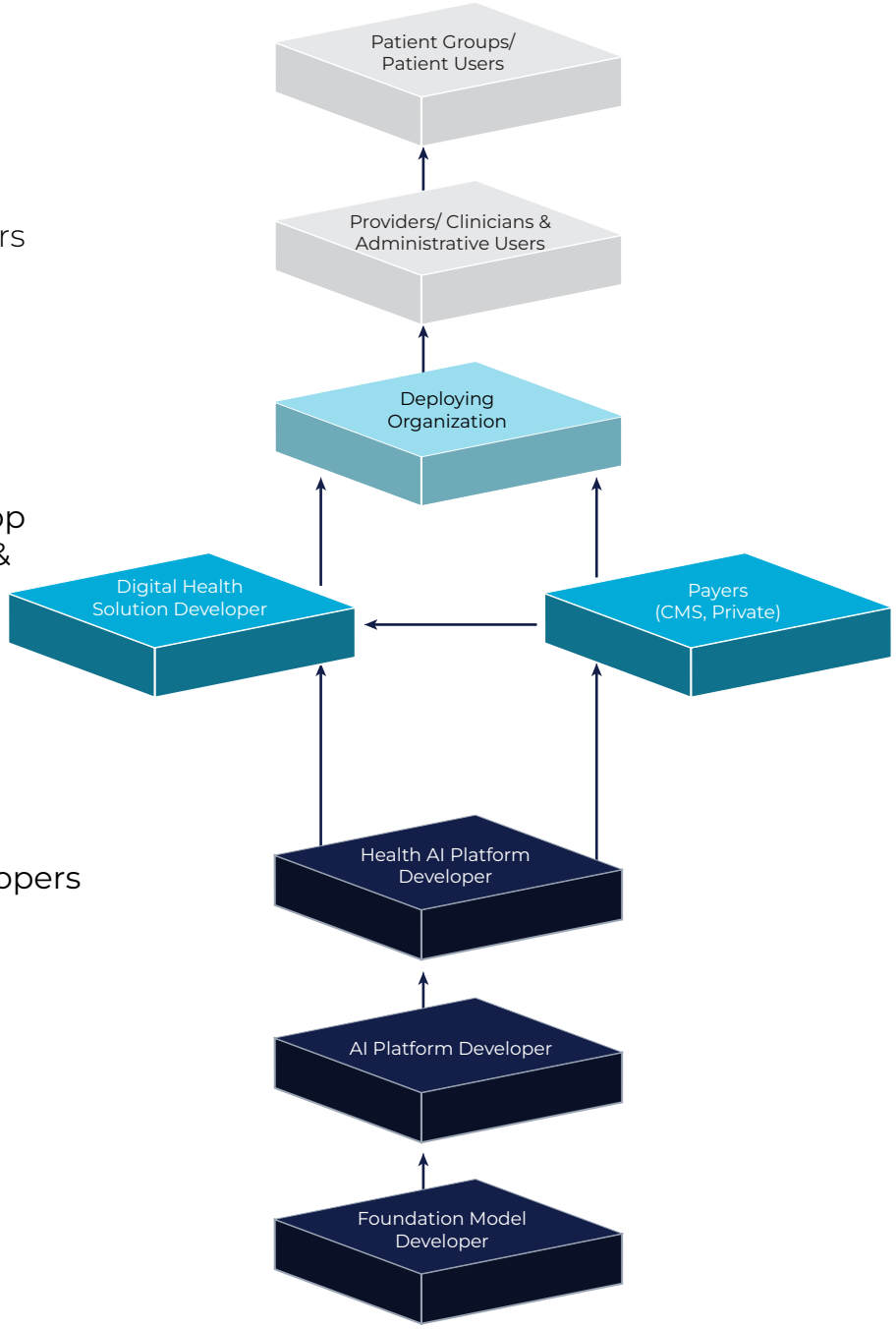
CHI urges all stakeholders in the healthcare ecosystem that are developing and using AI to align with CHI's consensus health AI principles, which recognize the shared responsibility for AI safety, efficacy, and transparency. CHI supports (1) leveraging a risk-based approach to AI harm mitigation where the level of review, assurance, and oversight is proportionate to potential harms and (2) those in the value chain with the ability to minimize risks based on their knowledge and ability, and having appropriate responsibilities and incentives to do so.

Further, managing AI/Machine Learning (ML) risks will be more challenging for small to medium-sized organizations, depending on their capabilities and resources. Building on these general health AI principles, CHI proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use. Then, CHI suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept. These roles and interdependencies are also mapped to the Functions defined in the National Institute of Standards and Technology's (NIST's) AI Risk Management Framework (RMF).

1
Solution Users

2
Solutions/App Developers & Deployers

3
AI/ML Developers



Note: Depending on the use case, some of the roles in the healthcare AI/ML value chain may be occupied by the same party; in other scenarios, some roles may not be occupied.

Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
AI/ML Developers	Someone who designs, codes, researches, or produces an AI/ML system or platform for internal use or for use by a third party. **See below for defined Subgroups of this Stakeholder Group along with recommendations specific to that Subgroup.**	• Informing deployers and users of data requirements/definitions, intended use cases/populations and applications (e.g., disclosing sufficient detail allowing providers to determine when an AI-enabled tool should reasonably apply to the individual they are treating), including whether the AI/ML tools are intended to augment human work versus automate workflows, and status of/compliance with all applicable legal and regulatory requirements. • Prioritizing safety, efficaciousness, transparency, data privacy and security, and equity from the earliest stages of design, leveraging (and, where appropriate updating) existing medical AI/ML guidelines on research and ethics, leading standards, and other resources as appropriate. • Employing algorithms that produce repeatable results and, when feasible, are auditable, and make decisions that (when applied to medical care) are clinically validated, fostering efficacy through continuous monitoring. • Utilizing risk management approaches that scale to the potential likely harms posed in intended use scenarios to support safety, protect privacy and security, avoid harmful outcomes due to bias, etc. • Providing information that enables those further down the value chain can assess the quality, performance, equity, and utility of AI/ML tools. • Aligning with relevant ethical obligations and international conventions on human rights and supporting the development of new ethical guidelines to address emerging issues as needed.	AI Deployment; Operation and Monitoring; Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight

Stakeholder SubGroup	Definition	Roles
Foundation Model Developer	Someone who creates or modifies large and generalizable machine learning models that can be used/adapted for various downstream tasks and applications, such as natural language processing, computer vision, or software development.	***Building on the cross-AI/ML Developer roles noted above:*** • Assessing what bias and safety issues might be present in its Foundation Model, and documenting steps taken to mitigate those issues in its Transparency Documentation (e.g., Transparency Notes, System Cards and product documentation). • Providing clear guidance on (1) how to use and adapt its Foundation Model for various foreseeable downstream tasks and applications, and (2) what limitations or risks may arise from doing so based on challenges discovered during testing and deployment.
AI Platform Developer	Someone who leverages existing foundation models and builds an industry-agnostic platform that enables other developers to access, customize, and deploy these models for various use cases and applications, such as natural language processing, computer vision, and/or software development.	***Building on the cross-AI/ML Developer roles noted above:*** • Testing for, identifying, and mitigating bias and safety issues that may arise from using or modifying existing foundation models for its AI Platform, and documenting these issues and steps taken to address them in its transparency documentation (e.g., transparency notes, system cards and product • documentation).
Health AI Platform Developer	Someone who creates or uses AI-powered platforms that are tailored for the healthcare domain, such as administrative efficiency, diagnostics, therapeutics, or research. These platforms may leverage foundation models (or other types of machine learning models or solutions), such as AI platforms, that are suitable for specific healthcare problems and data sources.	***Building on the cross-AI/ML Developer roles noted above:*** • Meeting specific requirements and standards of the healthcare domain, such as accuracy, efficacy, explainability, and compliance with regulations. • Testing for, identifying, and mitigating any bias and safety issues that may affect the health outcomes of patients or the performance of clinicians using the Health AI Platform, and documenting these issues and the steps it has taken to address them in its transparency documentation (e.g., transparency notes, system cards and product documentation).
Digital Health Solution Developer	Someone who creates complete digital tools and technologies to improve health and healthcare outcomes, such as providing diagnostic and administrative solutions for clinicians, patients, and healthcare organizations. They may build digital health solutions with both health AI platforms, which are specialized for the health care domain, and AI platforms, which are more general and adaptable for various use cases and applications.	***Building on the cross-AI/ML Developer roles noted above:*** • Specifying appropriate uses for its digital health solution to avoid amplifying bias or safety issues that may exist in the underlying foundation models, AI platforms, or health AI platforms. • Designing user interfaces to enable an end user to safely and effectively act upon the output of the tool, such as providing explanations, feedback mechanisms, or human oversight options, providing clear documentation to Deploying Organizations and Users to help them avoid bias and safety issues.

Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
Deploying Organization (Healthcare Provider or Payor)	Someone who is a healthcare providers and health care payors that and is deploying solutions built by Digital Health Solution Developers. They may also have their own internal IT staff that use health AI platforms or general AI platforms to develop their own custom digital health solutions.	***Respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources:*** • Adopting AI/ML Developer instructions for use, specifying appropriate uses for Users through governance policies to avoid bias and safety issues that may exist in the underlying foundation models, AI platforms, or health AI platforms. • Developing and leveraging digital health solutions that augment efficiencies in coverage and payment automation, facilitate administrative simplification/reduce workflow burdens, and are fit for purpose. • Setting organization policy/designing workflows to reduce the likelihood that a User will act upon the output of the tool in a way that would cause fairness/bias or safety issues (tailored explanations, feedback mechanisms, and/or human oversight options). • Developing and organizational guidance on how the digital health solution should and should not be used. • Creating risk-based, tailored communications and engagement plans to enable easily understood explains to patients about how the digital health solution was developed, its performance and maintenance, and how it aligns with the latest best practices and regulatory requirements.	Assessment; Procurement; Governance and Oversight
Provider/Clinician Users and Administrative Users	Someone who directly interacts with or benefits from the digital health solutions that are built by Digital Health Solution Developers or by the internal IT staff of the Deploying Organization. They may include clinicians, such as doctors, nurses, or pharmacists, and administrative staff, such as billing, claims, or customer service personnel, in the provider and payor organizations.	***Respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources:*** • Taking required training and incorporating employer guidance about use of AI/ML digital health solutions. • Documenting (through automated processes or otherwise) whether AI is being used in medical records and report any issues or feedback to the developer, such as errors, vulnerabilities, biases, or harms (where AI/ML's use is known by the User). • Ensuring there is appropriate clinician review and review of the output or recommendations from each digital health solution prior to acting on it (where AI/ML's use is known by the User).	AI Deployment; Operation and Monitoring; Domain Expert; AI Impact Assessment; Procurement; Governance and Oversight

Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
Payer Users (Centers for Medicare and Medicaid Services [CMS], State Medicaid, Private)	Someone that pays for the cost of healthcare services administered by a healthcare provider.	• Leveraging AI/ML systems that improve efficiencies in coverage and payment automation, facilitate administrative simplification, and reduce provider workflow burdens. • Aligning with medical AI/ML definitions, present-day and future AI/ML solutions, the future of AI/ML medical coding changes and trends. • Developing support mechanisms for the use of AI/ML by providers based on clinical validation, aligning with clinical decision-making processes familiar to providers, and high-quality clinical evidence. • Assuring that AI/ML systems allow for the individualized assessment of specific medical and social circumstances and provider flexibility to override automated decisions, ensuring that use of AI/ML does not improperly reduce or withhold care, or overrides the provider's clinical judgement. • Disclosing information about training and reference data to demonstrate that AI/ML systems do not create or exacerbate inequities and that protections are in place to mitigate bias. • Developing and proliferating easy to understand resources for beneficiaries and their providers that capture how and when AI/ML is being used, what information it is leveraging, and what it means to patients.	AI Deployment; Operation and Monitoring; Domain Expert; AI Impact Assessment; Procurement; Governance and Oversight
Patient Groups/ Patient Users	Someone who uses digital tools and technologies that are built by Digital Health Solution Developers or experiences their use in treatment.	• Developing and proliferating easy to understand resources that capture how AI/ML is being used and what it means to patients/patient groups, including explanations on the purpose and limitations of the digital health solutions that they use or benefit from (e.g., diagnostic, therapeutic, administrative). • Raising awareness of patients' rights and choices when using digital health solutions, such as consent, access, correction, or deletion of their personal data.	Human Factors
Standard-Setting Organizations	An organization whose primary function is developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise contributing to the usefulness of technical standards to those who employ them.	• Developing and promoting adoption of international voluntary/non-regulatory consensus standardized approaches and resources to steward a shared responsibility approach to AI.	Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight

Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
Certification Bodies & Test Beds	A certification body is a third-party organization that assures the conformity of a product, process or service to specified requirements. A test bed is a platform for conducting rigorous, transparent, and replicable testing of scientific theories, computing tools, and new technologies to a standard.	• Creating and making available transparent and reliable processes for the assurance of conformity to voluntary AI standards. • Creating and making available voluntary sandbox environments to help evaluate the usability and performance of AI/ML-based high-performance computing applications to advance the understanding of how reliable and efficacious AI, and to provide an appropriate assurance of reliability and efficacy.	Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight
Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards	Accrediting and licensing bodies are governing authorities that establish the suitability of any participating certification body. Notably, state-level board serve this purpose for physicians, nurses, and other clinicians to standards set by each state. Medical specialty societies are organizations for physicians, research and clinical scientists who are actively involved in the study of a particular specialty.	• Based on clinical needs and expertise, developing and setting the medical standard of care and ethical guidelines to address emerging issues with the use of AI/ML in healthcare needed to advance the quadruple aim. • Identifying the most appropriate uses of AI-enabled technologies and developing and disseminating guidance and education on the responsible deployment of AI/ML in healthcare, both generally and for specialty-specific uses.	Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight
Academic and Medical Education Institutions	Tertiary educational institutions, professional schools, or forms a part of such institutions, that teach medicine and awards a professional degree for physicians or other clinicians.	• Developing and teaching curriculum that will advance understanding of and ability to use healthcare AI/ML solutions responsibly, which should be assisted by inclusion of non-clinicians such as data scientists and engineers as instructors. • Developing curriculum to advance the understanding of data science research to help inform ethical bodies (e.g., Institutional Review Boards that are reviewing protocols of clinical trials of AI/ML-enabled medical devices).	Human Factors; Domain Expert; AI Impact Assessment

ConnectedHealth

Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

OCTOBER 2021

Connected Health is an initiative of ACT | The App Association

1401 K Street NW Suite 501, Washington, DC 20005

202.331.2130 | connectedhi.com

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Executive Summary

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

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

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

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

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

About the Connected Health Initiative

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Developers of AI/ML SaMD should:

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

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

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

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

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

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

Providers should:

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

The Food and Drug Administration (FDA) should:

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

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

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

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

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

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

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

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

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

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

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

The Federal Trade Commission (FTC) should:

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

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

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

Academic and Medical Education Institutions should:

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

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

Conclusion

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

ConnectedHealthInitiative

Value-based Payment Reform:

LEVERAGING SAAS TECHNOLOGIES FOR CARE MODEL INNOVATION

About Connected Health Initiative (CHI)

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of cases. We actively advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies to promote responsible pro-digital health policies and laws. Particular areas of focus include 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 AI (AI) in care delivery.
For more information, see www.connectedhi.com.

About Robert Longyear

Robert Longyear is CEO of Longyear Health, a health technology, business strategy, and policy consulting firm. Longyear Health works with domestic and international clients to understand the U.S. healthcare market, the regulatory and policy environment, and to design and develop their software and services products to maximize clinical and economic impact. The firm has clients in healthcare workforce management, health technology, supply chain management and logistics, remote patient monitoring, hybrid-virtual inpatient nursing, artificial intelligence, and clinical decision support. He is the former president and co-founder of Avenue Health, a seven-state remote patient monitoring and chronic disease management company. He has been a strategic advisor to successful digital health technology companies including Limber Health, As You Are, and Nexus Bedside. He is on the board of the Commission for Nurse Reimbursement and was appointed to the Washington, D.C. Health Information Exchange Policy Board. Robert is the author of *A Virtual Care Blueprint* (Routledge) and has published academic research and policy analysis in *NEJM Catalyst, Health Affairs Forefront*, the *American Journal of Nursing*, the *American Journal of Medical Genetics*, the *Journal of Nursing Administration*, via the *Institute for Medicaid Innovation*, *Practice Innovations* (APA), and as a working paper with the *National Bureau of Economic Research.*

Purpose

This issue brief details key policy issues that inhibit care delivery organizations from adopting modern software infrastructure, Software as a Service (SaaS) clinical technologies, SaaS medical devices, and AI technologies that leverage patient-generated health data (PGHD) to transform care delivery models whereby improving system efficiency, quality of care, and per capita cost.

U.S. health policy in the post-Patient Protection and Affordable Care Act era is marked by experimentation with system incentives via payment reform, with mixed results. Payment reform must be coupled with care delivery model reform to meet performance expectations. Yet, payment models and other policies have not always been designed with clinical innovation enablement as a key objective. New alternative payment models are often built on foundations set by legacy payment systems like prospective payment and the Medicare Part B Physician Fee Schedule which also are not well-adapted to the modern clinical tool set thus hindering modern and emerging technology adoption by providers of care.

This issue brief summarizes payment reform efforts of the last 15 years, outlines policy-created barriers to technology adoption and care model innovation, and offers solutions where possible.

Background

Consistent pressure to control U.S. healthcare expenditures and improve quality in government programs has led to an effort to increase participation in value-based payment models among physicians and hospitals. A recent report by the Commonwealth Fund underscores that U.S. health system performance continues to lag the Organisation for Economic Co-operation and Development (OECD) peer-countries in both performance and per capita cost.[1] Value-based payment models take many forms and, in theory, align financial incentives with quality outcomes and cost efficiency by adjusting payment based on measurable health outcomes (e.g., clinical outcomes and care utilization). This paradigm shift, accelerated by the Patient Protection and Affordable Care Act (ACA) and subsequent initiatives at the Centers for Medicare and Medicaid Innovation (CMMI), represents a strategic response to addressing the Quadruple Aim[2] of healthcare improvement: improving the health of populations, reducing per capita expenditures, enhancing the experience of care, and addressing clinician wellbeing in the workplace.

Government healthcare programs, mainly Medicare, rely on two primary payment models on to which value-based payment

models are layered or derived: fee-for-service and prospective payment. In hospitals, Medicare's transition from cost-charge based reimbursement to a prospective payment system (PPS) in the early 1980s represented a landmark shift in healthcare financing policy. The implementation of the inpatient PPS in 1983 fundamentally altered provider incentives by establishing predetermined, diagnosis-based payment rates rather than retrospectively reimbursing for actual costs incurred. This paradigmatic change was designed to contain escalating Medicare expenditures while simultaneously promoting efficiency in service delivery. Research indicates that the transition successfully moderated cost growth by encouraging hospitals to reduce unnecessary services, decrease lengths of stay, and improve operational efficiency.[3] However, prospective payment lacks links to quality of care and health outcomes, so quality monitoring and metrics were developed in response along with later programs such as the Readmission Reduction Program[4] and the Hospital Value-based Purchasing Program.[5] Prospective payment approaches have since expanded beyond inpatient care to other healthcare settings like skilled nursing facilities, hospital outpatient procedures, and ambulatory surgical centers, establishing prospective payment as a cornerstone of Medicare's ongoing efforts to balance fiscal sustainability with quality service provision.

However, prospective payment is a blunt-force instrument for cost containment with unintended consequences that shape care delivery organizations, labor markets, and population health.

Medicare's payment reform initiatives have further evolved beyond prospective payment to address fragmentation, quality incentives, and expenditure growth through various value-based payment models. The models developed over the prior 15 years primarily target outpatient provider-delivered care. These models, via different payment adjustments, incent providers to deliver more efficient care by transferring financial risk to physicians and hospitals for spending above a threshold or benchmark (e.g., capitation or bundled payments), to reduce unnecessary downstream and costly acute care services (e.g., accountable care organizations [ACOs], shared savings, full-risk models), or to better coordinate amongst a consortium of disparate care delivery organizations across the continuum of care (e.g., global budget models, ACOs). The Medicare Shared Savings Program, for example, established ACOs that incentivize provider networks to coordinate care while sharing in generated savings that are linked to lowering patient spending and meeting defined quality benchmarks.[6] CMS has also experimented with bundled payment models, like the Bundled Payments for Care Improvement (BPCI) initiative, which assign a single payment for an entire episode of care like

joint replacement surgery, including the hospital and physician services, as well as related care, such as rehabilitation, durable medical equipment, and costs due to complications, such as readmissions. These models are much more targeted, but not too dissimilar from prospective payment models, with mixed cost-outcome results.[7] Meanwhile, state-wide all-payer models, exemplified by Maryland's Total Cost of Care Model,[8] expand reform beyond Medicare to standardize payment rates across all insurers within a state, creating consistent incentives for all hospitals regardless of patient insurance type. The ongoing refinement of these value-based payment models continues to shape healthcare delivery system transformation. However, meaningful results in the form of net cost savings to Medicare have only occurred in six out of 50 CMMI models evaluated, with four models eligible for expansion to the entire program meeting the cost-savings with equivalent or better-quality standard established by Congress.[9]

Success for physicians and hospitals under VBP models is contingent on the strength and structure of the economic incentive and the participating care delivery organization's ability to operationalize the changes necessary to perform. VBP models have three primary incentives for care delivery organizations with varying degrees of influence depending on model structure:

1. **Internal cost efficiency;**
2. **Improvements in quality and health outcomes;**
3. **Reductions in unnecessary utilization.**

To achieve these goals, care delivery organizations must make significant operational and clinical changes to perform under these incentive domains.[10] Software, informatics, and emerging technologies are often employed by particularly innovative care delivery organizations to perform under these models. Yet, structural policy barriers to adoption still exist due to unintentional consequences of Medicare payment policy.

Congress and agencies across the executive branch have indicated a desire to lead the world in PGHD-driven innovation across AI, advanced SaaS technologies, predictive analytics, and health technology. In health however, this goal must be met with a critical examination of the economic incentives, technology limitations / risk, and policy barriers present in care delivery to realize the perceived future value.

The rapid adoption of telemedicine starting in 2020 illustrates the critical role of payment policy as both a barrier and potential catalyst for the uptake of care model reforms. Many medical specialties had been practicing telemedicine and developing an evidence base to support its use for decades; the 2020 expansion in access was made possible only when long-standing payment barriers were removed. This widespread, rapid, and impactful innovation in care delivery resulted not from any

of the CMS VBP models, but from changes to the Medicare Part B Physician Fee Schedule.

CMS's statutory and historical bias against software-enhanced care delivery models is exemplified by the case of the Medicare Diabetes Prevention Program (MDPP). The translation of outcomes from the CDC-piloted virtual Diabetes Prevention Program to the Medicare Diabetes Prevention Program provides substantial evidence that demonstrates virtual program delivery yields positive patient health outcomes that meet or exceed the CDC's program goals. Nonetheless, CMMI has refused to include CDC-recognized virtual providers in the MDPP expansion.[11] As a result, an expanded MDPP continues to inexplicably omit virtual modalities, a disservice to the high percentage of Medicare patients at risk of developing diabetes. This payment-policy induced barrier may also result in forgone cost savings for CMS.

Patients with geographic or transportation barriers required access to telehealth services long before 2020, but even new alternative payment models had not resolved the barriers restricting physicians from providing these services. This left many patients unable to follow up using digital technologies with physicians who knew them and felt that the appropriate standard of care could be delivered without in-person encounters—leading to delays in needed care and unnecessary cost and travel time. It also prevented innovative care delivery models like the Acute Hospital Care at Home Program, which was initially supported by a CMMI-funded Health Care Innovation Award but then discontinued when that grant program ended.

The response by physicians and hospitals to the removal of telehealth payment barriers was swift because the need among patients for the services was real, and because care delivery organizations and clinicians are responsive to changes in regulatory and policy changes. Telehealth care modalities serve as a single example of how care model innovation is inhibited by explicit limitations set by CMS. Yet, in some cases, the barriers are unintended and there are opportunities to remove them to promote the adoption of high value care.

Value-Based Payment Models Must Be Matched with Care Model Innovation

For value-based payment models to achieve their intended outcomes, healthcare organizations must undertake fundamental care model innovation that transcends mere participation or financial restructuring.[12] [13] Evaluations of the Medicare Shared Savings Program (MSSP) have produced mixed results of its effect on quality and Medicare expenditures.[14] [15] Yet, the program contains both high performers and low performers that can be studied to understand the factors associated with their respective performance. Certain care delivery organizations perform better under VBP models than others due to patient-level, organization-level, and regional-level factors that affect the organization's ability to adapt its operations and innovate along the payment model's prescribed incentives. For example, MSSP participating care delivery organizations with higher risk patients as measured by hierarchical condition categories are more likely to drop out of the program due to perceived

non-performance or other factors, whereas organizations with higher levels of care coordination services are associated with remaining in the program.[16] Further evidence suggests that MSSP Accountable Care Organizations (ACO) who better manage spending and utilization for patients with serious illness are also more likely to achieve shared savings under the model.[17] These two concepts suggest that MSSP participants must operationalize interventions, including care coordination, to identify and address unmet health needs for high-cost patients.

Financial restructuring under a risk-based, shared-savings based, or capitated payment model requires complex reorganization of systems to understand a care delivery organization's own performance, but success in VBP models like the MSSP often requires market-level, patient population-level, and patient-level intervention design to route patients to lower costs of care, to develop effective clinical programs, and to ultimately reduce cost while managing the expectations of quality. Care delivery organizations that succeed in these areas require organizational efforts to adopt and consistently deliver high-value care, continuous quality improvement, risk stratification systems, and effective population health interventions. Each of these activities requires complex and comprehensive use of internal clinical, administrative, and external health information exchange-based data.[18] If CMS is to realize the promise of payment reform and expand on the successes of the few models that have demonstrated value, it is critical that it support care delivery organizations in the care model and operational redesign required to succeed.

Care delivery organizations must develop methodologies to measure and understand patient and financial risk across many variables and data sets while also developing scalable, cost-effective operational and clinical systems to manage that risk. In many cases that means developing strategies to increase the provision of preventive services and developing proactive intervention strategies to improve quality, preventing unnecessary spending, and therefore reducing risk among attributed patients.[19] ACO participants specifically report that care management and intensive care transition management is a critical component of ACO performance.[20] Such care model innovation necessitates the systematic identification, implementation, and scaling of interventions and approaches that demonstrate robust clinical- and cost-effectiveness. Healthcare delivery organizations must strategically reconfigure their organizational structures, clinical workflows, and resource allocation frameworks to prioritize evidence-based preventive services, chronic disease management protocols, and care coordination mechanisms that collectively improve quality outcomes while concurrently reducing unnecessary utilization and expenditures.[21] In many cases, this transformation requires providers to develop data analytics capabilities for quality management, and in some cases, risk stratification and intervention targeting, establish multidisciplinary care teams that can address patients' medical and social needs comprehensively, and cultivate organizational cultures that value continuous quality improvement and outcome measurement.[22]

The success of value-based payment thus hinges upon this parallel evolution in care model innovation that deliberately aligns clinical operations and breaks down financial barriers to produce demonstrable value for patients, providers, and payers alike. Policy and payment models must accurately reflect the set of modern technological expenses born by both care delivery organizations participating in alternative payment models and those paid by legacy systems. No longer is the model of the humble physician in a small office the reality of care delivery. Organizations, to succeed under payment reform, must become more sophisticated technology- and informatics-driven organizations. Importantly, the mere adoption of an electronic health record is no longer the benchmark. The data contained in EHRs must be converted into useful and actionable information about individuals, populations, and future risk.

Data analytical software, now enhanced by AI technologies, plays a critical role in both the administration and clinical care components of care model innovation. At a basic level, electronic medical records and standardized and trusted coding systems are critical for capturing clinical and administrative information related to financial and quality metrics.[23] At a higher level of adoption, care delivery organizations use sophisticated data analytics and information systems to facilitate innovative care delivery protocols, coordinate across a multidisciplinary care team, and intervene for patients attributed under a VBP model. Indeed, evidence suggests that a higher level of information technology use is both critical to operationalize ACOs and associated with higher performing ACOs.[24] [25] However, this requires expertise that may be cost prohibitive to care delivery organizations, particularly those that have fewer capital resources such as smaller, independent, and rural organizations. Advanced and automated clinical and financial analytics technologies can help close this gap by reducing the human capital costs needed to analyze data and develop new care intervention strategies under VBP models.[26]

There is an opportunity to build a more comprehensive approach at CMS to support care delivery organizations in adopting both mature and emerging SaaS clinical technologies such as AI and remote patient monitoring/wearables that collect vital PGHD. Given the significant amount of policy discourse surrounding SaaS care delivery and AI in health, it is critical for Congress and CMS to examine both the legacy and current VBP payment environment to ensure that innovation is supported while ensuring value for taxpayers these types of PGHD-driven innovations are not intentionally or unintentionally inhibited. The goal is to harness the exponential growth in innovative software technologies to propel American healthcare into the future, while ensuring appropriate guardrails are in place and these technologies are used as tools that support physician- and clinician-led care, thereby improving the performance of the U.S. healthcare system and ensuring patients receive high-quality care.

Clinical and Administrative Software Technologies Enable Care Model Redesign

Software has helped to transform healthcare delivery via the digitization of patient health records into EHRs. Via incentives created by the Health Information Technology for Economic and Clinical Health (HITECH) Act, the implementation of EHRs laid the foundation for additional streams of innovation including telehealth, remote patient monitoring, digital therapeutics, and AI. This, along with cloud computing and the concurrent growth of smartphones and the internet, has created the infrastructure for a care delivery system that leverages technology to improve patient care. Yet, while policies incentivized and enabled the rapid adoption of EHRs, modern and advanced SaaS technologies have been adopted by care delivery organizations inconsistently and at a much slower pace due to payment and other policy barriers.

Despite their clinical benefits, to date Medicare coverage and payment for software-enabled clinical services has been haphazard and lacking a clear strategy,[27] limiting its reach to many patient-populations that could stand to benefit most and producing disparate outcomes across several classes of innovative technologies. Telehealth services provide one clear example. Another example is the relative adoption rates of remote patient monitoring verses digital therapeutic technologies. The coverage of remote physiological monitoring (RPM) current procedural terminology (CPT) codes in the 2018 Medicare Physician Fee Schedule and the later coverage of remote therapeutic monitoring (RTM) codes ushered in a new wave of Medicare software-enabled care delivery. Around the same time, the U.S. Food and Drug Administration (FDA) reviewed and approved the first digital therapeutic.[28] Both technologies are built on modern cloud-based mobile and telecommunications software infrastructure. Yet, while remote patient monitoring-enabling clinical software technologies have been broadly adopted,[29] digital therapeutic technologies, which are similar in both form and function, largely have not. Despite good clinical evidence supporting both technologies (e.g., prescription digital therapeutics have FDA clearance), differences in reimbursement have produced adoption of remote patient monitoring technologies, but limited adoption of digital therapeutics. Indeed, while technologies used to facilitate remote patient monitoring are reimbursed under the Physician Fee Schedule, reimbursement for digital therapeutics is generally unavailable due to statutory limitations.[30]

Despite the high-level of interest on Capitol Hill, CMS payment policies may yield similar adoption outcomes with AI-based clinical technologies. AI clinical technologies come in many forms, but most fall into three major categories: administrative, diagnostic, or treatment.[31] AI technologies can help care delivery organizations analyze administrative data to understand cost, efficiency, and opportunities in the broader care delivery market. It may also assist in reducing clinician work burden by automating repetitive tasks and tedious administrative processes. Diagnostic and treatment technologies can improve diagnostic accuracy and facilitate the

assessment of patient risk, and they can help a clinician determine the right intervention for a given patient at the right time (e.g., precision medicine). In some cases, as with digital therapeutics, they can take the form of a software-delivered intervention for a particular patient diagnosis or need.

Clinical software technologies are often classified as SaaS or as clinical decision support (CDS) by the FDA.[32] These technologies serve to automate manual tasks, augment clinician cognition, enable new diagnostic or cognitive capabilities that were heretofore constrained by human capacities, and in some limited applications can even automate diagnostic or therapeutic tasks performed by clinicians.[33]

AI technologies are inherently multi-modal and span clinical specialties. In 2024, Yasin et al. published an article proposing a five-level classification framework for health AI (Table 1) in line with guidance from FDA.[34]

While levels 1 and 2 of the framework,

Table 1: Yasin et al. Five-Level Classification Framework for Health Artificial Intelligence (AI)

Level	Description	Patient risk	Description	Example use cases	Criteria to implement	Potential risks
1	Back office - administrative	Minimal	• Automation of administrative tasks which do not directly impact medical care. Little or no clinician involvement	• Revenue Cycle Management • Prior authorization submission/Utilization Management review	• Financial • Process integrity	• Financial misadventure • Administrative confusion
2a	Clinical process automation	Low	• Automation of low-level clinical processes and information organization, freeing clinician time to improve satisfaction and efficiency	• Virtual scribes (ambient documentation) • EHR summarization • Facilitated reference access	• Documentation accuracy • Process Integrity • Improved clinician experience/efficiency	• Inaccurate documentation
2b	Patient enablement	Low	• Educating patients on their conditions, recommended, medications, test results etc. • Collecting information from patients (e.g. meds, basics of clinical history)	• EHR inbox management • Patient education/promotional content generation • Patient chatbots • Smart questionnaires for intake • Member services/call centers	• NOT diagnostic or treatment advice • Improved patient experience	• Nontransparency with patients • Misinformation on non-medical issues
3	Clinical Decision Support - non-device CDS	Moderate	• Supporting clinicians in prognosis, diagnosis, or treatment, where clinicians make explicit choices to finalize plan, based on explanations provided by the system	• Computer assisted diagnosis and recommended treatments • Prediction of sepsis • Prior authorization review/approval	• Recommendations explainable and traceable to source • Clinician + CDS perform better than clinician alone	• Incorrect guidance given to physicians which they don't adequately review
4	Clinical Decision Support - SAMD	High	• Supporting clinicians in prognosis, diagnosis, or treatment, where the AI's reasoning is not always transparent, and the AI often provides a specific recommendation • Direct advice to patients through chat, etc w/o HITL	• Automatic pathology and radiology reading • Smart, advice-giving chatbots for patients • Suggestions about ventilator management	• Tightly defined use parameters • Accuracy at least equivalent to expert clinician • Equitable performance tested in a diverse patient population • Speed substantially better than human expert clinician as Gold Standard	• Automated incorrect medical decision making
5	Digital Doctor - SAMD+	Highest	• Autonomous decision making (prescribing, treating, test ordering, diagnosing) by algorithms without human intervention	• Algorithms which would prescribe or make remote diagnoses with no human present	• Clinical outcomes at least equivalent to human expert clinician as Gold Standard • Equitable performance tested in a diverse patient population • Requires new legal/ regulatory framework	• Automated bad medical practice

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administrative technologies like revenue cycle management or workflow automation technologies, are readily adopted by care delivery organizations due to their internal cost-reducing effects, levels 3, 4, and 5 often face coverage barriers akin to those faced by digital therapeutics. As Ben-Israel et al. note in their 2020 systematic review of machine learning in patient care services, despite over 20 years of research, these technologies have not meaningfully made their way into routine clinical practice.[35] Even if AI clinical technologies, without significant efficiency effects, may demonstrate clinical value or gain FDA regulatory approval but face a payment policy environment without clear reimbursement pathways, their adoption is limited both in the FFS environment under both legacy and innovative payment models.

The payment policy barriers to adoption for these technologies exist in the multiple prospective payment models, the Medicare Physician Fee Schedule, and under Value-based Payment models, which typically require some form of financial savings respective to a financial baseline determined by FFS reimbursement. If these technologies are not already currently reimbursed within the FFS environment, adopting them not only has to pay for itself, but generate additional savings all within the performance cycle of the VBC model, which is typically only a couple of years removed from the baseline financial benchmark. Therefore, it is critical to address them via a unified and comprehensive strategy across the Centers for Medicare & Medicaid Services. If Congress and CMS intend to expand VBP models as the primary cost containment strategy over the next several decades, then these barriers to reimbursement of clinical support technologies must be addressed now to ensure their broad adoption and use. Over time, widespread use of advanced AI analytics, predictive technologies, automation technologies, and technologies for real-time patient data collection can help facilitate proactive and high-quality clinical performance and reduce utilization of low-value services, thereby helping to achieve cost savings and success under value-based payment models.[36]

A critical opportunity for action includes CMMI's Transforming Episode Accountability Model (TEAM), a new, mandatory Medicare payment approach that holds selected hospitals financially accountable for the cost and quality of care during surgical episodes, spanning from the procedure through 30-days post-discharge. Running from 2026 to 2030, the model requires hospitals in designated regions to coordinate care across providers, meet quality benchmarks, and manage costs within prospectively set target prices based on historical and regional data. Hospitals that deliver efficient, high-quality care below the target price can earn additional payments, while those exceeding the target must repay Medicare. Unique to TEAM, there is a strong emphasis on health equity-hospitals must submit health equity plans, screen for social needs, and target prices are adjusted for social risk factors. The model also encourages collaboration by allowing hospitals to share savings with physicians and care teams, and it mandates primary care referrals post-discharge to support ongoing patient recovery and reduce care fragmentation. Overall, the TEAM model aims to improve outcomes, lower costs, and advance equity by aligning financial incentives with coordinated, patient-centered surgical care.

Connected Health Initiative Recommendation	TEAM Element or Opportunity
Reimburse software-enabled care (AI, RPM, etc.)	Could be piloted via optional innovation stipends or as add-ons within TEAM's reconciliation process for specific procedures.
Tie health equity to financial incentives	TEAM includes optional health equity plans and social risk adjustments—these could be made mandatory and tied to quality scoring and payment multipliers.
Enable Coverage with Evidence Development (CED)	TEAM could allow conditional reimbursement for digital therapeutics or clinical AI tools under evaluation, reducing innovation adoption risk.
Support team-based, digitally enabled care coordination	TEAM's emphasis on post-discharge coordination and readmission reduction aligns well—CMS could explicitly allow documentation of digital care team activities.
Adjust risk models to account for new care modalities	TEAM's use of HCCs and social risk factors could be extended to reflect variation from novel, tech-enabled workflows.

Unintended and Intended Barriers to Adoption Challenges to Address

The adoption of innovative software technologies by care delivery organizations is influenced by clinical, operational, safety, and financial considerations. Accordingly, most issue briefs and scientific articles exploring the value of AI and other SaaS clinical technologies focus on myriad technical, methodological, regulatory, and implementation barriers (e.g., interoperability, FDA regulation, liability, and clinical evidence). In addition to the safe development, deployment, and use of AI, financial incentives created by Medicare are likely the biggest predictors of real-world implementation into care delivery simply for two reasons: 1) care delivery organizations and clinicians incur direct costs to adopt and implement these technologies and, 2) other payors often use Medicare determinations as their benchmarks for coverage.

If the real-world outcomes are to meet the expectations of Congress and other observers, then CMS must develop a comprehensive strategy to analyze policy barriers to adoption and develop a comprehensive strategy to promote adoption of clinically- and cost-effective technologies. This supports both providers that participate in legacy payment models and those who opt for new ones.

Challenges with Reimbursement Under the Medicare Physician Fee Schedule (MPFS)

1. **Reimbursement barriers under the Medicare Physician Fee Schedule**
2. **Challenges for providers under value-based payment models such as the Medicare Shared Savings Program**
3. **Payment policy, or the lack thereof, inhibits evidence generation for SaaS technologies**
4. **Challenges with other technology-related regulatory policies**

Under the Medicare Physician Fee Schedule, the primary question is whether SaaS clinical technologies should be considered a direct or indirect expense under the resource-based relative value scale (RBRVS) and if there is risk of overestimating the clinician time component (Work Relative Value Units [RVUs]) of services that leverage SaaS technologies. Frank and Colleagues suggest that direct reimbursement of clinical technologies is critical to ensure an adequate business model for technology developers and that practices can fund their adoption. CMS has commented, in several iterations of the Medicare Physician Fee Schedule Final Rule, most recently in 2024, that their practice expense methodologies and systems do not account well for SaaS practice expenses. For practices, many clinical software

technologies and software as a medical device technologies produce direct costs incurred by practices in order to use them for a particular service. Thus, CMS should prioritize addressing the lack of direct practice expense reimbursement for software technologies that have a direct cost relationship with the volume of services rendered to patients. CMS should update and significantly enhance rules surrounding the indirect expense component of the RBRVS to ensure that practices are compensated for the use of other non-direct expense technologies, like non-medical device SaaS data analytics infrastructure and technologies that enhance clinical care.

For SaaS clinical technologies that demonstrate a clear improvement to internal cost and productivity (e.g., AI scribes), adoption is readily facilitated under fee-for-service, prospective payment, and many VBP models due to improvements in profitability that quickly outweighs the cost of implementing the technology. This is in line with levels 1 and 2 of the Yasin framework and incentive 1 outlined above.

Some technologies are multimodal and have both significant clinical value over and above standard of care and efficiency gains derived from automation. However, technologies that add significant clinical value with no immediate significant effect on internal cost, or for those that may actually add to workload or create new processes in the short-run, adoption may run contrary to financial incentives under a FFS structure, as well as APMs with relatively short performance cycles based on achieving savings relative to a FFS financial baseline or benchmark. Examples of technologies in this category include remote patient monitoring, telehealth technologies, and certain applications of AI such as clinical decision support technologies.[37] For example, under a bundled payment model for joint replacement, a surgeon may choose not to adopt remote patient monitoring in the post-operative period because the cost of the technology and monitoring operations eat into the profit margins under the bundle without cost-offset. Clinical value[38] and reduced future utilization from the RPM technology monitoring interventions would therefore be inhibited. Because of this effect, CMS unbundled remote patient monitoring services from the global period for certain surgical procedures in the 2024 final rule period. However, this type of payment barrier is present in many places throughout payment models employed by CMS and should be addressed.

The importance of a system or incentive to adopt clinically beneficial technologies without corresponding immediate improvements in internal efficiency is well-understood under other Medicare payment systems. Programs like the Transitional Pass-through Payments (TPT),[39] under the Outpatient Prospective Payment System (OPPS), and New Technology Add on Payment (NTAP),[40] under the Inpatient Prospective Payment System (IPPS), provide marginal payment for the incorporation of new technologies. These technologies generally must be new, substantially improve the diagnosis or treatment relative to the current standard of care, and not be sufficiently covered by the current payment. Similarly, programs like the Transitional Coverage for Emerging Technologies (TCET)[41] are designed to help facilitate payment for breakthrough technologies as designated by the FDA, however, Frank and colleagues note that software-only

technologies may not qualify for even these limited carve-outs in some payment systems due to statutory or regulatory uncertainty.

Unfortunately, these new technology programs are procedure-focused and isolated to hospital and surgical sites of care, which may impede broader population-level interventions or VBP models. These types of technology adoption programs should be expanded and/or replicated across healthcare settings including physician offices and outpatient settings to facilitate the type of innovations that could result from advanced clinical software technologies like predictive analytics. For example, an AI model developed by Jawad and colleagues demonstrated the ability to predict short-run and long-run mortality from data collected at the point of emergency department engagement.[42] This technology could lead to improved speed of intervention, better quality of care, and resource allocation within hospital facilities. CMS should use the new technology payments under the OPPS and IPPS as a model and work to ensure there are similar payment incentives under the MPFS to help ensure the adoption of technologies that demonstrate significant clinical efficacy, safety, and utility are not inhibited from the start due to perverse reimbursement incentives (or lack thereof). Notably, CMS should establish a formal payment framework for algorithm-based health care services (ABHS) to encourage ongoing innovation and safeguard Medicare beneficiaries' access to these AI-driven technologies, consistent with CMS' Software as a Service (SaaS) payment policy set in the 2023 Medicare OPPS Final Rule.

Coding, too, must continue to evolve to support VBP innovation. Codes for care management services, care team collaboration, and interprofessional e-consultations are important to allow reporting of medical services delivered under a team approach to care, especially under many VBP models. Codes must adapt to a "systems of care" approach in which teams and organizations are sharing responsibility for an intervention. Coding must also reflect the need to support preventive and population health approaches to care such that providers can fund the services and tools that can prevent downstream acute care utilization rather than procedure-focused care alone.

For example, the Chronic Care Management and Complex Care Management CPT Codes were developed to reimburse the time spent by clinicians, primary care in particular, helping patients manage conditions, coordinating care between providers, and navigating their care proactively. These codes support care delivery organizations in adopting a more proactive and preventive operation rather than the reactive, episodic model that has marked care delivery for the prior decades. The remote physiological monitoring code set also supported this care delivery orientation by allowing real-time patient generated health data to be transmitted for review by a care team. Together, CCM and remote patient monitoring reimbursement, which can be billed concurrently, serve as catalysts for significant care delivery innovation through fee for service.

Now, imagine a scenario where a predictive AI clinical decision support technology is developed and available for use by primary care providers managing congestive heart failure patients. The combination of continuous wearable monitoring via the remote patient monitoring code set and a machine learning-based analytic technology

was able to accurately predict hospitalization risk for heart failure patients with between a 76 percent to 88 percent sensitivity and an 85 percent specificity in a 2020 published study by Stehlik and colleagues.[43] The wearable device and the data transmission are covered by the remote patient monitoring code set, but the machine learning analytic module is not currently factored into reimbursement as a cost. In theory, this technology could significantly reduce expenditures on heart failure which affects 6 million Americans, costs around $17,830 per hospitalization, and is expected to grow in prevalence by 46 percent to total expenditures of $53 billion by 2023.[44]

CMS, to help the care delivery system adopt modern software and analytics infrastructure, must redesign the components of the RBRVS to account for modern practice expenses associated with SaaS technologies. CMS should develop a system to centrally evaluate and adopt new technologies into the Medicare Physician Fee Schedule akin to the TPT and NTAP programs. CMS should also clarify the rules around SaaS technologies under the TCET program.

Policies to Improve Provider Participation and Performance Under Value-based Payment Models

Congress and CMS envision a future where value-based payment models dominate the payment policy space. CMS has set a goal to have all patients in traditional Medicare under a risk-based model by 2030. The MPFS also plays a determinative role in shaping the payment and care delivery landscape within which VBP models operate in the form of being used to calculate bundled payments and target pricing for episodic models, and financial benchmarks for population models, creating a complex interplay that significantly affects care model transformation under VBP models. Thus, addressing SaaS clinical technologies under the Medicare Physician Fee Schedule is even more critical to ensuring readiness among providers to accept alternative payment models and helping them perform when they agree to participate.

Few VBP models provide up-front investment funding to organizations that need to hire multidisciplinary teams, establish care management infrastructure, and purchase technologies essential for VBP success. For example, a practice newly planning on participating in an ACO-like payment model, such as the Medicare Shared Savings Program (MSSP), must make investments in both basic and advanced software technologies to improve patient outcomes, meet quality benchmarks, and to generate shared savings. However, because any shared saving payments are uncertain and typically lag by two years, investments in technologies like AI clinical decision support software, population health analytics, and the requisite expertise eat into the practice's existing profit margins. Worse, Medicare physician payment has dropped 33 percent since 2001 when accounting for the growth in the cost to run a medical practice.[45] As a result, physician practices have little available capital to make the necessary up-front investments in staff and technology to be successful in VBP.

For example, a machine learning model evaluated by Peterson and colleagues (2021)[46] demonstrated predictive value in identifying cancer patients at risk of preventable emergency department (ED) visits and hospitalizations. Without direct reimbursement under the MPFS, the oncology clinic has little incentive to pay the hypothetical $25 per patient per month to license this technology for use. If layered into a shared savings-like model with incentives to prevent future utilization, the practice may choose to make the initial investment, but that choice hinges on the degree of available evidence of return on investment.

CMS should consider building similar technology-based carve outs into Alternative Payment Models (APM) benchmark and payment methodologies, as well as considering longer performance measurement cycles that would allow downstream savings from care model innovation and redesign be more fully recognized, which is hard to achieve within 1-2 years, as most APMs are presently designed. By addressing key issues in the Physician Fee Schedule, practices can be prepared, technologically, to develop continuous quality improvement operations that are critical to their performance under VBP models. Extending the performance period during participation also allows providers the opportunity to innovate in their care models.

When the Medicare physician payment system does not keep up with the cost of providing high-quality care, organizations face capital constraints that limit their ability to redesign care pathways, implement decision support tools, or develop patient engagement strategies critical to achieving quality metrics and cost targets under VBP arrangements. Inadequate coding, flexibility, and coverage for SaaS care delivery models under the MPFS can create a cashflow issue. The VBP program provides an incentive, but the cashflow issue creates a decision point at which return on investment and evidence becomes critical.

Clinical Evidence Generation is Inhibited by Payment Policy

The Present Paradox for Evidence Generation: Novel Technologies Need Payment Policy

Care delivery organizations navigating technology adoption must make decisions with the evidence available at the time. However, robust clinical and cost-effectiveness research is expensive for innovative technology companies. Therefore, companies typically seek the “path of least resistance” and lowest cost option to demonstrate the clinical effects of the technology. In many cases, this is done under pathways established by the U.S. Food and Drug Administration (FDA) to regulate safety and efficacy claims. Evidence for the effect of a technology, or services that use a technology, on cost or future utilization requires additional investment above minimum regulatory requirements, which may be cost prohibitive. While CMS may cover a new technology that has passed muster at the FDA, care delivery organizations paid under a VBP model may not take the risk on an unproven technology.

Pharmaceutical companies, on one end of the evidence-spending spectrum, spend over $1 billion to bring a new drug technology to market.[47] This is possible due to the

well-established and high-priced reimbursement pathways available for drug technologies. Said differently, major pharmaceutical companies are willing to risk the investment in evidence generation over and above FDA requirements given the future returns. For emerging products, or those with less certainty in the path to coverage and payment, investment in high-risk, high-reward research is inhibited. This is especially true for small businesses and early-stage companies where research and development (R&D) investment requires access to government and private capital sources. The investment in research to establish clinical and economic value must be aligned with future revenue opportunities.

Given the absence of clear and present SaaS clinical technology reimbursement and payment models, a paradox exists for innovative clinical software technology companies. The uncertainty around future returns yields lower levels of investment in evidence-generation. Thus, these companies may invest in evidence generation that allows for baseline FDA compliance, but that does not definitively prove to care delivery organizations under a value-based payment model of its potential to yield a return on investment.

Digital therapeutics, as a class of innovative software technologies, provide an excellent example of this effect: two of the early companies in this space, Pear Therapeutics and Akili Interactive, received FDA approval for a computerized behavioral therapy device[48] and a digital therapeutic software for attention deficit hyperactivity disorder,[49] respectively. Indeed, despite adequate clinical evidence for FDA approval, these technologies failed to gain adoption for a number of reasons with lack of reimbursement as a primary driving factor. Pear Therapeutics filed for bankruptcy in 2023 and Akili Interactive, after financial troubles, sold its technology assets in 2024. While these high-profile companies obtained substantial levels of investment despite a lack of pathway to sustainable coverage., they are both outliers in terms of investment, but demonstrate the effect of a lack of reimbursement on clinical adoption.

This “market-failure” observation related to SaaS clinical technologies is not new; adoption has been inhibited by financial constraints related to reimbursement for the last two decades. Deveraj and colleagues[50] note this effect in the adoption of computerized clinical decision support software, Watson et al.[51] note this effect with machine learning and predictive analytics, and Lin et al.[52] found the same with telehealth services prior to the reimbursement policy changes of the Covid-19 pandemic era.

Coverage with Evidence Generation Approaches Should be Expanded

Coverage with evidence development (CED) is a policy framework that enables conditional coverage for promising medical interventions that is contingent on simultaneously collecting

additional clinical evidence about their effectiveness.[53] Medicare may extend coverage for certain items or services through the CED framework, which establishes "reasonable and necessary" status under Section 1862(a)(1)(E) of the Social Security Act. This provision connects to Section 1142, enabling the CMS to collaborate with the Agency for Healthcare Research and Quality (AHRQ) in conducting evaluations. This partnership authorizes CMS to finance the clinical research costs associated with these investigations.

Rather than making binary coverage decisions with limited data as is most common at present, CED allows Medicare to provide access to innovative treatments or diagnostics on the condition that patients participate in registries or clinical studies that generate real-world evidence on outcomes, safety, and appropriate use.[54] This approach strikes a balance between ensuring Medicare beneficiaries have timely access to potentially beneficial technologies and the need for sufficient scientific evidence to support long-term coverage decisions and that should be considered in the context of rate determination. CED has been particularly valuable for complex interventions such as advanced imaging technologies, surgical procedures, and novel therapeutic devices where traditional clinical trials alone may not adequately address all questions about a treatment's value in the diverse Medicare population. Since its introduction in 2005, and as of 2022, CED has been selectively implemented across a relatively modest number of Medicare coverage determinations, with approximately 27 national coverage determinations (NCDs) incorporating CED requirements to date.[55] Notable examples include coverage for lung volume reduction surgery, positron emission tomography (PET) scans for cancer diagnosis, transcatheter aortic valve replacement (TAVR), and chimeric antigen receptor T-cell (CAR-T) therapy. CMS has faced implementation challenges including administrative complexity, stakeholder concerns about study design requirements, and questions about the transition from evidence development to standard coverage. While CED has successfully expanded access to innovative treatments while generating valuable clinical evidence, critics point to lengthy timelines for evidence collection and inconsistent processes for graduating technologies from CED to routine coverage. This is an area of opportunity to help address reimbursement and business model issues with the adoption of clinical software technologies under both FFS and VBP payment models.

Regulatory and Compliance Barriers

Interoperability at ONC: Newly Housed at CMS

A major roadblock to adoption of data analytic technologies has been the lack of standardized data elements and classes across providers, programs, systems, and patients. While significant progress has been made by HHS in enhancing health data interoperability and health data flows, including through the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information

Technology (ASTP/ONC) information blocking rules (yet these rules will increase provider burden and necessitate regulatory review), there is still much more to be done before both certified electronic health records, innovative software platforms, and SaaS technology can exchange data seamlessly.

At the same time, rather than working collaboratively with ASTP/ONC, CMS seems to have gone its own path with overly stringent regulations that prevent adoption of innovative clinical support technologies that could improve patient care and support value-based care models. For example, CMS continues to rely on Certified Electronic Health Record Technology (CEHRT) for MIPS program participation and Advanced Alternative Payment Models (APM) qualification. Overly prescriptive CEHRT requirements have effectively bound participants to use CEHRT products that are built primarily to measure and report on CMS requirements, rather than truly innovating patient care and population health. If CMS CEHRT standards are not sufficiently flexible to keep pace with developing standards for health data exchange as well as evolving technology capabilities, CEHRT requirements may disincentivize MIPS participants from adopting truly innovative technology that advances patient care. For example, there are population health and chronic disease management software technologies that are focused on delivering interventions to patients and monitoring treatment progress, yet providers are often bound to use legacy systems that serve to enable CMS reporting rather than proactive clinical interventions.

The HITECH Act is another example of federal regulations on technology products that are well-intended but overly rigid to the point they stifle true innovation that could potentially benefit patient care. The HITECH Act was originally intended to incentivize physicians to purchase and use EHRs to digitize medical records to reduce issues associated with paper charts and records, including legibility, access, and loss. However, excessive regulation and overly prescriptive federal requirements have created unintended consequences. For example, CMS requires providers to use EHRs in highly specific, often non-clinical ways, which for over a decade has shaped how EHR developers design their products. Put simply, EHR design and the dominance of legacy systems has been driven by prescriptive CMS program requirements—and studies have shown that these regulations are directly tied to provider burden and burnout.[56]

Program participants are now bound to use poorly functioning CEHRT products, built primarily to measure and report on CMS requirements. The program thus disincentivizes patients from adopting truly useful technology built using modern data infrastructure and user experience. CMS should expand the definition of CEHRT in its programs and/or award credit in MIPS, APMs, and other federal VBP programs for use of connected health IT products that build on CEHRT.

Recommendations

While the policy conversation has advanced to AI in health, basic software infrastructure like telehealth access remains at risk despite positive clinical evidence and improved

access to care. Here a statutory barrier continues to limit market innovation around care models in both legacy and VBP models, yet there are also significant agency-level rulemaking opportunities that can improve care model evolution toward a more proactive and preventive orientation through the use of advanced technologies.

Under its existing authorities, CMS should look holistically for ways to support care delivery organizations in adopting SaaS technologies to advance towards a value-based care system. It is clear that for VBP to result in cost control for Medicare, both the alternative payment models themselves and care delivery models under them must be pushed to modernize and evolve. For prospective payment models (where payments are made in advance and are knowable before care is provided to beneficiaries), CMS should provide a stipend or other marginal payment dedicated to the appropriate adoption of evidence-based tech-driven tools to improve outcomes and/or lower costs. For retrospective payment models, such as the MSSP (where shared savings or losses are determined by what services have been rendered to beneficiaries two years in the past), excluding initial expenditures on tech-driven tools from an official budget will improve outcomes and lower costs for providers. Similarly, as the MSSP and other VBP models are reliant on fee-for-service, it is critical that CMS adapt the Medicare Physician Fee Schedule RBRVS to accept SaaS technologies in an evidence-based and consistent manner.

CMS is overdue to enhance and accelerate testing models that leverage digital health innovation tools. The approach and process of CMS and its Innovation Center to the testing of new value-based models, which currently takes up to five years, has been inadequate to date in supporting the transition to a value-based care system that leverages tools like new digital health technologies. Systemic change to the CMMI evaluation process through statutory updates is needed and should include condensed timetables for model development and evaluation, as well as a requirement for CMS actuaries to fully account for cost savings due to both prevention and treatment.

Congress will not meet its goal of realizing innovative APMs unless CMMI works with stakeholders to find eligible alternatives to MIPS. At a minimum, CMMI must prioritize the utilization of SaaS technologies (both Medicare telehealth services and asynchronous modalities) in a significantly expanded way. CMMI should develop model tests that allow physicians and other providers to include a broader range of digital health technologies across Medicare and Medicaid. CMMI's development and evaluation criteria for models should prioritize transparency and memorialize its commitment to exploring connected health technologies across Medicare and Medicaid as a guiding principle.

If both FDA-regulated (e.g., software as a medical device) and non-regulated clinical software technologies are increasingly important parts of the transition from FFS to value-based payment due to their role in enabling care model innovation, then CMS and CMMI should remove barriers and create sustainable funding models for their adoption.

Key Barriers to Adoption:

1. **Lack of direct reimbursement of software practice expense under the MPFS**
2. **The lack of payment flexibilities under legacy and VBP models that facilitate the adoption of effective SaaS clinical technologies**
3. **The cost of large-scale evidence development for both clinical- and cost- effectiveness**
4. **Overburdensome compliance/administrative burdens**

These barriers affect the adoption of clinical software technologies into care delivery organizations under both the MPFS and VBP models.

Consistent With the Above Overarching Changes, CMS/CMMI and Congress Should Seize the Following Specific Opportunities to Reduce Barriers:

- Provide enhanced coverage to innovative digital health tools (e.g., asynchronous remote patient monitoring) demonstrated to advance the Quadruple Aim as a key step in transitioning to VBC.
- Ensure that digital health efficiencies are fully embraced by CMMI models.
- Enhance PE methodologies to reimburse certain clinically effective and safe SaaS clinical technologies as direct practice expenses under the MPFS.
- Make valuable SaaS more accessible to Medicare beneficiaries by evolving its PE methodology to reflect the value that software provides by incorporating the value of software into CPT codes to address PE and/or work intensity for RVUs. Specifically, the value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs, and the value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs. As CMS allows for SaaS reimbursement as direct supply inputs, CMS should obtain the most accurate estimate of the per-service cost of the input as possible, particularly by relying on invoices. CMS' equipment amortization formula should only apply in the case of locally installed computer programs with an upfront payment where a useful life can be estimated and where that SaaS is only used in one service at one time.
- In alignment with coding developments, support and expand responsible payment for clinical SaaS technologies/SaaS, including augmentative and autonomous AI tools that will drive greater access to innovative and efficacious care for Medicare beneficiaries, with national rates for the payment of such services (shifting away from contractor pricing that encourages disparate approaches among Medicare Administrative Contractors).
- CMS should establish a formal payment framework for ABHS to encourage ongoing innovation and safeguard Medicare beneficiaries' access to AI-driven technologies, consistent with CMS' SaaS

payment policy set in the 2023 Medicare OPPS Final Rule.

- Develop a capitated system for investment in new technologies for care delivery modernization.

- Create pathways for coverage with evidence generation for clinical SaaS technologies to demonstrate clinical and cost-effectiveness to support Medicare coverage and reimbursement.

- Bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaaS, are included in existing benefit categories.

- Minimize unnecessary burdens for MIPS participation and support greater digital health use across MIPS measures (e.g., CMS should provide credit for capturing information using either CEHRT or non-CEHRT in both Promoting Interoperability measures and Improvement Activities).

- Waive payment and program requirements as appropriate to provide flexibility for use of digital health innovations in APMs and foster adoption.

- Implement a payment model similar to the one suggested by Pham et al.[57] such that a layered capitation model provides the unrestricted cashflow needed to fund adoption of advanced technologies.

- Across its programs, incent adopting truly useful technology built using modern data infrastructure and user experience by such steps as expanding the definition of CEHRT in its programs and awarding credit in MIPS, APMs, and other federal VBP programs for use of connected health IT products writ large.

Conclusions

Medicare has consistently pioneered payment model and coverage innovation within the U.S. healthcare system, establishing precedents that influence broader industry practices through initiatives like the Hospital Readmissions Reduction Program, Bundled Payments for Care Improvement, and Accountable Care Organizations. These CMS-driven innovations serve as critical templates that commercial insurers and state Medicaid programs frequently adapt and implement within their own payment structures, allowing these entities to benefit from Medicare's substantial investment in model development and evaluation. The cascading influence of Medicare's payment reforms extends throughout the healthcare ecosystem, as CMS coverage determinations for new technologies and services often establish de facto standards that other payers reference when making their own coverage decisions, thereby amplifying Medicare's role as the nation's foremost catalyst for healthcare delivery transformation.

The current PFS reimbursement methodology and regulatory structures are not currently designed to spur technology adoption that improves the efficiency and quality of patient care and in turn promotes VBP adoption and optimal performance. CMS must address these issues to both facilitate innovation under legacy payment models, but also under future efforts to promote value-based payment models.

Level	Description	Patient risk	Description	Example use cases	Criteria to implement	Potential risks
1	Back office - administrative	Minimal	• Automation of administrative tasks which do not directly impact medical care. Little or no clinician involvement	• Revenue Cycle Management • Prior authorization submission/Utilization Management review	• Financial • Process integrity	• Financial misadventure • Administrative confusion
2a	Clinical process automation	Low	• Automation of low-level clinical processes and information organization, freeing clinician time to improve satisfaction and efficiency	• Virtual scribes (ambient documentation) • EHR summarization • Facilitated reference access	• Documentation accuracy • Process Integrity • Improved clinician experience/efficiency	• Inaccurate documentation
2b	Patient enablement	Low	• Educating patients on their conditions, recommended, medications, test results etc. • Collecting information from patients (e.g. meds, basics of clinical history)	• EHR inbox management • Patient education/promotional content generation • Patient chatbots • Smart questionnaires for intake • Member services/call centers	• NOT diagnostic or treatment advice • Improved patient experience	• Nontransparency with patients • Misinformation on non-medical issues
3	Clinical Decision Support - non-device CDS	Moderate	• Supporting clinicians in prognosis, diagnosis, or treatment, where clinicians make explicit choices to finalize plan, based on explanations provided by the system	• Computer assisted diagnosis and recommended treatments • Prediction of sepsis • Prior authorization review/approval	• Recommendations explainable and traceable to source • Clinician + CDS perform better than clinician alone	• Incorrect guidance given to physicians which they don't adequately review
4	Clinical Decision Support - SAMD	High	• Supporting clinicians in prognosis, diagnosis, or treatment, where the AI's reasoning is not always transparent, and the AI often provides a specific recommendation • Direct advice to patients through chat, etc w/o HITL	• Automatic pathology and radiology reading • Smart, advice-giving chatbots for patients • Suggestions about ventilator management	• Tightly defined use parameters • Accuracy at least equivalent to expert clinician • Equitable performance tested in a diverse patient population • Speed substantially better than human expert clinician as Gold Standard	• Automated incorrect medical decision making
5	Digital Doctor - SAMD+	Highest	• Autonomous decision making (prescribing, treating, test ordering, diagnosing) by algorithms without human intervention	• Algorithms which would prescribe or make remote diagnoses with no human present	• Clinical outcomes at least equivalent to human expert clinician as Gold Standard • Equitable performance tested in a diverse patient population • Requires new legal/ regulatory framework	• Automated bad medical practice

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Endnotes

[1] Source: David Blumenthal et al., Mirror, Mirror 2024: A Portrait of the Failing U.S. Health System — Comparing Performance in 10 Nations (Commonwealth Fund, Sept. 2024). https://doi.org/10.26099/ta0g-zp66

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