

# Leveraging Digital Health to Realize Value-Based Care

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# Executive Summary

Today, an estimated 133 million Americans – nearly half the population – suffer from at least one chronic illness, such as hypertension, heart disease, and arthritis, which is 15 million higher than just a decade ago and expected to reach 170 million by 2030. From a cost perspective, chronic illnesses account for 75 percent of the \$2.2 trillion we spend on health care each year in the United States. The COVID-19 pandemic has also made disparities and inequities in the American healthcare system even more apparent than ever before. Given these staggering statistics, it's more important than ever that the American healthcare system needs to shift from the traditional approach of paying for discrete services in a fragmented manner, with gaps in payment for many high-value services, to one that supports value and improved health outcomes, but this goal remains far from realized.

Digital healthcare technologies provide an essential major means for advancing value-based care, yet they remain underutilized or completely unused to this end. Seven years out from the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the time is now to truly incent the use of digital healthcare innovations so that a transition to value-based care happens.

Based on the views and experiences of a diverse range of interests and voices from throughout the healthcare ecosystem, the Connected Health Initiative (CHI) identified key challenges to the responsible use of digital health technologies in advancing value-based care, and recommendations to policymakers on how to overcome them. CHI's Value-Based Care Task Force's (Task Force) recommendations include:

- Congress and the Centers for Medicare and Medicaid Services (CMS) should enable providers to use digital health tools to enhance care quality while the transition to value-based care continues, eliminating barriers to the responsible use of digital health innovations in the Merit-based Incentive Payment System (MIPS) as a pathway to Advanced Alternative Payment Models (APMs) and modernizing MIPS components, like Program Integrity (PI) protections, to support the use of digital health tools.
- Congress and the U.S. Department of Health and Human Services (HHS) should enhance and accelerate CMS testing models that leverage digital health innovation tools and support the use of digital health tools and responsible use of technology in APMs. HHS should also leverage the work underway in the private sector by partnering with health plans to develop multi-payer models.
- HHS should advance the appropriate two-way flow of health information to enhance value throughout the care continuum.
- Congress and federal agencies should take coordinated steps to provide high-speed broadband to America's underserved communities to support the use of digital health tools in advancing value-based care.
- Congress should modernize privacy and security frameworks to support the use of digital health tools in value-based care scenarios widely.

# 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. CHI aims to realize an environment in which Americans can improve their health



through policies that allow for connected health technologies to enhance health outcomes and reduce costs. CHI members are developers and users of connected health technologies across a wide range of use cases. CHI is 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/augmented intelligence (AI) in care delivery.

In 2021, CHI formed its Value-Based Care Task Force. This group works to identify key legislative and regulatory changes needed at the federal level to advance value-based care in the American healthcare system by leveraging digital technologies. Numerous CHI Steering Committee members and other key stakeholders from throughout the healthcare value chain committed to realizing value-based care participate in the Task Force. The recommendations in this paper are based on an evaluation by the Task Force of the healthcare ecosystem's implementation of value-based care models to date, including in the context of Medicare.

For more information, please visit [www.connectedhi.com](http://www.connectedhi.com).



## What is Value-Based Care?

Conventionally, healthcare providers are paid for each discrete service delivered to patients, which is called the fee-for-service (FFS) model. In contrast, the newer value-based care arrangements such as alternative payment models, including value-based payment and delivery models, typically are designed to reduce avoidable health care spending while improving the quality of care, often using performance requirements that are designed to advance quality of care such as care coordination, costs, and health information technology, into payment models. While value-based care can take many forms, they all incentivize healthcare providers to meet specified quality metrics or goals that demonstrate value as well as improved approaches to the cost of care. Value-based care may afford the healthcare provider greater flexibilities than most FFS arrangements so that the provider itself can determine the best way to meet quality goals and furnish services to patients that might not otherwise be covered. Well-designed value-based care arrangements encourage healthcare providers to seek new ways to deliver care more effectively, while providing adequate payments and incentives for high quality, cost-efficient care. Therefore, these care arrangements can also empower healthcare providers to take on greater transparency and accountability for health care outcomes and costs than FFS.

Today, some FFS models incorporate elements of value-based care through provider accountability and rewarding improved quality and more efficient spending, but a shift from FFS models that may not adequately support diagnostic accuracy and prevention to well-designed value-based care models can enable healthcare providers to be proactive with their patient populations. Successful value-based care models must prioritize efficacious use of preventative measures and engage and activate patients, particularly hard to reach patients. With 12 percent of U.S. citizens having five or more chronic conditions (accounting for 41 percent of total healthcare expenditure),<sup>1</sup> systemic changes are clearly necessary to enhance proactivity and prevention in the healthcare system as well as to shift away from the fragmentation and gaps in care that often characterize FFS. Patient-generated health data (PGHD) that is actionable, relevant to clinical care, frictionlessly integrated into clinician workflow and patient portals, timely and properly scoped enables providers and patients to identify health trends early, preventing the disease development and costly treatments.<sup>2</sup>



Value-based care models should enable care that (1) utilizes sites of service with the lowest cost of care when safe and clinically appropriate to do so, (2) is focused on health maintenance (as opposed to disease treatment); (3) coordinates decisions and treatments among extended care teams; (4) addresses other factors impacting health outcomes and costs including social determinants of health

and structural inequalities; (5) advances patient-centered medical homes; and (6) facilitates innovative cost reductions throughout the healthcare value chain. They aim to lower the costs for providers, patients, and plans through alternatives to FFS payments that reimburse a provider for each service, procedure, or test, such as through bundled payments for conditions or episodes of care, shared savings arrangements such as accountable care organizations, partial or full capitation, or budgets tied to the health care needs of a patient population. With health spending projected to grow at an average annual rate of 5.4 percent, reaching an annual spend of \$6.2 trillion by 2028,<sup>3</sup> policymakers and other stakeholders must advance value-based care as soon as practicable to manage rising costs in healthcare.<sup>4</sup>

CHI supports the public and private efforts to date to define and categorize the healthcare ecosystem and what value means within it, and we aim to build upon this great work. For example, in 2015, HHS launched the Health Care Payment Learning & Action Network (LAN),<sup>5</sup> a public-private partnership (PPP). The LAN, in collaboration with America's Health Insurance Plans (AHIP) and the Blue Cross Blue Shield Association (BCBSA), measures the health system's shift from FFS to alternative payment models and has categorized payments into four categories, ranging from Category 1 (traditional FFS) to Category 4 (capitated payments that enable greater risk-taking and innovation by providers). Building upon this and other efforts, CHI proposes the goal of a value-based care system that enables all providers and patients to participate in advanced, value-focused models fully and proactively. While existing shared savings models are a positive step in the right direction, not all providers can engage in them and more bridges to well-designed alternative payment models are needed. Today's value-based care framework, and the models within it, must be viewed as valuable mechanisms to transform our healthcare system. This new healthcare system must enable all providers to be rewarded for their innovations in improving outcomes while lowering costs.

Lawmakers widely accept the need to shift away from traditional FFS to more value-based care models. In 2015, Congress passed the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015<sup>6</sup> (MACRA). This Act received strong bipartisan agreement<sup>7</sup> that the government should incorporate value into its payment systems rather than the historic approach focused on each individual face-to-face encounter. MACRA repealed the sustainable growth rate (SGR) cap on Medicare physician payments through the Medicare program administered by the CMS and directed CMS to shift from an FFS system to a new value-based Medicare system. As of 2019, most Medicare providers must participate in the program via two pathways under CMS' Quality Payment Program (QPP): MIPS or an APM.<sup>8</sup>

## Value-based care models should

- ✓ Utilize lowest cost sites of care
- ✓ Focus on health maintenance
- ✓ Coordinate decisions and treatments among extended care teams
- ✓ Address other factors impacting health outcomes and costs
- ✓ Advance patient-centered medical homes
- ✓ Facilitate innovative cost reductions throughout the healthcare value chain

MIPS is the default method of participation in the QPP, which adjusts payments based on performance in four categories: Quality, Promoting Interoperability (which replaced the Meaningful Use program), Improvement Activities, and Cost.<sup>9</sup> MIPS payment adjustments began in 2019, and, fully implemented, offers a range of potential bonuses and penalties of plus or minus 9 percent, which are made on a budget-neutral basis. In addition to budget neutral payment adjustments, Congress established an annual \$500 million bonus pool for exceptional performers to earn up to an additional 10 percent adjustment through the 2024 payment year. The goal to shift all providers to APMs, with MIPS serving as a temporary pathway, unfortunately remains behind schedule.

While MIPS makes performance-based adjustments based on value-based activities, it does not move the needle much in terms of payment reform; it retains the FFS payment structure and was intended to serve as on-ramp to APM participation. In an Advanced APM, a healthcare provider assumes financial risk (“more than a nominal amount”) for higher-than-expected spending and poor-quality performance, in exchange for potential financial rewards. Advanced APMs also require the provider to use certified electronic health record (EHR) technology. Current APMs include accountable care organizations, patient-centered medical homes, and payments for bundled episodes of care. In addition to the potential for financial savings under the model, MACRA provided a 5 percent lump sum bonus based on prior year Medicare Part B billings through payment year 2024 for Advanced APM providers that achieve certain threshold levels of payments or patients under the APM entity. Additionally, Advanced APM providers who achieve these thresholds are exempted from MIPS requirements and receive a higher Medicare FFS update than non-Advanced APM providers starting in payment year 2026.

Notably, CMS already prioritized a shift from FFS to value-based care since before the passage of MACRA. The Affordable Care Act codified the creation of the Center for Medicare & Medicaid Innovation (CMMI), which CMS continues to oversee; as well as the national Medicare Shared Savings Programs for accountable care organizations, seven value-based care programs which are available to providers in certain states, all of which have the goals of connecting the quality of provider performance to payment.<sup>10</sup>



Private payers are also embracing value-based care models.<sup>11</sup> Health insurance providers have partnered with CMMI on multi-payer models, such as Primary Care First, participated in payer-focused initiatives such as the Medicare Advantage Value-Based Insurance Design model, and enrolled in CMMI’s Direct Contracting model as participating entities. In addition to participation in Medicare and Medicaid APMs, health insurance providers embraced outcomes-based payments by investing a substantial amount of resources toward developing and implementing their own network of APMs. The Task Force’s goals

align with the Innovation Center's in transforming care delivery and moving toward paying for value. Over half (53.6 percent) of health care payments from Medicare Advantage plans, and nearly one-third of commercial payments (30.1 percent) were tied to a value-based alternative payment model in 2018.<sup>12</sup>

Without question, realizing greater adoption of value-based care will require systemic changes. A new and focused approach to the use of technology across the continuum of care is necessary to affect these needed systemic changes. Data and clinical evidence from several use cases continue to demonstrate how the connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill.<sup>13</sup> Connected health tools, including wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, can fundamentally improve and transform American healthcare through preventing and managing disease. Leveraging standardized terminology and technical interoperability protocols, these tools can render meaningful and actionable outcomes by responsibly and securely collecting key health data points over time. With standardized transport-level as well as semantic and syntactic approaches, they can also enable the exchange of health information and incorporating PGHD into the continuum of care. As such, providers and patients must responsibly leverage innovative digital health tools to realize a value-based care system.

## Challenges and Opportunities to the Shift from Fee-For-Service to Value-Based Care

With FFS remaining a significant factor in soaring healthcare costs and the fragmentation of care,<sup>14</sup> the need for value-based care is striking. Today, an estimated 133 million Americans – nearly half the population – suffer from at least one chronic illness, such as hypertension, heart disease, and arthritis, which is 15 million higher than just a decade ago and expected to reach 170 million by 2030.<sup>15</sup> From a cost perspective, chronic illnesses today account for 75 percent of the \$2.2 trillion we spend on health care each year in the United States.<sup>16</sup> Studies project that between 2016 and 2030, chronic diseases in America will cost around \$42 trillion.<sup>17</sup>

Digital healthcare technologies offer a major means for advancing value-based care, yet they remain underutilized or completely unused to this end. Below, the Task Force identifies several key areas where barriers to the responsible use of digital health technologies in advancing value-based care persist.

### Payment & Incentives for Value

Despite the best efforts of CMMI to increase the number of Advanced APMs, many providers in certain geographies, specialties, and practice settings lack viable options for APM participation over a decade since CMMI's inception, particularly when pro-digital health policies could incent the move to APMs. Moreover, CMMI's existing suite of Advanced APMs do not adequately embrace innovative



technological healthcare delivery mechanisms. Value-based care models that are currently in place do not provide the flexibilities needed to incorporate the full range of virtual care modalities (except for voice/video) into digitally enabled care models.

Moreover, CMMI models are typically only run for five years since CMMI must pilot test models before making them permanent. CMMI has sole authority to “expand” models for either permanent or wide geographic implementation if the model is expected to decrease spending without decreasing quality of care, or if the model is expected to increase quality without increasing spending. As of February 2021, CMMI tested 54 models; in 2020, CMMI was actively operating 24 payment and delivery models. Seven of these models received designation as Advanced APMs. Despite testing dozens of models, only four CMMI models have met the criteria for expansion into a nation-wide program, including only one Advanced APM— The Pioneer Accountable Care Organizations (ACO) model—which served as a model for one of the tracks in the MSSP program, the current Enhanced Track. Given the critical need for transformation of the American healthcare sector and the rapid development of new technologies that can contribute to CMS’ value-based care mission, this process can be astonishingly slow. For the 2019 Quality Payment Performance Period, 195,564 eligible clinicians earned Qualifying APM Participant (QP) status while another 27,995 eligible clinicians earned partial QP status; in contrast, 954,614 eligible clinicians participated in MIPS in 2019.<sup>18</sup>

While CMS has long stated that its goal is for the vast majority of providers to participate in APMs, rather than MIPS, this is far from realized and there are insufficient APM options for most specialists. The Physician-Focused Payment Model Technical Advisory Committee (PTAC),<sup>19</sup> charged with recommending new specialty-relevant APM models to CMS for testing under CMMI, has to date received and evaluated 39 proposed APMs and recommended that the Department of Health and Human Services (HHS) take action on 28 of them.<sup>20</sup> While PTAC has authority to recommend models to CMMI to pilot test, its authority is merely advisory as CMMI has sole authority to test, implement, and expand APMs. Congress envisioned that the PTAC would help accelerate the development of new Advanced APM options, which could be exploring new digital health-driven efficiencies and ways to bring greater quality into the care continuum while reducing costs. However, HHS has not, to date, adopted a single PTAC-recommended model for testing. This result represents a marked failure in the federal government’s efforts to realize Congress’ goals established in MACRA.

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### [Legacy Program Integrity Measures](#)

Legacy regulatory constructs also present an immense challenge. For example, consider providers examining the use of new digital health technologies, such as remote monitoring tools, to care for



patients with acute and chronic conditions. In this process, providers are uncertain as to whether offering access to equipment or software platforms to a patient for free may inadvertently trigger liability under the Anti-Kickback Statute (AKS).<sup>21</sup> The Task Force commends the HHS' Office of the Inspector General's (OIG's) recent finalization of AKS reforms to enable value-based care. However, further uncertainties remain over basic use cases, such as for patients utilizing their own smart devices with multiple functions like smartphones or tablets, which must be addressed through new agency rulemakings. These uncertainties may cause AKS liability, even when patients primarily use the device to manage their healthcare, including the social determinants that impact health, including finances, scheduling, and transportation, and creates a chilling effect on innovation.

Further, a few policymakers are still skeptical about the use of new technology-driven modalities. CHI, for example, continues to encounter policymakers that insist that the delivery of care via a virtual modality brings with it an inherent heightened risk of fraud or overuse. This damaging mantra has no basis in evidence (including in data from the COVID-19 pandemic) and is addressed by guardrails in policies and procedures. On the contrary, the responsible deployment of digital health technologies will greatly assist in detecting and eliminating fraud and overuse. Using digital footprints (e.g., signatures, time stamps, etc.) and blockchain technologies, digital health tools can much more easily spot anomalies and trends in data in near-real-time by leveraging efficacious cloud computing-based big data analytics.<sup>22</sup>

## [Disparities in the American Healthcare System](#)

The COVID-19 pandemic highlights longstanding health disparities, as well as a growing digital divide,<sup>23</sup> among diverse communities, including people of color, women, and residents in rural communities. Health disparities are structural and built into the American healthcare system. They affect not only

In a value-based payment world, it can be more challenging to meet quality metrics and spending targets for historically underserved populations.

those facing the disparities, but significantly decrease the overall medical and public health in the country, resulting in higher costs for health care and poor public health capabilities. The issue is particularly relevant today given the existing and projected diversity of the U.S. population coupled with declining health outcomes compared to other developed nations. For example, preliminary Medicare data shows the rate of hospitalization for Black people with COVID-19 was a rate of 465 per 100,000. Among other racial/ethnic groups, Latinos had 258 hospitalizations per 100,000; Asian American and Pacific Islanders had 187 per

100,000; and Whites had 123 per 100,000.<sup>24</sup> Disparities in access, service use, and health outcomes persist, and continue to grow.<sup>25</sup> In a value-based payment world, it can be more challenging to meet quality metrics and spending targets for historically underserved populations.

## [Actionable, Accurate, and Accessible Data](#)

Ultimately, we cannot realize value-based care unless there is a frictionless sharing of standardized data elements and classes across providers, programs, systems, and patients.

The Task Force supports the significant progress made by HHS in enhancing health data interoperability and health data flows, including through the Office of the National Coordinator for Health IT's (ONC's) information blocking rules. Yet, significant barriers remain in place for needed data flows that would advance value-based care.

For example, CMS continues to rely on Certified Electronic Health Record Technology (CEHRT) for MIPS program participation and Advanced APM qualification. Overly prescriptive CEHRT requirements have effectively bound participants to use poorly functioning CEHRT products, built primarily to measure and report on CMS requirements. If they do not keep pace with developing standards for health data exchange as well as evolving technology capabilities (which in some cases has made the CEHRT/non-CEHRT distinction arbitrary), CEHRT requirements may disincentivize MIPS participants from adopting truly useful and appropriate technology.

And while access to data is essential, so is the data's timeliness, accuracy, and efficacy. Barraging a provider with too many unneeded data points can create more work for the provider without adding value to the care it delivers.<sup>26</sup>

While the United States Core Data for Interoperability (USCDI) and alignment with ONC's information blocking rules will provide the next (syntactic) level of interoperability, policymakers must also act quickly to build on existing stakeholder agreement on the best data categories and elements to then share (semantic) between them. A lack of full interoperability at both levels prevents leveraging the social determinants of health (SDOH), lab data, behavioral health data, and other data sets necessary to shape value-based care systems. For example, safety net providers such as federally qualified health centers (FQHCs) need access to SDOH data to accomplish population health management goals. Today, these frontline providers simply do not have timely or uniform access to the data they need.

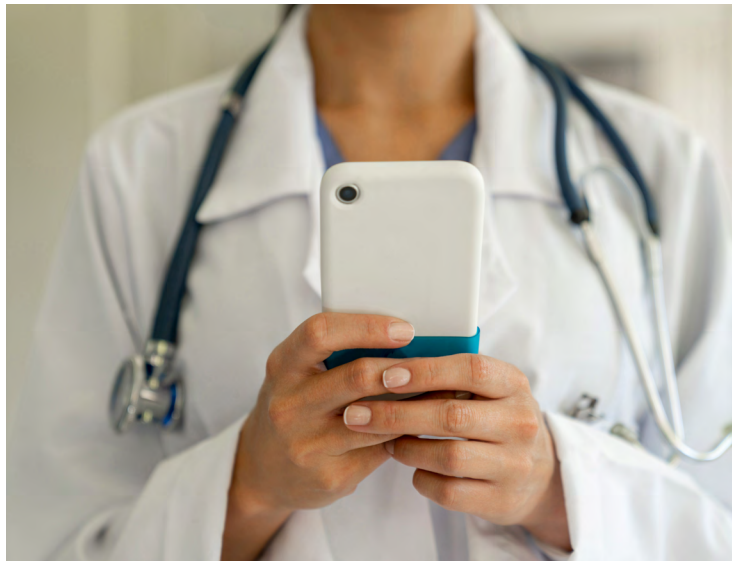
## [Broadband Infrastructure to Support Digital Health's Capabilities](#)

Before and during the COVID-19 pandemic, a lack of adequate broadband infrastructure needed to support digital health capabilities has significant recognition as a contributing factor to widening healthcare disparities.<sup>27</sup> While important efforts have been taken to address measure and address broadband internet availability,<sup>28</sup> further steps are needed to equip the caregivers and patients with high-speed internet capabilities. Without this support, providers and plans will lack the infrastructure support they need to leverage new digital health capabilities as they search for ways to advance value-based care.

## Privacy & Security

Patient privacy, a patient's rights as to how their personal information is collected, used, stored, and shared, is distinct but linked to cybersecurity, the measures taken to protect an electronic system against unauthorized access and harm. Continued uncertainty, along with uncoordinated approaches across states, disincentivizes the uptake of digital health tools that can provide quality care at lower costs.

Healthcare sector-specific requirements for privacy and security, such as regulations developed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),<sup>29</sup> unfortunately have not kept pace with technology's capabilities nor patients' expectations. As a result, providers, patients, and technology developers do not have up-to-date and clear information about compliance expectations for technology companies across several key use cases. Similarly, they lack the necessary insights into standards that can help technology companies conform to the regulations. For example, stakeholders continue to lack guidance related to the use of text messaging, chat services, and app-based push notifications that would greatly assist them during patient care, including care coordination and communication with family and caregivers.



Further, use cases continue to emerge that fall outside of the reach of HIPAA.<sup>30</sup> While the Federal Trade Commission (FTC) clarified that it would protect patients under general consumer protection laws when the data at issue falls outside of HIPAA's scope,<sup>31</sup> confusion persists amongst providers, technology developers, patients, and others as to what their rights and obligations are.

Notably, numerous states took action to address consumer and patient data security and privacy through their own laws. While a patchwork of approaches has long existed for some areas of cybersecurity (such as breach notification<sup>32</sup>), new laws are increasingly introduced and passed by state legislatures addressing consumer and patient privacy (e.g., the California Consumer Privacy Act,<sup>33</sup> the Virginia Consumer Data Protection Act,<sup>34</sup> and Illinois's Biometric Information Privacy Act<sup>35</sup>), which treat HIPAA-covered data differently. The increasing number of state laws addressing health privacy and security contribute to a patchwork of requirements that make understanding rights and obligations difficult throughout the healthcare value chain. More must be done at the national level to strengthen provider and patient trust in digital health tools' use of electronic health information.

# How Should Digital Health Tools Be Leveraged to Realize Value-Based Care?

Six years have passed since the passage of MACRA, and the COVID-19 pandemic has revealed the need for even greater systemic changes in healthcare. The time is now to truly leverage digital health tools to better deliver value-based care.

Data and clinical evidence from several use cases continue to demonstrate how the connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. “Telehealth,” “mHealth,” “store and forward,” “remote patient monitoring,” “remote physiologic monitoring,” “communication technology-based services,” or other similar terms all describe the use of digital health tools. These tools include wireless health products, mobile medical devices, software as a medical device, mobile medical apps, cloud-based portals, and dashboards. All of them can fundamentally improve and transform American healthcare.

During the COVID-19 pandemic, the adoption and sustained use of digital health technologies increased exponentially since 2020.<sup>36</sup> According to the Centers for Disease Control and Prevention (CDC), data submitted from four large national telehealth providers indicates that telehealth use rose by 50 percent in just the first quarter of 2020 and 154 percent in the last week of March 2020 alone compared with the same period in 2019.<sup>37</sup> Similar increases occurred for other asynchronous modalities, such as remote monitoring.<sup>38</sup> Clearly, providers see value in using digital health technologies to provide care.<sup>39</sup> This dramatic rise in use of digital health technologies occurred as soon as CMS removed the financial barriers that had prevented its adoption. Notably, it occurred when removing barriers in the fee-for-service payment system, not as a result of any alternative payment model. Telehealth adoption provides an important model for how public policy can help achieve health care transformation by removing financial, administrative, and regulatory barriers to innovations in patient care.

The need for value-based care is even more imperative considering the COVID-19 crisis in the United States, and the federal government rightfully responded to it by temporarily removing barriers to the use of connected health tools to address the challenges COVID-19 presents. All parts of the healthcare value chain must leverage the wide range of connected health tools and services available today, as well as those in development, to advance value-based care and lower costs.

Leveraging health data (including SDOH and PGHD) with AI tools holds incredible promise for advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems to ensure value. CHI and the digital health stakeholder community developed health AI guidance for policymakers. The guidelines urge stakeholders to realize value through the use of new AI-driven tools in healthcare.<sup>40</sup>



One of the most helpful ways to see the utility of digital healthcare tools in advancing value-based care is to view the question through the lens of the “quadruple aim” framework.<sup>41</sup> The quadruple aim builds on the Institute for Healthcare Improvement’s “triple aim,”<sup>42</sup> a widely accepted compass to optimize health system performance. It focuses on four key areas where health systems need to be improved and acknowledges concerns of key stakeholders. The four areas are:

- Enhancing population health;
- Improving patient experience, satisfaction, and health outcomes;
- Better clinician and healthcare team experience and satisfaction; and
- Lowered overall costs of healthcare.

**Policymakers can leverage digital health tools to realize value-based care, consistent with the quadruple aim, by acting in the following areas:**

Medicare has a high impact and significant influence on the wider healthcare ecosystem. CMS should, therefore, refocus on removing barriers to caregivers and patients to promote the responsible use of digital health tools to advance a value-based care healthcare ecosystem. To accomplish this goal, Congress and the federal agencies must work together to enact the following policies:

**Congress and CMS should enable providers to use digital health tools to enhance care quality while the transition to value-based care continues.**

Notably, Congress should lift Medicare’s telehealth restrictions in Section 1834(m) of the Social Security Act. This transitional step is important for payment systems, including the regular FFS system as well as all shared savings programs and APMs, including payment bundles and medical home demonstrations. Provider and patient expectations have long ago moved out of alignment with the onerous restrictions on Medicare telehealth services, namely geographic constraints limiting eligibility to patients residing in rural Healthcare Professional Shortage Areas (in effect excluding all Medicare beneficiaries in urban or suburban areas of the country from using Medicare telehealth services) and excluding the patient’s home from being an originating site of care. With an accelerated uptake of digital health tools during the COVID-19 pandemic (including those subject to the 1834(m) restrictions) enabled by public health emergency allowances that waived such limitations, the reinstatement of those restrictions would suppress the use of basic voice/video call capabilities to the detriment of countless patients and would inhibit providers’ efforts to realize value-based care arrangements.

CMS must also maintain and enhance its support for asynchronous modalities (not just live voice/video) that are increasingly providing value and cost savings today. For example, CMS already took significant steps to support virtual check-ins and e-visits<sup>43</sup> and activate and pay for four remote physiologic monitoring (RPM) codes.<sup>44</sup> CMS also ensured the utilization of RPM in existing APMs such as Medicare Advantage, confirming RPM’s eligibility for inclusion as a basic benefit. These steps are commendable, and CMS should build on them as we further leverage digital health tools to realize value-based care. Without question, CMS took numerous meaningful steps across its existing payment systems to shift to outcome-based payments and reduce unnecessary burdens for providers and patients. CMS should

maintain these steps past the end of the COVID-19 public health emergency, particularly for those in APMs. An extension of such allowances may require congressional action or could be possible under existing authorities. The continuation of these allowances is crucial to enhancing value across Medicare.

Under its existing authorities, CMS should look holistically for ways to leverage digital health tools to advance towards a value-based care system. For prospective payment models (where payments are set in advance and are knowable before care is provided to beneficiaries), CMS should provide a stipend or other incentive dedicated to the appropriate adoption of tech-driven tools to improve outcomes and/or lower costs. For retrospective payment models (where payments are determined by what the provider charged after services have been rendered to beneficiaries), excluding initial expenditures on tech-driven tools from an official budget will improve outcomes and lower costs for providers.

**CMS should remove barriers to, and advance positive incentives for, the responsible use of digital health innovations in MIPS as a pathway to APMs.**

CMS can accomplish this goal by minimizing unnecessary burdens for MIPS participation and supporting greater digital health use across MIPS Measures. At the same time, CMS should also facilitate those participating in MIPS to shift to Advanced APMs by adopting stakeholder-developed APMs with onramps allowing broad participation.

For example, the Medicare program must shift to allow credit for embracing technical solutions and approaches that capture PGHD. Medicare should also provide credit for capturing information using either CEHRT or non-CEHRT (in both Promoting Interoperability measures and Improvement Activities). CMS has already explored this idea using a “yes/no” attestation approach for new measures within the Promoting Interoperability category of MIPS.

The Health Information Technology for Economic and Clinical Health (HITECH) Act incented physicians to purchase and use EHRs. Digitizing medical records helped 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. 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. CMS should identify methods to reduce the overreliance on CEHRT in its programs. Instead, it should allow for physician and patient choice to drive the adoption and use of health IT products by leveraging the value of connected health technology innovations that build on CEHRT.

CMS should also improve the quality data submission criteria to reflect the increased use of digital health tools, and broadly account for the savings achieved by using those tools in MIPS (e.g., in the Cost Performance Category). Medicare must transition from the existing four silos of reporting criteria to facilitate a glide path for MIPS participants to APMs via the voluntary MIPS Value Pathways (MVPs). MVPs have the potential to help CMS capture savings, particularly from preventive care, if CMS allows flexibility to move away from use of a measure template that includes a one-year measurement period. CMS should continue to develop narrowly tailored episode-based cost measures as rapidly as possible, and strive to capture savings from prevention.

For example, a diabetes prevention MVP would align objectives across all four MIPS categories by helping Medicare patients avoid costly diabetes care, as well as kidney, ophthalmic, and other sequelae of diabetes by promoting screening and participation in the Medicare Diabetes Prevention Program (MDPP) and other effective prevention care delivery options. Physicians participating in a diabetes prevention MVP would leverage digital health tools, such as virtual tools that track and engage patients toward meeting the goals of MDPP, rather than simply checking the boxes of the Promoting Interoperability measures.

**Congress and HHS should modernize program integrity (PI) protections to support, rather than prevent, the use of digital health tools and even recruit them to help with PI efforts.**

The use of new technology modalities that enable more efficient care does not inherently translate to greater waste, fraud, and abuse. On the contrary, program integrity is more easily ensured through real-time data analytics that greater use of connected health technologies provides. Both **Congress and HHS should** proactively embrace digital health technologies with the demonstrated ability to avoid and prevent programmatic waste and instances of fraud, and further efforts to modernize anti-fraud frameworks to enable a connected care continuum will smooth the pathways to value-based care.<sup>45</sup>

**Congress and HHS should enhance and accelerate CMS 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. **CMS and its Innovation Center should** expand its current APM telehealth waivers to match the flexibilities granted under the public health emergency (PHE).

Unfortunately, numerous use cases illustrate the systemic problems with CMMI's model development process. For example, substantial evidence demonstrates that virtual programs deliver 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 Medicare Diabetes Prevention Program (MDPP) expansion.<sup>46</sup> 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.

Further, 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 digital health 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. Additionally, CMMI must prioritize the use of digital health technologies in each model tested and developed and minimize the burdens of reporting on model participants.

At the regulatory level, a holistic review of CMMI's approach is necessary, and **CMMI should** do all that it can under its existing authority to streamline its process and appropriately include the range of digital health solutions available to enhance value in care. For example, building on steps already taken by CMS to support new digital health tools such as remote physiologic monitoring, in testing new models, CMMI should further incent the use of new and innovative remote monitoring technologies (which are not telehealth under 1834(m), and, therefore, do not face its geographic, originating site, and other restrictions). **CMS should** also prioritize coordination and increased model options across Medicare and Medicaid that will remove barriers to APM participation.

Further, **CMS should** recognize and build upon the successes of some Medicaid providers. For example, the Medicaid systems at the University of Mississippi Medical Center<sup>47</sup> and the University of Virginia Karen S. Rheuban Center for Telehealth provide immense value to their patient populations.<sup>48</sup> In these states (and some others), Medicaid programs have taken steps to support not only telehealth but, more importantly, remote monitoring innovations. Remote monitoring brings PGHD into the continuum of care based on demonstrated improvements to patient outcomes and significant cost savings. In addition, we encourage CMS to build upon the successes of the Veterans Health Administration in its use of connected health technologies.<sup>49</sup> CMS can and should play a crucial role in building on these successes and building on them in Medicare.

**HHS should** also leverage the work being done in the private sector by partnering with health plans to develop multi-payer models. Multi-payer arrangements can drive long-term success and sustainability by aligning incentives, model objectives, and measures; thereby expediting the process for bringing new APMs to market and saving CMMI research and development investment costs in the process.

### **Congress should incent the use of digital health tools and support the responsible use of technology in APMs.**

To fully realize the benefits of digital health in value-based care, Congress should clarify its intent for APMs to leverage digital health tools by enacting statutory language. Further, **Congress should** revise the APM development process to ensure that a percentage of funding for testing of APMs is dedicated to reducing inequities and helping underserved communities using digital health tools. Specifically, new positive incentives and flexibilities for all safety net providers (including Federally Qualified Health Centers [FQHCs]) and rural providers participating in value-based models to use digital health tools. These policy changes should build on the experiences of FQHCs to date.

As soon as practicable (e.g., in its next annual rulemaking for the QPP), **CMS should** waive payment and program requirements as appropriate to provide flexibility for use of digital health innovations in APMs. Congress has already granted CMS broad authority to implement telehealth use in APMs, but the agency has so far been reluctant to allow its use. For example, Medicare provides telehealth waivers for two-sided ACOs who use prospective attribution. But this limits telehealth's use to a mere 17 percent of ACOs in the Medicare Shared Savings Program. Instead, all ACOs, regardless of risk selection or use of attribution, should enjoy this flexibility.



**HHS should advance the appropriate two-way flow of health information to enhance value throughout the care continuum.**

Actionable, accurate, and accessible data will help to enable the ultimate goal of a fully integrated value-based care system. To this end, policymakers must ensure timely and reasonable interoperability and patient access to health information to improve value-based care coordination and decision-making.

HHS should rigorously enforce ONC information blocking rules<sup>50</sup> (and companion CMS rules<sup>51</sup>) to establish a baseline of behavior for health IT actors. And although **OIG should** consider hardship exemptions for overly burdened entities (e.g., small practices with limited resources and those in rural settings) while ensuring those allowances do not enable flagrant information blocking rule violations by entities that already can comply with the rules. Education efforts for the provider and patient communities will also be key in ensuring that enhanced data flows must go together with further policy development and enforcement.

More widely, realizing value-based care will require enhanced payer-to-payer or provider-to-payer exchanges of data, and policymakers should act to spur wider use of APIs to assist with disparate EHR systems between providers. For example, building on its efforts under the 21st Century Cures Act, **ONC should** update the Trusted Exchange Framework and Common Agreement (TEFCA) and the United States Core Data for Interoperability (USCDI). Such an update should fully support the necessary elements for payer-to-member, payer-to-payer, and payer-to-provider information exchanges. Building on its established approach, **ONC should** follow a predictable, transparent, and collaborative process to expand the USCDI, including proactively soliciting public input to ensure USCDI data elements can be protected through data governance and technical data privacy and security means. Participants in value-based care approaches, including safety net providers like FQHCs, need access to the right data at the right time to deploy much-needed population health tools. Notably, the USCDI needs SDOH data to support APMs, paired with scaled privacy and security measures to protect patient privacy and provide confidence to the ecosystem. Given the sensitivity of SDOH data, CMS should send a clear message that the agency expects information exchange in conjunction with privacy-preserving practices.

As discussed above, USCDI and alignment with ONC's information blocking rules will provide the next (syntactic) level of interoperability. At the same time, stakeholders will also need to agree on the best data categories and elements to then share (semantic). Building on the recommendations from the Health Information Technology Advisory Committee (HITAC) USDCI Task Force,<sup>52</sup> CHI calls on Congress, ONC, the U.S. Food and Drug Administration,<sup>53</sup> and public and private stakeholders to collaborate to standardize categories and elements that will drive semantic interoperability. In addition to enhanced interoperability, continued collaboration between the public and private sectors in this space will demonstrate the substantial return on investment and value to the healthcare ecosystem. Such cooperation will also significantly improve the ability to effectively contract for value-based care arrangements.

**Congress and federal agencies (including HHS, the Federal Communications Commission (FCC), the National Telecommunications and Information Administration (NTIA), and the U.S. Department of Agriculture (USDA)) should take coordinated steps to provide high-speed broadband to America's underserved communities to support the use of digital health tools in advancing value-based care.**

This effort should improve broadband mapping techniques and leverage health data (including SDOH) to identify the areas and communities of greatest need and leverage all opportunities to provide high-capacity broadband wireline and wireless access for those communities. Improved broadband infrastructure is essential to supporting wider use of digital health tools throughout the healthcare value chain that will support greater value in care.

**Congress should modernize privacy and security frameworks to support the use of digital health tools in value-based care scenarios widely.**

With continued uncertainty as to privacy- and security-related obligations and liabilities for providers using digital health tools and preventing their use in providing value-based care, HHS should modernize HIPAA rules and guidance and Congress must act to update statutory health data privacy requirements and approaches. Promoting the privacy-by-design concept and other advanced techniques (e.g., differential privacy, data labeling and segmentation, etc.) builds and maintains trust throughout the ecosystem. Recognizing that a substantial proportion of health-related data now flows and materializes outside of HIPAA's coverage, Congress should update the Federal Trade Commission (FTC) Act to better account for the security and privacy risks presented by the collection and processing of health-related data by entities not subject to HIPAA. Lawmakers should also provide positive incentives to ensure the secure exchange of information (e.g., use of the strongest technical protection mechanisms [TPMs], including end-to-end encryption and multi-step authentication). Further, policymakers should require that organizations provide individuals with transparency about how their health data is collected, used, stored, and shared. Organizations must clearly outline their data privacy policies and practices by providing and attesting to a privacy policy or other public statement. Policymakers should also consider additional actions to ensure conformance to such attestations. Policymakers should also prohibit organizations from knowingly retaining an individual's health data beyond the time appropriate to provide the expected function or service unless otherwise agreed to by the individual or required by law.

Congress and regulators addressing cybersecurity should also leverage scalable risk management frameworks that will enable dynamically identifying and addressing a system's weakest links. Many cybersecurity incidents that impact patient privacy can be prevented through basic cybersecurity hygiene which can be advanced through public-private partnership-driven provider and patient education campaigns. Further, to gain and maintain the trust of providers and patients, incentivizing the use of cutting-edge TPMs and practices that are responsive to patient concerns and expectations is essential. Protecting privacy and providing security is crucial, regardless of whether the data at issue is subject to the requirements of sector-specific rules such as HIPAA or is subject to general consumer protection.

## Conclusions & Next Steps

CHI's Value-Based Care Task Force hopes that the views and recommendations in this paper assist policymakers in their efforts to realize value-based care in the United States (and elsewhere). The guidance in this paper means to prompt new, bold action by policymakers to rapidly shift the American healthcare system to one that rewards quality, not quantity. CHI calls on Congress, the federal agencies, and other policymakers to take steps consistent with the above as soon as possible.

Moving forward, CHI plans to advance the recommendations in this paper and develop further granular proposals under the themes and recommendations raised above. CHI also intends to socialize the views and suggestions in this paper with the broader digital health community and make updates and changes to them that reflect community consensus positions identified.

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