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

View Table 1 Full Size on Page 24

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

Return to Top

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

[2] Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. Ann Fam Med. 2014 Nov-Dec;12(6):573-6. doi: 10.1370/afm.1713. PMID: 25384822; PMCID: PMC4226781.

[3] Coulam RF, Gaumer GL. Medicare's prospective payment system: a critical appraisal. Health Care Financing Review. 1992 Mar;1991(Suppl):45.

[4] Ayabakan S, Bardhan I, Zheng Z. Triple Aim and the hospital readmission reduction program. Health Services Research and Managerial Epidemiology [Internet]. 2021 Jan 1;8:233339282199370. Available from: https://doi.org/10.1177/2333392821993704

[5] Beauvais B, Whitaker Z, Kim F, Anderson B. Is the Hospital Value-Based Purchasing Program Associated with Reduced Hospital Readmissions? Journal of Multidisciplinary Healthcare [Internet]. 2022 May 1;Volume 15:1089–99. Available from: https://doi.org/10.2147/jmdh.s358733

[6] Kaufman BG, Spivack BS, Stearns SC, Song PH, O'Brien EC. Impact of Accountable Care Organizations on Utilization, care, and Outcomes: A Systematic review. Medical Care Research and Review [Internet]. 2017 Dec 12;76(3):255–90. Available from: https://doi.org/10.1177/1077558717745916

[7] Agarwal R, Liao JM, Gupta A, Navathe AS. The Impact of bundled payment on health care spending, utilization, and quality: A Systematic review. Health Affairs [Internet]. 2020 Jan 1;39(1):50–7. Available from: https://doi.org/10.1377/hlthaff.2019.00784

[8] Machta R, Peterson G, Rotter J, Stewart K, Heitkamp S, Platt I, et al. Evaluation of the Maryland Total Cost of Care Model: Implementation Report [Internet]. U.S. Department of Health And Human Services, Centers For Medicare & Medicaid Services. Mathematica; 2021. Available from: https://mhcc.maryland.gov/mhcc/pages/apc/apc_icd/documents/MD_Tcoc_Implementation_Rpt.pdf

[9] The Center for Medicare and Medicaid Innovation. INNOVATION CENTER STRATEGY REFRESH [Internet]. INNOVATION CENTER STRATEGY REFRESH. Available from: https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper

[10] A Decade of Value-Based Payment: Lessons Learned and Implications for the Center for Medicare and Medicaid Innovation, Part 2 [Internet]. Health Affairs Forefront. 2021. Available from: https://doi.org/10.1377/forefront.20210607.230763

[11] CMS, Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19, 85 Fed. Reg. 84830- 84841 (Dec. 28, 2020).

[12] Ying M, Forman JH, Murali S, Gauntlett LE, Krein SL, Hollenbeck BK, et al. Factors affecting ACOs' decisions to remain in or exit the Medicare Shared Savings Program following Pathways to Success. Health Affairs Scholar [Internet]. 2024 Jan 1;2(1). Available from: https://doi.org/10.1093/haschl/qxad093

[13] Ouayogodé MH, Colla CH, Lewis VA. Determinants of success in Shared Savings Programs: An analysis of ACO and market characteristics. Healthcare [Internet]. 2016 Sep 30;5(1–2):53–61. Available from: https://doi.org/10.1016/j.hjdsi.2016.08.002

[14] Markovitz AA, Hollingsworth JM, Ayanian JZ, Norton EC, Yan PL, Ryan AM. Performance in the Medicare Shared Savings Program after accounting for nonrandom exit. Annals of Internal Medicine [Internet]. 2019 Jun 17;171(1):27. Available from: https://doi.org/10.7326/m18-2539

[15] McWILLIAMS JM, Hatfield LA, Landon BE, Chernew ME. Savings or selection? Initial spending reductions in the Medicare Shared Savings Program and considerations for reform. Milbank Quarterly [Internet]. 2020 Jul 22;98(3):847–907. Available from: https://doi.org/10.1111/1468-0009.12468

[16] Bleser WK, Saunders RS, Muhlestein DB, McClellan M. Why do accountable care organizations leave the Medicare Shared Savings Program? Health Affairs [Internet]. 2019 May 1;38(5):794–803. Available from: https://doi.org/10.1377/hlthaff.2018.05097

[17] Kaufman BG, Anderson D, Bleser WK, Muhlestein DB, Smith N, Clough J, McClellan MB, Saunders R. Association of ACO shared savings success and serious illness spending. Journal of Healthcare Management. 2021 May 1;66(3):227-40.

[18] How the most successful ACOs act as factories of Innovation [Internet]. Forefront Group. 2018. Available from: https://doi.org/10.1377/forefront.20180124.514403

[19] Huang H, Zhu X, Wehby GL. Primary care physicians' participation in the Medicare shared savings program and preventive services delivery: Evidence from the first 7 years. Health Services Research [Internet]. 2022 Jul 9;57(5):1182–90. Available from: https://doi.org/10.1111/1475-6773.14030

[20] Khullar D, Schpero WL, Casalino LP, Pierre R, Carter S, Civelek Y, et al. Accountable Care Organization Leader perspectives on the Medicare Shared Savings Program. JAMA Health Forum [Internet]. 2024 Mar 15;5(3):e240126. Available from: https://doi.org/10.1001/jamahealthforum.2024.0126

[21] Saunders R, Bleser W, Japinga M, U.S. Medical Management. Serious Illness approaches by ACOs: U.S. Medical Management [Internet]. CASE STUDY. 2019 Apr. Available from: https://healthpolicy.duke.edu/sites/default/files/2019-11/case_study_1_-_usmm.pdf

[22] D'Aunno T, Broffman L, Sparer M, Kumar SR. Factors that distinguish High-Performing Accountable Care Organizations in the Medicare Shared Savings Program. Health Services Research [Internet]. 2016 Dec 26;53(1):120–37. Available from: https://doi.org/10.1111/1475-6773.12642

[23] Balio CP, Apathy NC, Danek RL. Health Information Technology and Accountable Care Organizations: A Systematic Review and Future Directions. eGEMs (Generating Evidence & Methods to Improve Patient Outcomes) [Internet]. 2019 Jul 8;7(1):24. Available from: https://doi.org/10.5334/egems.261

[24] Bao C, Bardhan IR. Performance of accountable care organizations: health information technology and quality–efficiency trade-offs. Information Systems Research. 2022 Jun;33(2):697-717.

[25] McClellan M, Udayakumar K, Thoumi A, Gonzalez-Smith J, Kadakia K, Kurek N, et al. Improving care and Lowering costs: Evidence and lessons from a Global analysis of accountable care reforms. Health Affairs [Internet]. 2017 Nov 1;36(11):1920–7. Available from: https://doi.org/10.1377/hlthaff.2017.0535

[26] Van De Craen D, De Massari D, Wirth T, Gwizdala J, Pauws S. Leveraging financial analytics for healthcare organizations in Value-Based care environments. In: Springer eBooks [Internet]. 2019. p. 347–67. Available from: https://doi.org/10.1007/978-3-030-05249-2_14

[27] Frank R, Jarrin R, Krumholz HM. The challenge of federal coverage and payment for AI innovation in health care [Internet]. Forefront Group. 2023. Available from: https://doi.org/10.1377/forefront.20230901.949745

[28] Office of the Commissioner. FDA permits marketing of mobile medical application for substance use disorder [Internet]. U.S. Food and Drug Administration. 2017. Available from: https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder

[29] Tang M, Nakamoto CH, Stern AD, Mehrotra A. Trends in remote patient monitoring use in traditional Medicare. JAMA Internal Medicine [Internet]. 2022 Aug 1;182(9):1005. Available from: https://doi.org/10.1001/jamainternmed.2022.3043

[30] Van Kessel R, Roman-Urrestarazu A, Anderson M, Kyriopoulos I, Field S, Monti G, et al. Mapping factors that affect the uptake of digital therapeutics within health systems: Scoping review. Journal of Medical Internet Research [Internet]. 2023 Jul 25;25:e48000. Available from: https://doi.org/10.2196/48000

[31] Stern AD. The Regulation of Medical AI: policy approaches, data, and innovation incentives [Internet]. 2022 Dec. Available from: https://doi.org/10.3386/w30639

[32] Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. Npj Digital Medicine [Internet]. 2020 Feb 6;3(1). Available from: https://doi.org/10.1038/s41746-020-0221-y

[33] Along with significant opportunity to improve patient care, all new technologies in health care will likely present certain risks and limitations that providers must carefully navigate during the stages of clinical implementation of new systems and tools. AI-enabled tools are no different and are perhaps more challenging than other advances as they present novel and complex questions and risks. To best mitigate these risks, it is critical that providers understand AI-driven technologies and have access to certain information about the AI tool or system being considered, including how it was trained and validated, so that they can assess the quality, performance, bias, and utility of the tool to the best of their ability. AI transparency, both in disclosing use to physicians and to patients as well as disclosure of key information to physicians regarding the tools by AI developers and deployers, is an essential component to managing risk and potentially reducing physician liability resulting from the use of AI.

[34] A Five-Level path to AI automation in health care [Internet]. Forefront Group. 2024. Available from: https://doi.org/10.1377/forefront.20240617.335248

[35] Beaulieu-Jones, B.K., Yuan, W., Brat, G.A. *et al.* Machine learning for patient risk stratification: standing on, or looking over, the shoulders of clinicians?. *npj Digit. Med.* 4, 62 (2021). https://doi.org/10.1038/s41746-021-00426-3

[36] Parikh RB, Kakad M, Bates DW, American Medical Association. Integrating Predictive Analytics into High-Value Care: The Dawn of Precision Delivery. JAMA [Internet]. 2016 Feb 16;315(7):651–651. Available from: https://www.jvsmedicscorner.com/Miscellaneous_files/Integrating%20Predictive%20Analytics%20Into%20High-Value%20Care.pdf

[37] These come in many forms and functions, so it is a heterogenous group.

[38] Rosner BI, Gottlieb M, Anderson WN. Effectiveness of an automated digital remote guidance and telemonitoring platform on costs, readmissions, and complications after hip and knee arthroplasties. The Journal of Arthroplasty [Internet]. 2017 Dec 2;33(4):988-996.e4. Available from: https://doi.org/10.1016/j.arth.2017.11.036

[39] Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC) | CMS [Internet]. Available from: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc

[40] Morey JR, Katana M, Li L, Hohmann S, Weber E, Ferket B. Adoption and trends in the Medicare New Technology Add-On Payment Program. Journal of General Internal Medicine [Internet]. 2020 Jun 24;36(7):2174–6. Available from: https://doi.org/10.1007/s11606-020-05930-y

[41] Farmer SA, Ashby LM, Blum JD. Medicare's new pathway for transitional coverage for emerging technologies. JAMA Health Forum [Internet]. 2024 Nov 22;5(11):e243901. Available from: https://doi.org/10.1001/jamahealthforum.2024.3901

[42] Jawad BN, Shaker SM, Altintas I, Eugen-Olsen J, Nehlin JO, Andersen O, et al. Development and validation of prognostic machine learning models for short- and long-term mortality among acutely admitted patients based on blood tests. Scientific Reports [Internet]. 2024 Mar 11;14(1). Available from: https://doi.org/10.1038/s41598-024-56638-6

[43] Stehlik J, Schmalfuss C, Bozkurt B, Nativi-Nicolau J, Wohlfahrt P, Wegerich S, et al. Continuous wearable monitoring analytics predict heart failure hospitalization. Circulation Heart Failure [Internet]. 2020 Feb 25;13(3). Available from: https://doi.org/10.1161/circheartfailure.119.006513

[44] Osenenko KM, Kuti E, Deighton AM, Pimple P, Szabo SM. Burden of hospitalization for heart failure in the United States: a systematic literature review. Journal of Managed Care & Specialty Pharmacy [Internet]. 2022 Jan 31;28(2):157–67. Available from: https://doi.org/10.18553/jmcp.2022.28.2.157

[45] Physician update [Internet]. 2025. Available from: https://www.ama-assn.org/system/files/2025-medicare-updates-inflation-chart.pdf

[46] Peterson DJ, Ostberg NP, Blayney DW, Brooks JD, Hernandez-Boussard T. Machine learning applied to electronic health records: identification of chemotherapy patients at high risk for preventable emergency department visits and hospital admissions. JCO Clinical Cancer Informatics [Internet]. 2021 Nov 9;(5):1106–26. Available from: https://doi.org/10.1200/cci.21.00116

[47] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics [Internet]. 2016 Feb 13;47:20–33. Available from: https://doi.org/10.1016/j.jhealeco.2016.01.012

[48] 510(k) Premarket Notification [Internet]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173681

[49] U.S. Food & Drug Administration, Singh B. Letter from U.S. Food & Drug Administration to Akili Interactive Labs, Inc. regarding EndeavorRx [Internet]. Letter. 2023 Dec. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231337.pdf

[50] Devaraj S, Sharma SK, Fausto DJ, Viernes S, Kharrazi H. Barriers and Facilitators to Clinical Decision Support Systems adoption: A Systematic review. Journal of Business Administration Research [Internet]. 2014 Jul 24;3(2). Available from: https://doi.org/10.5430/jbar.v3n2p36

[51] Watson J, Hutyra CA, Clancy SM, Chandiramani A, Bedoya A, Ilangovan K, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? JAMIA Open [Internet]. 2020 Apr 8;3(2):167–72. Available from: https://doi.org/10.1093/jamiaopen/ooz046

[52] Lin CCC, Dievler A, Robbins C, Sripipatana A, Quinn M, Nair S. Telehealth in health centers: key adoption factors, barriers, and opportunities. Health Affairs [Internet]. 2018 Dec 1;37(12):1967–74. Available from: https://doi.org/10.1377/hlthaff.2018.05125

[53] Council for Technology & Innovation | CMS [Internet]. Available from: https://www.cms.gov/medicare/coverage/determination-process/technology-innovation

[54] Daval CJR, Kesselheim AS. Authority of Medicare to limit coverage of FDA-Approved products. JAMA Internal Medicine [Internet]. 2023 Jul 28;183(9):999. Available from: https://doi.org/10.1001/jamainternmed.2023.3961

[55] Zeitler EP. Coverage with evidence development: where are we now?. The American Journal of Managed Care. 2022 Aug 1;28(8).

[56] E.g., Wu Y, Wu M, Wang C, Lin J, Liu J, Liu S, Evaluating the Prevalence of Burnout Among Health Care Professionals Related to Electronic Health Record Use: Systematic Review and Meta-Analysis, JMIR Med Inform 2024;12:e54811, doi: 10.2196/54811.

[57] Pham HH, Berenson RA, Cavanaugh S. Using the Medicare Shared Savings Program to innovate primary care payment [Internet]. Forefront Group. 2022. Available from: https://doi.org/10.1377/forefront.20221013.766203.

ConnectedHealthInitiative