Connected Health Is Here! Are You Ready?

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Health care delivery is changing rapidly with the explosion of technological innovation and the availability of connected health tools. Health systems and payers nationwide are using connected health to meet the cost-savings goals of delivery system reforms. As private entities and the government look to bend the cost curve, the ability to use technology to minimize the costs of providing services and to change how services are provided will be significant. In addition, technology that drives convenience and individual engagement is beginning to change expectations in health care, just as it has in other industries.

As a result of these trends, there is much optimism for connected health, but there is also uncertainty and challenges. This article will define connected health, discuss federal policy that is affecting the market for connected health, and discuss challenges that must be addressed. As health care providers and health plans begin to think about incorporating these new products and services, understanding the risks and opportunities can help health care organizations become leaders in connected health and support improved patient satisfaction and outcomes.

What Is Connected Health?

There are many different terms used to talk about changes in health care delivery enabled by technology. For purposes of this article, we define key terms as follows:

- *"Connected health"* is a model for health care delivery that uses technology to connect providers and patients, deliver patient care, or manage health outside of the hospital or doctor's office, including telehealth and remote patient monitoring, with the goal of improved engagement and health outcomes.
- *"Telehealth"* (also called virtual health) is the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance."[1] Telehealth encompasses a broad definition of technology-enabled health care services and involves a wide range of telecommunications, health information, videoconferencing, and digital image technologies.[2]
- *"Remote patient monitoring"* occurs when digital technologies transmit data from an individual in one location to a provider in a different location for assessment and recommendations.[3]

What Federal Policies Are Driving or Limiting Connected Health Activities?

There is limited but growing recognition of the value of telehealth and remote patient monitoring under Medicare and Medicaid as well as other programs. Department of Health and Human Services (HHS) "Delivery System Reform" efforts[4] are leading the Centers for Medicare & Medicaid Services (CMS) to consider and incorporate creative and alternative ways to pay for value.

Traditional Federal Health Care Payment Policy

Medicare

Reimbursement for telehealth has been permitted under Medicare since the Balanced Budget Act of 1997[5], but has been long criticized for its limited coverage. The Medicare Fee-For-Service (FFS) Program reimburses telehealth services[6] under certain scenarios. As a condition of payment, eligible providers must use an interactive audio and video telecommunications system that permits real-time communication between the provider at the "distance site"[7] and the beneficiary at the "originating site."[8] Each of these conditions adds restrictions that limit the ability to use telehealth under Medicare. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either: (1) a rural Health Professional Shortage Area located either outside of a Metropolitan Statistical Area (MSA) or in a rural census tract; or (2) a county outside of an MSA. Telehealth services offered outside of these regions are not reimbursed under Medicare. Currently, while there is nothing to preclude Medicare Advantage organizations (MAOs) from providing telehealth, those services are not separately paid for by Medicare.

Medicaid

Reimbursement under Medicaid has similar restrictions. Under Medicaid, "telemedicine" means two-way, real-time interactive communication between the patient and a practitioner at the distant site.[9] This requirement for real-time communication using a/v equipment limits options for connected health. States have the flexibility to cover telemedicine services, the types of telemedicine to cover, where it can be covered, how it is provided, and how much to reimburse for it.[10] CMS encourages states to "use the flexibility inherent in federal law to create innovative payment methodologies for services that incorporate telemedicine technology."[11] For example, states may reimburse both a provider at a distant site and reimburse a facility fee to the originating site. Given variations in state laws, however, use of telemedicine across state borders may not be reimbursed.

Delivery System Reform

HHS is focused on Delivery System Reform to provide better care, promote smarter spending, and improve health outcomes. The goals are to shift a substantial number of Medicare providers to Alternative Payment Models (APMs) focused on how well providers care for their patients, and to tie virtually all Medicare FFS payments to quality and value.[12] And there is emphasis on making data more available for use by clinicians, patients and researchers.

Health IT Policy and Connected Health

Interest in connected health has grown as a result of the Office of the National Coordinator for Health Information Technology's (ONC's) inclusion of a goal on consumer e-Health[13] in the "Federal Health Information Technology Strategic Plan 2011-2015."[14] This came against a backdrop of a growing number of mobile health tools and interest in leveraging technology to support increased consumer engagement. Objectives included improving patient and caregiver access to patient health information and integrating patient-generated health information to support patient-centered care. Since then, ONC and CMS have built consumer engagement and connected health into their programs.

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Medicare and Medicaid EHR Incentive Programs (Meaningful Use)

The Health Information Technology for Economic and Clinical Health (HITECH) Act established incentive payments and avoidance of downward payment adjustments to eligible professionals (EPs), eligible hospitals (EHs), critical access hospitals, and MAOs to encourage the adoption and meaningful use of certified electronic health record technology (CEHRT).[15] ONC published rules setting standards and certification requirements for CEHRT to support the achievement of Meaningful Use and support the goal of a nationwide health information network. CMS published rules establishing increasing requirements for "meaningful use" of CEHRT, including requirements for the electronic capture of clinical data and increasing interoperable health data sharing among providers.

The ONC 2015 Edition Health Information Technology Certification Criteria Rule[16] and the CMS Meaningful Use Stage 3 Rule[17] lay the foundation for the growing use of connected health tools to support consumer engagement, including remote patient monitoring tools. Specifically, the ONC rule adopted criteria for EHRs to support "patient health information capture," which was intended to require at least one means for accepting patient health information directly and electronically from patients in the most flexible manner possible. The companion CMS Meaningful Use rule requires patient generated health data, or data from a nonclinical setting, to be incorporated into the CEHRT for a subset of patients. CMS notes that the sources of data may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient-reported outcome data, and other methods of input for patient and non-clinical setting generated health data.[18]

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

Recently finalized MACRA rules are mixed with respect to promoting connected health. MACRA repealed the Medicare sustainable growth rate and replaced it with the Merit-Based Incentive Payments System (MIPS) and APMs.[19] MACRA sunset the Meaningful Use payment adjustments for EPs (but not EHs and others) under the Meaningful Use Program at the end of calendar year 2018 and incorporated it into MIPS.

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The final MIPS provisions under the MACRA rules are a setback for connected care. They change the term "meaningful use" to "advancing care improvement" and dramatically cut back on the requirements for Meaningful Use.[20] They made optional for EPs the patient generated health information provisions and the practice of ensuring that patients "view, download and transmit" data from an EHR, which were required under Meaningful Use. Furthermore, while the MACRA statute specifically identified inclusion of telehealth and remote monitoring under new requirements regarding clinical practice improvement,[21] CMS missed the opportunity to encourage this in its regulations.

The true opportunity for leveraging telehealth and remote monitoring of patients under MACRA is the push for participation in APMs. APMs are an alternative to Medicare FFS and incorporate quality and total cost of care into reimbursement. Connected health tools can help support these goals. MACRA clarifies that providers in APMs may provide telehealth services even if the service is not reimbursed under the Medicare fee schedule.[22] Under MACRA, providers who participate in a Medicare or Other Payer Advanced APMs can opt to participate in the APM pathway and potentially receive a positive payment adjustment. To meet the criteria under the APM pathway, participants must use CEHRT, among other criteria.[23]

Other Policies

Many other programs support connected health:

- *Patient-Generated Health Data (PGHD):* ONC continues to promote the use of PGHD and is currently engaged in a two-year effort to develop a policy framework and conduct pilot demonstrations to test implementation.[24]
- *Chronic Care Management:* CMS has a new chronic care management FFS billing code enabling reimbursement of health care providers for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions.[25]

Legislative Efforts

Proposed legislation offers promising incentives that would bridge some of the current reimbursement gaps related to geographic restrictions under Medicare and would provide reimbursement for telehealth services under MAOs.

The Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT for Health) Act was introduced in Congress in 2016.[26] The bill would promote adoption of telehealth and remote patient monitoring services through additional FFS coverage in various clinical scenarios. It also would allow MAOs to provide benefits under the original Medicare FFS program using telehealth services by waiving certain limitations. Additionally, it would establish a telehealth and remote patient monitoring services "bridge" demonstration waiver program, through which CMS would waive requirements as a condition of payment for telehealth services for providers participating in qualifying APMs under MACRA.

The Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2016 (CHRONIC Care Act) is a draft bill.[27] It aims to improve adoption of telehealth. The bill would expand locations at which telehealth can be used by renal dialysis patients, improve the convenience for MAO enrollees, and provide Accountable Care Organizations (ACOs) the ability to expand use of telehealth.

Private Sector and Real World Applications

Private Insurers

Connected health coverage policies vary amongst private payers: some health insurers do not cover telehealth services, while others provide comprehensive coverage. UnitedHealth Group offers telemedicine visits for provider networks that connect physicians and patients via mobile device, tablet, or computer, covering more than 10 million UnitedHealth members.[28] Anthem uses LiveHealth Online to connect patients with providers via real-time audio and video chat as an alternative to costly visits, such as emergency room and urgent care.[29] Many insurers and employers use telehealth providers (e.g., Teledoc, Doctor on Demand, and American Well) to provide services for beneficiaries. The American Well mobile smartphone application, which connects app users to a doctor, has been downloaded by consumers 1.2 million times. Although less than half of the states require insurers to reimburse providers for telehealth services in ways comparable to reimbursement provided for in-person services,[30] there is a growing trend amongst private payers to cover these services.

Payers also recognize the value of remote monitoring devices. In September, Aetna announced that it will subsidize the cost of the Apple Watch in order to "revolutionize members' consumer health experience."[31] Aetna is developing integrated health apps for Apple products, including for care management and wellness and medication adherence, to improve consumers' ability to manage their health and increase healthy outcomes.

Health Care Providers

Use of connected health tools is becoming more widely accepted among U.S. hospitals. A recent survey found that 81% of respondents stated that their organization uses at least one connected health tool and 67% reported deploying multiple solutions across their organization.[32] Many hospitals and health systems have established their own innovation platforms,[33] and most are using connected health tools.[34]

Many believe these tools promise improvements in health and health care at lower cost. Although there is limited data on the financial benefits of connected health, health systems around the country are embracing connected health and seeing substantial financial benefits. For example, HealthCare Partners, a DaVita Medical Group, operates in three states and launched a successful remote patient monitoring program for patients age 65 and older with chronic conditions and reduced hospital admissions and emergency room visits. In the first year, the program provided a return on investment of 30%.[35]

While such programs demonstrate the promise of connected health, more studies need to be conducted to develop the evidence needed for providers and payers to select the right tools for the right patients. Efforts are underway to try to quantify the benefits of connected health tools, including the Network of Digital Evidence in Health (NODE Health) which brings evidence-based medicine together with emerging health care technologies in an effort to share information and publish and disseminate results.

Challenges

Reimbursement

While government regulations seek to reward providers offering connected health services, Medicare does not currently reimburse for these services in large regions of the country, and various telehealth services remains uncovered. In 2015, Medicare paid only $17.6 million for telemedicine services.[36] While this represents an increase of approximately 25% from the year prior, it is nonetheless a fraction of the $634 billion program. Comprehensive telehealth coverage by Medicare would increase the likelihood and rate of adoption by private payers. As federal government incentives encourage the use and adoption of connected health tools, health systems will increase their technological capabilities, creating the network and infrastructure necessary for private payers to reimburse telehealth services on a more widespread basis.

State Laws

Varying policies and regulations across state lines create complexity and uncertainty. Medical licensure falls under the authority of states, which determine provider qualifications, services and circumstances for providing health care, and patient protections. Most states require providers to be licensed in the state in which the patient receives care which is problematic for telehealth services that may extend beyond state borders. Likewise, if a patient receives telehealth or remote patient monitoring services out-of-state, it can be difficult for both the patient and the provider to know which state's laws apply. This uncertainty creates risk and chills the use of telehealth services. Additionally, some states require patients to be seen in the office first before a receiving telehealth services, significantly limiting the application and potential benefits of telehealth and remote patient monitoring.

Privacy and Security Risks

Privacy and security remains a critical concern when considering new uses of technology to capture and share health information. Protections of patient and beneficiary data is governed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[37] HIPAA privacy and security rules do not prohibit the use of connected health tools; however, confusion about how the rules apply, heightened concerns about security threats, and the prospect of fines lead some entities to avoid using such tools. The HHS Office for Civil Rights, which enforces the HIPAA rules, has provided guidance to support the use of connected health tools.[38] For entities already employing connected health tools, it is critical to include the use of these tools in security risk assessments and mitigation strategies.

Safety and Effectiveness

Lack of consistent oversight of safety and effectiveness leads to hesitation by developers to invest in connected health tools and hesitation by providers and payers to adopt these tools. The U.S. Food and Drug Administration (FDA) released

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mobile medical application guidance[39] and also released the Food and Drug Administration Safety and Innovation Act (FDASIA) health information technology (health IT) oversight framework[40] to clarify that it will take a risk-based approach to the oversight of health IT functionality and will exercise enforcement discretion over various health IT tools. Despite the issuance of this guidance, many questions remained. Congress responded through the 21st Century Cures Act by limiting the FDA's enforcement of certain connected health tools. However, this change in FDA authority still leaves HHS with discretion to oversee medical software functionality, continuing to leave technology developers with uncertainty over how the government's authority will be used in the future.

Fraud and Abuse

With new services come new relationships between parties that may raise fraud and abuse concerns. Connected health innovators are looking for ways to share in the benefits that these services can provide, and these new tools and service relationships can lead to scrutiny under the fraud and abuse laws. Health care institutions must ensure that the provision of connected health tools and related payment arrangements comply with federal and state fraud and abuse laws, such as the Stark Law[41] and Anti-Kickback Statute.[42] Certain waivers and legal exceptions may apply to such arrangements that would allow for greater ease of adoption and use.

Policy Changes on the Horizon

The biggest challenge of all is the uncertainty on the horizon resulting from a change in administration. While there has been limited policy discussion by the Trump administration regarding health IT and connected health tools, significant change is anticipated in health policy, including fundamental changes to the Affordable Care Act and efforts to reduce regulatory burden. That said, we believe the supply and demand for connected health tools will continue through the Trump administration, considering the momentum by developers and the technological investments made by providers and payers. Given the potential for cost-savings, we expect the new administration and the Republican-led Congress will support value-based care and continue to encourage private sector innovation.

Conclusion

Government and private payer policies are shifting toward the use of connected health; CMS payment policies provide some financial incentives. ONC continues to push the policy framework and technical capabilities to support connected health. And OCR continues to issue guidance supporting the use of connected health tools by HIPAA covered entities. More importantly, innovation in the market is soaring; private payers increasingly are covering telehealth services; the practice of clinicians and health systems using connected health tools, such as telehealth and remote monitoring, is gaining significant traction; and consumers are beginning to demand these tools. We will likely see increasing adoption of connected health services by hospitals and providers as health care systems move toward APMs, where payment is based on outcomes rather than procedures. And as data on the financial benefits of connected health become increasingly available, private payers are likely to offer and develop such services as a cost-savings strategy.

This is a growing area of health care, and despite current challenges, presents significant opportunities for health care improvement. If you are not considering connected heath, now is the time!

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