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ANALYSIS

Building A Regulatory And Payment Framework Flexible Enough To Withstand Technological Progress

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ABSTRACT The evolution of digital health is entwined with federal regulation and policy. Whether considering what is or is not a medical device, the reimbursement for digital medical technologies, or physician services under Medicare or Medicaid related to remote patient monitoring or telehealth, the rules and policies governing digital health have not been easy to distinguish. In the face of rapid innovation, it has been difficult to fit these products and services into existing regulations of the Food and Drug Administration and the Centers for Medicare and Medicaid Services, particularly when these frameworks never contemplated what communications technologies can do today. Instead, rules have been misapplied, and in some cases, they have hampered the use of these technologies, depressing the proliferation of associated services. However, regulations have begun to change. We discuss the policy and regulatory changes that have begun to evolve and where they should continue to head.

In the mid-1980s several technological advances such as analog fax machines, first-generation (1G) cellular telephones, and personal computers that operated at 64 kilobits per second ushered in a new era of medical practice. What is popularly called telemedicine collapsed time and space, allowing instant access to medical services unlike ever before. Initially it was performed using point-to-point connections, typically with a dedicated T1 line, conducting live virtual interactive face-to-face sessions between physicians and patients. For the first time, the stuff of science fiction and Hollywood dreams began to seem possible, using advanced communications technologies. Doctors were now able to provide live consultations via video communications with patients who were hundreds, if not thousands, of miles away. Audio/video technology could now deliver evaluation and management services that had typically been conducted in person. Early on, many telemedicine projects were supported by grants, typically to academic medical centers that were gathering evidence.

By the 1990s innovators had begun developing telemedicine services delivered over the internet, including the development of store-and-forward models of service, such as Nighthawk remote radiology interpretation and pathology slide review services. But despite how these advancements promised to upend health care, their use and adoption remained low and mostly relegated to services between large urban medical centers and rural hospitals and providers.

Several factors impeded the proliferation of telemedicine, including reluctance by the medical community to embrace new and unfamiliar technologies, ambiguous yet restrictive regulations governing this innovative space, and a lack of financial incentives or reimbursement

for medical services provided through these technologies. It was not until 2000 that payment for telehealth services was covered by the Centers for Medicare and Medicaid Services (CMS) and added to the Social Security Act, and it wasn't until 2001 that CMS created a definition for what it considered to be a "telecommunications system," which required live voice and video. But despite the lagging regulatory payment framework and restrictive modality of live voice and video, physicians and other qualified health care professionals continued slowly but steadily to adopt telemedicine for services such as patient history, virtual physical examinations, remote diagnoses, and managing patients at a distance from practitioner's offices.

Over the past forty years the increasing capabilities of digital communications technologies have led to a metamorphosis of traditional telemedicine services that paved the way to the growing field of digital health. As this area continues to evolve, digital health tools, mobile health apps, artificial intelligence, wearable sensors, and chatbots are becoming more common in the delivery of health care services.

Old Regulations And New Technologies

The ability to track patient-generated health data and how those data flow between the provider and anyone else has made it difficult to fit these continually evolving products and services into existing regulations, particularly medical device regulations and reimbursement. The Medical Device Regulation Act of 1976 was introduced in Congress after a finding by the Senate that faulty medical devices had caused 10,000 injuries, including 731 deaths.[1] The law applied safety and effectiveness measures to new devices. The intent by Congress was to cast a wide net and make sure that any devices made available for use and intended for medical purposes in humans or animals would be adequately identified and regulated accordingly. There is still no simple regulatory designation for what is, or is not, a medical device. Rather, the test relies partly on whether a product is labeled, promoted, or used in a manner that meets the definition of a *device*. The definition in part describes how a device can be anything that is intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.[2] This definition proved problematic as everyday technologies began to be used in ways that infringed on that definition while tracking general health and fitness.

Entrepreneurs today enjoy the scalability of broadband services through wireless and mobile platforms. This development fostered capabilities such as 24/7 remote telestroke consultation services and, later, patient-centered online acute care through a portal on a computer or smartphone. The result has been myriad interconnected technologies that create new medical services through converged medical devices using software in a medical device (SiMD) or software as a medical device (SaMD). Interactive services use internet-to-cloud-based systems through an arrangement of wired, wireless, and mobile interfaces. Smartphones and tablets have now become commonplace, while innovators have leveraged their increased processing power, decreased battery consumption, reliable connectivity, perpetual location-based services, high-definition graphics, and multimedia capabilities.

The Food And Drug Administration Encounters Innovation

As health care innovation increased, traditional device manufacturers and nontraditional developers remained cautious about where the regulatory boundaries lay. What was and was not regulated as a medical device by the Food and Drug Administration (FDA) became a national debate, often played out in the press and Congress.[3,4] As Karen Rheuban and coauthors have described, regulatory policy had lagged innovation at every stage in the evolution from telemedicine to digital medicine.[5] The FDA was a notable exception. It set out to aggressively provide clarity and predictability on existing regulations that covered digital health products by exercising its authority through rule making, guidance, and other initiatives, including the creation of its Digital Health team within the Center for Devices and Radiological Health. For example, as early as 2011 the FDA finalized a rule that reclassified Medical Device Data Systems (MDDSs)—devices that transfer, store, convert, or electronically display medical device data from class III (highest risk, requiring premarket approval) to class I (lowest risk, requiring general controls). Just a few years later the FDA placed MDDS products under "enforcement discretion"—a mechanism by which the FDA will not enforce requirements under the Food, Drug, and Cosmetics Act[6] (in 2016 Congress would deregulate those products).

But starting in 2011 the FDA would begin to issue significant guidance documents—such as those for mobile medical apps, MDDSs, cybersecurity, general wellness, accessories, and the Food and Drug Administration Safety and Innovation Act of 2012. Some of these guidance documents placed low-risk digital medical devices under enforcement discretion.[6,7] On Decem-

ber 13, 2016, the 21st Century Cures Act was signed into law by President Barack Obama. The act clarified which digital health applications constitute medical devices and which functions will not be regulated as devices (for example, administrative or clinical support, promoting healthy lifestyle or wellness, maintaining electronic patient records, and transferring or storing medical device data), as well as removing certain software functions from the *device* definition. Congress accomplished this by "codifying" (that is, formalizing) several guidance documents that the FDA had issued exercising enforcement discretion on general wellness, mobile medical applications, off-the-shelf software, and MDDSs.

It could be argued that those guidances created the environment for innovators to develop technologies that passively, actively, or in real time remotely monitor patients or the most chronically ill—in turn leading to the increased use and proliferation of digital health products (both regulated and not regulated). Popular digital medical devices include Bluetooth-connected weight scales, finger-prick blood glucose monitors, blood pressure cuff monitors, and peak flow meters, which are all capable of sending physiologic readings to physicians for virtual review. Increasingly, wearable sensors and devices can capture data streams for continuous monitoring. In some instances, alerts derived by algorithms may be sent to the patient's nurse, physician, or loved one when out-of-range data points or irregular trends are detected. Digital medicine aims to produce rapid intervention and change management. It is hoped that active monitoring will lead to better health outcomes when treating heart failure, type 2 diabetes, and asthma.

Additionally, artificial intelligence (AI) will soon be deployed in medicine to manage complex data. In June 2017 the FDA announced the Digital Health Innovation Action Plan. The plan outlined the FDA's imminent efforts to foster digital health innovation in several ways, including by issuing guidance to provide clarity on the medical software provisions of the 21st Century Cures Act and launching the innovative pilot program to precertify health software called Pre-Cert.[8] The program is a new regulatory paradigm that focuses on a manufacturer or developer as opposed to the medical device it is producing. The program proposes to develop assessment criteria for organizations that perform "high-quality software design, testing, and monitoring" along with having a demonstrated "culture of quality and organizational excellence" and a commitment to monitoring product performance.[9] Pre-Cert addresses a way for SaMD product developers to respond to glitches, adverse events, and safety concerns in a quick manner. Citing artificial intelligence's promise for the future of medicine, on April 26, 2018, FDA Commissioner Scott Gottlieb announced the agency's active involvement in developing a new regulatory framework to promote AI innovation and support the use of AI-based technologies and the benefits of machine learning, which enables the technology to learn and improve as it is used.[8]

Medicare And Medicaid Rules On Telehealth

MEDICARE Medicare's rules and regulations for remote physician services have not kept pace with the exciting developments in the field of digital health. Payment for telehealth services was added to the Social Security Act in 2000.[10] Section 1834(m) of the Social Security Act had stipulated payment for telehealth services that are furnished via a telecommunications system by a physician, but the term *telecommunications system* was not defined in that section or any other provision of the Social Security Act. That allowed CMS, through rule making, to do so.

In the final rule for the 2001 Physician Fee Schedule, CMS promulgated a regulation that establishes billing rules for Medicare telehealth. In that regulation CMS offered a definition of *interactive telecommunications system* that included "audio and video equipment permitting two-way, real-time interactive communication between the patient and distant-site physician or practitioner," thus limiting telehealth to live voice and video communications. The regulation stated that "telephones, facsimile machines, and electronic mail systems do not meet the definition of interactive telecommunications system;"[11] as a consequence, neither do modern non-face-to-face monitoring technologies that make up the bulk of digital health.

Additionally, the regulation requires that the technology must be synchronous (that is, no store and forward unless as part of a federal demonstration project in Alaska or Hawaii); the beneficiary must present in a Health Professional Shortage Area and not in a Metropolitan Statistical Area; the service must originate in a site as stipulated by CMS (such as a skilled nursing facility, hospital, or mental health facility); and the distant-site practitioner must be a doctor, nurse, or other stipulated medical professional. Section 1834(m) of the Social Security Act also defined the term "telehealth services," to mean professional consultations, office visits, and office psychiatry services, and it allows the secretary of health and human services to specify

additional Medicare telehealth services using an annual process to add or delete services from the Medicare telehealth list, which currently includes psychotherapy, pharmacologic management, nutrition therapy, smoking cessation, transitional care management, and services related to end-stage renal disease, to name a few.

For a long time, the lack of remote (that is, not face-to-face) patient monitoring payment options in Medicare forced digital health services to be incorrectly categorized as telehealth—an impossibility given the modality restrictions. The rigid requirements governing telehealth services meant that few providers could appropriately offer those services, and then only in discrete locations and specific situations. This may be why reimbursement for telehealth represents a small fraction of the Medicare budget. In 2016 that budget was approximately $588 billion, while the level of telehealth reimbursement was $28.7 million, up from $22.4 million in 2015.[12] In recent years Medicare has instituted several telehealth service waivers on originating sites and geographic restrictions for programs such as the Bundled Payments for Care Improvement initiative, Medicare Shared Savings Program accountable care organizations (ACOs), Next Generation ACOs, and the Comprehensive Care for Joint Replacement model.

MEDICAID Medicaid has a different set of regulations, and interestingly, under Medicaid, the term *telemedicine* has a different and more expansive meaning where it is considered to be a cost-effective alternative to face-to-face services delivered by a provider to a patient. States can choose to cover telemedicine services under Medicaid, although the federal Medicaid statute does not recognize telemedicine as a distinct service. Medicaid's policy regarding telemedicine includes the use of telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices used to collect and transmit patient data for monitoring and interpretation.[13] While they do not meet the Medicaid definition of *telemedicine*, they are often included under the broad umbrella of telehealth services and may be covered and reimbursed as part of a Medicaid-coverable physician service.[13] In fact, states are encouraged by CMS to create payment methodologies for innovative services including telemedicine and can reimburse costs such as those of technical support, transmission charges, and equipment. States have the flexibility to determine whether to cover telemedicine, what types of telemedicine to cover, where in the state it can be covered, how it is covered, and what types of providers may be reimbursed—as long as the providers are recognized and qualified according to Medicaid statutory regulations, and the reimbursement for telemedicine services does not exceed federal upper limits.[13]

An Evolving CMS

In 2013 CMS began exploring separate payments for non-face-to-face services through Transitional Care Management (TCM) and, soon after, Chronic Care Management (CCM). For TCM, Medicare would allow telephone, email, or services furnished via telehealth. For CCM, Medicare would allow access to care and care continuity by telephone, secure messaging, secure internet, or other asynchronous non-face-to-face consultation methods (for example, email or secure electronic patient portal). Despite the limits CMS placed on allowable technologies for TCM and CCM services, studies provided evidence that these services could result in cost savings.[14]

In 2015, in conjunction with the Office of the National Coordinator for Health Information Technology, CMS issued a final rule on stage 3 of the Electronic Health Record Incentive Program and modifications to meaningful use. Included was a new objective for the "coordination of care through patient engagement" that involved the use of application program interfaces; view/download/transmit; secure messaging; and the ability to upload patient-generated health data into the EHR.[15,16] The last point was noteworthy because data generated by a patient or a patient's authorized representative included medical device data; home health monitoring data; fitness monitor data; nutritional, home-use medical device data; patient-reported outcome data; and so on.

Eventually, meaningful use would be absorbed into the Quality Payment Program of the Medicare Access and Chip Reauthorization Act (MACRA) of 2015.[17] MACRA changes how Medicare pays health care providers by ending use of the Sustainable Growth Rate formula and creating a new framework to reward providers for better health care by combining existing quality reporting programs into one new system. The enactment of MACRA provided renewed hope for the advancement of telehealth and remote monitoring technologies. Congress provided statutory references in the act for telehealth and remote monitoring. However, CMS initially all but ignored telehealth and remote monitoring during its rule making. Later in 2017 CMS proposed a new improvement activity measure for beneficiary engagement with digital health tools. Providers could engage patients using digital tools for ongoing guidance and assessments outside of face-to-face encounters, including patient-generated health data, to make recommendations for changes in management.[18]

Remote Patient Monitoring Is Not Telehealth

In the 2018 Medicare Physician Fee Schedule, CMS delivered a declarative policy statement on remote patient monitoring services. "Comment Solicitation on Remote Patient Monitoring" specifically sought comments on whether to make separate payments for *Current Procedural Terminology*(CPT) codes that describe remote patient monitoring.[19] CMS would specify that remote patient monitoring services would not generally be considered Medicare telehealth services as defined under section 1834(m) of the Social Security Act; rather, "these services involve the interpretation of medical information without a direct interaction between the practitioner and beneficiary. As such, they are paid under the same conditions as in-person physicians' services with no additional requirements regarding permissible originating sites or use of the telehealth place of service code." CMS was particularly interested in CPT code 99091, which was a decades-old medical service code that was bundled with no assigned payment or coverage.

Of note, CMS had no commonly recognized type of service for remote patient monitoring. A 2017 Government Accountability Office report on telehealth and remote patient monitoring highlighted the facts that CMS had not even conducted a separate analysis of remote patient monitoring services and that the number of Medicare beneficiaries who used this service was unknown.[20] A Medicare Payment Advisory Commission report showed that in 2014 Medicare had spent more than $189 million for remote cardiac monitoring services and for remote monitoring of heart rhythms through implantable devices such as pacemakers.[21] But there was no federal reimbursement for remote patient monitoring of physiologic data as derived from mobile or home-use medical devices such as weight scales, blood pressure monitors, pulse oximeters, glucometers, thermometers, and asthma inhaler sensors.

In the 2018 Physician Fee Schedule final rule,[19] CMS unbundled and established a separate payment for CPT code 99091. CMS noted that monitoring services could be a significant part of ongoing medical care, and "we should recognize these services for separate payment as soon as practicable," starting on January 1, 2018. Moreover, the activation of CPT code 99091 would serve to facilitate these services in the short term and further implied that CMS was aware that the American Medical Association's Digital Medicine Payment Advisory Group was in the process of developing new CPT code proposals for different types of remote physiologic data monitoring and other digital medical services.[22] Indeed, three new remote patient monitoring code proposals were approved by the CPT Editorial Panel on September 15, 2017, and the codes would be considered by CMS in the 2019 Physician Fee Schedule proposed rule.[23] CMS would go on to establish payment and coverage for chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457), effective January 1, 2019.

The creation of CPT codes is a well-known rigorous and evidenced-based process that includes the input of physicians, researchers, statisticians, medical societies, attorneys, and economists. Quite simply, the application process for CPT codes demands clinical evidence to justify the formation of new codes. The chronic care physiologic monitoring codes were no exception, and CPT relied upon a vast body of evidence. It is important to also note the systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ)[24] and the meta-analysis of quality measures by the National Quality Forum (NQF),[25] both of which analyzed a large and disparate body of evidence about telehealth and remote patient monitoring. AHRQ's evidence map included the finding that "a large volume of research reported that telehealth interventions produce positive outcomes when used for remote patient monitoring, broadly defined, for several chronic conditions and for psychotherapy as part of behavioral health."[24]

Other positive research reports have highlighted the opportunities presented by remote patient monitoring of physiologic patient-generated health data, such as those by Accenture Federal Services,[26] the Brookings Institution,[27] the World Economic Forum,[28] and Deloitte Consulting Services.[29] All of this confirms that positive evidence does exist and may be why CMS's interest in remote patient monitoring would not end with the 2019 Physician Fee Schedule proposed rule. Weeks before, CMS also posited in the 2019 Home Health Prospective Payment System Rate Update proposed rule[30] that a change might be considered in regulations (at 42 CFR 409.46) to include the costs of remote patient monitoring as allowable administrative costs. Additionally, in the same notice CMS is considering requiring home infusion therapy suppliers to provide remote monitoring for the provision of home infusion and home infusion drugs.

Learning From The Past To Meet Future Needs

Since the mid-1980s the speed with which innovators have delivered technology has greatly outpaced policy, regulation, and legislation.[5] One

needs to go no further than the example of telehealth. Existing regulations never contemplated how communications technologies would transform society. Worse, as described above, some of these regulations were misapplied to seriously undermine and hamper the use of technology and potentially deprive those who most need services. However, since the early part of this decade—albeit slowly—regulations have begun to change.

Take, for example, the FDA, which clearly embraced the digital health movement. Through the proactive use of policy levers within its statutory authority, such as the aggressive issuance of guidance documents, the use of enforcement discretion, and exploratory agency initiatives, the FDA shed its conventional approach to help speed innovation. In exchange, it set out to focus on higher-risk digital medical devices. Some have questioned whether the FDA has gone too far toward deregulation. Its proposed Pre-Cert is a case in point. Although well-intentioned, Pre-Cert has been the subject of skepticism for its shift from pre- to postmarket review, and from oversight by the FDA to oversight by independent, nongovernment certifiers.[31] Even more curious have been several de novo device decisions by the FDA related to electrocardiogram mobile medical apps but not the hardware platforms they are run on—in essence, defying decades' worth of established FDA regulations and precedents.

Add to this numerous FDA initiatives, programs, and pathways that seek to advance innovation by aiming for greater efficiency and consistency, and it is fair to question whether the overwhelming number of efforts are beginning to convolute the predictable policy levers that the FDA has effectively employed in the past. Predictability of government policy and regulations is critical to innovation, whether in research, investments, a level playing field, or—most importantly—the development of medical devices, so they remain safe and efficacious.

Congress has also been busy assessing digital health device regulations and telehealth reimbursement. At any given time over the past few years, dozens of bills have been introduced dealing with telehealth. An example of congressional action related to medical devices was the passage of the 21st Century Cures Act. Congress was looking to exempt from regulation certain software device functionalities, including clinical decision support. However, the statute may have created more questions than it answered, particularly about software exemptions such as clinical decision support and functions of multiple-purpose devices. In fact, the 21st Century Cures Act may have contributed to uncertainty, making the FDA's stance on software less predictable—an unfortunate negative consequence.

On telehealth reimbursement, Congress has been diligent, including passage of the Bipartisan Budget Act of 2018, which expanded the use of telehealth within certain Medicare programs. However, those expansions and many other proposed bills are still very much subject to the arduous restrictions and modality limitations under section 1834(m) of the Social Security Act and the corresponding rules.[10] A reason for this could be the cost estimates by the Congressional Budget Office (CBO) for legislative proposals related to telehealth and remote patient monitoring. "Scoring," as it is called, analyzes health care legislative proposals and whether they could substitute for existing Medicare-covered services or reduce the use of those services. Simply stated, any telehealth or remote monitoring bill that receives a high CBO score is essentially doomed from the start. Because Medicare coverage of telehealth and remote monitoring was limited, the CBO argued that it did not have extensive data that could help project how expanding such coverage would affect federal spending in the Medicare program.[32] Thus, most telehealth and remote monitoring bills ended up with a high CBO score. However, given the vast and growing amount of data on these technologies—as demonstrated by the reviews of AHRQ[24] and the NQF[25]—it is difficult to justify the CBO's position. It will be interesting to review CMS's utilization data related to CPT codes 99091, 99453, 99454, and 99457, and how that may factor into the CBO's scoring.

Despite limited congressional action on digital health reimbursement, in the past two years CMS has made substantial advances in distinguishing remote patient monitoring services from telehealth and, more importantly, providing coverage and payment for these services. As mentioned above, in several proposed rules CMS has asserted that remote patient monitoring, although a service using a form of telecommunication, is not a Medicare telehealth service and not subject to telehealth statutory or regulatory restrictions. This exclusion of remote patient monitoring from telehealth is fundamental to reimbursement for associated physician services, showing once again how an agency's statutory authority through rule making can achieve much without requiring congressional intervention.

Like the FDA, with its promulgation of guidance and use of enforcement discretion, CMS has been able to distinguish chronic care remote physiologic monitoring from telehealth through a combination of policy and regulation. As evidenced by its proposal to cover and pay for phys-

iologic remote monitoring professional services, or its incentivizing the use of digital health tools, CMS seems committed to advancing digital medicine. Therefore, CMS should continue expanding Medicare program resources, using its policy and regulatory levers in areas such as additional CPT digital medical service codes, changes to coverage determinations on digital versions of durable medical equipment, or encouraging the use of remote patient monitoring in various parts of MACRA (that is, Alternative Payment Models and the Merit-based Incentive Payment System). Additional consideration may be given to the creation of reimbursement pathways for clinical decision support tools and artificial intelligence. Furthermore, the Center for Medicare and Medicaid Innovation's focus has not been to test the use of novel technologies in the delivery of care. Toward that end, like the FDA, CMS should consider the creation of a dedicated digital health reimbursement group.

Both the FDA and CMS can learn what not to do from their past and what to do going forward from each other. Both have at their disposal powerful levers to interpret arcane statutes and help spur innovation. Only when that proves impossible should Congress step in, and then only with the utmost caution, to not disrupt predictability or create overly restrictive or contradictory and confusing statutes. That is usually what hinders technological advancements the most. ■

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