Digital Health Applications: Use Cases and Regulatory Overview

By Emma Carey, Michael Purcell, and Jonathan Walland

I. Introduction

Digital health technologies (DHTs) refer to a broad universe of transformative technologies that hold the promise of revolutionizing the way individuals access and manage their health care. The U.S. Food and Drug Administration (FDA) has offered a broad definition of the term that captures just how varied the uses of such technologies can be:

> Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.[1]

While industry efforts to increase the development and uptake of digital health technologies DHTs predates the COVID-19 pandemic, the need for novel solutions to facilitate the provision of health care during the public health emergency drastically increased the pace of innovation and the recognition by regulators of the unique benefits that such technologies can provide. Regulators have freely acknowledged the various benefits of expanded DHT use, including the potential to increase access to care and convenience for patients – particularly for vulnerable patient populations like those in low-income and rural locations, as well as those experiencing infectious diseases or suffering from weakened immune systems

Individuals who reside in low-income communities often face various deleterious social determinants of health, which are non-medical factors that can negatively influence health outcomes. Some examples of social determinants of health include income and social protection, unemployment and job insecurity, working life conditions, food insecurity, housing, basic amenities and the environment, and access to affordable health services of decent quality. These adverse social determinants can make it difficult for patients to attend doctors' appointments due to lack of transportation, inability to take time off work, or the impact of disabilities. DHTs hold the promise to reduce or eliminate some of these barriers by allowing patients to attend their medical appointments electronically in the comfort of their own home or office. Individuals who reside in rural communities often have similar impediments to health care. According to a recent study by University of Pennsylvania's Wharton Health Care Management Alumni Association:

> Compared with urban populations, rural residents generally have higher poverty rates, a larger elderly population, tend to be in poorer health, and have higher uninsured rates than urban areas. At the same time, rural areas often have fewer physician practices, hospitals, and other health delivery resources. These socioeconomic and health care challenges place rural populations at a disadvantage for receiving safe, timely, effective, equitable, and patient-centered care.[2]

Beyond rural and low-income populations, other vulnerable patient populations like patients with infectious diseases, weakened immune systems, or other health issues making in-person care provision more dangerous may similarly benefit from the increased use of DHTs.

Another meaningful benefit that DHTs promise is the opportunity to maximize efficiencies for health care providers (HCPs).[3] Various DHTs offer opportunities to minimize day-to-day workload for HCPs by, among other things, increasing the ease of real-world data collection, offering platforms for virtual visits that allow HCPs to see more patients in a day, and streamlining the integration of data into electronic patient charts and minimizing the need for providers to spend time on clerical or administrative tasks.

Given these wide-ranging benefits, regulators like FDA, the Centers for Medicare & Medicaid Services (CMS), the U.S. Department of Health and Human Services (HHS) have sought to promote the development and use of these technologies by, among other things, seeking in put on how to establish more flexible regulatory frameworks to permit their use[4] and establishing programs aimed at fostering further innovation in this space.[5] However, DHT use in the health care space is not only forward-looking. From internet-enabled diagnostic medical devices to electronic health record (EHR) systems to telehealth, many digital technologies are already being deployed in the health care field. This article provides a discussion of current clinical uses of digital health in hos-

pitals, clinics, and other traditional patient care models, and explores the relevant laws that govern their development, approval, and use. It also discusses ongoing challenges facing DHT developers, HCPs, patients, payors, and other industry actors in their efforts to continue expanding the use of DHTs in patient care.

II. Regulation of DHTs

DHTs are regulated by various government agencies at both the federal and state[6] level. At the federal level, FDA, CMS, the HHS Office for Civil Rights (HHS-OCR), and the Federal Trade Commission (FTC) are among the regulators with the most significant enforcement authority over certain types of DHTs. Collectively, these agencies have established frameworks for regulating DHTs throughout their product lifecycles that are aimed at facilitating the safe and effective development, manufacture, commercialization, distribution, and use of DHTs within the health care industry. These regulators have aimed to assist DHT developers and manufacturers in understanding and assessing vital questions throughout the development and commercialization processes, including, among other things, the threshold question of whether the commercialization of a DHT is legally permissible under existing regulatory frameworks and, assuming so, what technical, operational, and validation requirements will apply; how government and private insurance payors will impact payment of new DHTs; and whether provision of such technologies may raise questions under anti-fraud and inducement laws, such as the Anti-Kickback Statute.[7]

A. FDA Regulation

Under the federal Food, Drug, and Cosmetic Act of 1938 (FDCA) and its implementing regulations, FDA's Center for Devices and Radiological Health (CDRH) has the authority to regulate firms who develop, manufacture, repackage, relabel, and/or import medical devices within the United States.[8]

1. Scope of FDA Authority Over DHTs

The FDCA defines a medical device as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . [among other things] intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.[9]

In 2016, as part of the 21st Century Cures Act, Congress clarified the scope of DHTs that qualify as medical devices, specifically excepting certain categories of commonly used low-risk DHTs from the medical device definition.[10]

Under the FDCA's definition, whether and when a product is considered a "medical device" and is therefore subject to regulation by FDA turns in large part on the intended use of the product; intended use can be established by, among other things, the design, function, and capabilities of the product; the circumstances surrounding its distribution; and any express or implied statements made by its developer, manufacturer, or distributor.[11] This means that a DHT that includes a diagnostic algorithm intended to interprets electrocardiograms would likely be considered an FDA-regulated medical device, whereas a direct-to-consumer app that recommends eating more fruits and vegetables to improve overall health would not. Less intuitively, however, the variety of considerations impacting a product's intended use means that it is possible that two products with the same functionalities may be classified differently – one as a medical device and one as a non-medical device – if evidence indicates that they are intended for different uses. For example, a wearable device that measures the pulse rate of users may be a medical device if it is intended to be used by patients with cardiovascular disease to collect data, monitor health status, or inform the provision of care, but might not qualify as a medical device if it provides less specific data to the user and is only marketed for monitoring the user's pulse rate during exercise because such a use is not related to a specific health purpose.

Given the complexity inherent in assessing whether a DHT falls within the definition of medical device – including

whether it falls within a statutory exception – FDA has issued numerous policy guidance documents to aid DHT developers and manufacturers in undertaking such assessments.[12] If a DHT is not a medical device, it falls outside of the scope of FDA's regulatory authority. FDA has also announced its intention to engage in a policy of enforcement discretion (i.e., to not enforce requirements under the FDCA) for certain low-risk DHTs that may qualify as medical devices under the FDCA, including certain software to facilitate telemedicine, certain functions that perform simple calculations routinely used in clinical practice, and certain "coaching" software functions that help patients self-manage their health.[13]

FDA has also established various resources, including the Digital Health Center of Excellence,[14] to provide additional advice and guidance for industry throughout the development, commercialization, and use of DHTs.

2. Medical Device Regulatory Framework

When any product, including a DHT, meets the definition of a medical device, it becomes subject to the regulation and oversight of FDA's CDRH. FDA regulations establish requirements that apply throughout the medical device product lifecycle including, but not limited to, premarket notification or approval, and product design, development, clinical validation, and quality management requirements.[15] Which FDA requirements apply to a given medical device depends on such device's level of risk and attendant classification.

CDRH categorizes medical devices into Class I, II, or III classifications, based on their level of risk.[16] Class I devices are those that present the lowest risk of illness or injury, while Class II covers moderate-risk tools. Both Class I and II are subject to a less burdensome regulatory process, with the focus on registration, manufacturing and labelling.[17] In contrast, Class III devices will typically necessitate generation of pre-clinical and clinical data to support a formal approval. A notable exception exists for Class III devices that can demonstrate safety and efficacy by proving substantial equivalence to existing "predicate devices."[18] In other cases, a de novo device can be approved without needing to identify a predicate device, based on FDA's determination that reasonable assurances of safety and effectiveness can be provided by general or special controls.[19] But the Premarket Notification pathway, often referred as 510(k) clearance, in reference to its section in the Food, Drug and Cosmetic Act – is often unavailable to novel digital health tools that consist of new innovative technology, for which there are no precedents and reliance on general or special controls is insufficient. This sometimes leads to a related pitfall where digital health developers are tempted to 'chase the approval' by reducing the functionality of a digital health tool in order to qualify as a Class I or Class II device. Limited function digital health tools may prove unappealing to patients and providers, and therefore commercially unviable.

Similarly, inexperienced developers are sometimes tempted to seek the easiest and quickest approval pathway, but might later find that their chosen pathway is rejected by CDRH based on the product risk profile, or while adequate for FDA purposes, is insufficient to generate the efficacy and quality data needed to support CMS or private payer reimbursement decisions. The software and technology start-up strategy of developing a "minimum viable product" – a bare-bones version with limited features and functionality, intended to provide proof of concept and solicit beta tester feedback – often doesn't work in the highly regulated health care field.

B. FTC Regulation

While the FDA's role in regulation of DHTs is limited to those that meet the definition of medical devices, the FTC regulates a broader universe of DHTs, sharing jurisdiction over medical device DHTs and also wielding regulatory authority over DHTs that do not meet the definition of medical device. However, the FTC's scope of regulatory authority is more narrow than FDA's, as it is focused on preventing "unfair or deceptive acts or practices,"[20] in large part as it relates to product advertising. In terms of digital health, the FTC's responsibility has grown in recent years, particularly in the area of direct-to-consumer (DTC) health apps and tools, which often fall outside the ambit of HIPAA regulation. FTC has stepped up to fill this void by aggressively regulating DTC DHTs to promote consumer protection by ensuring that product claims and advertisement is not deceptive or misleading to patients.

C. CMS Regulation

CMS' role in digital health is complex and often relies on its function as a significant payor in the U.S. health care market. CMS' efforts to promote equity in the health care system through promotion of digital health rely on various regulatory approaches, including the "stick" of CMS program rules and the "carrot" of CMS funding incentives and reimbursement to support digital health initiatives and pilot programs. Outside of Medicare/Medicaid funding, CMS is also bridging the digital health care gap among those beneficiaries with low digital literacy and in lower-income regions. A stated goal of CMS' 2024 Medicare Advantage program is to "develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits."[21]

CMS' role is vital to the successful uptake of DHTs, as a key barrier to their expanded use is the difficult process of negotiating with CMS and private insurance companies for reimbursement for each new digital health product. While

some DHT developers have successfully obtained CMS reimbursement by going through the lengthy process of seeking a new billing code and then obtaining a national coverage decision, many have been discouraged. Historically, new DHTs have needed to qualify under an existing benefit category, which can include very narrow eligibility criteria. For example, to meet the requirements for "durable medical equipment," a DHT would need to include specific types of hardware – which might exclude most software-only tools.

Another option when patients are remotely monitored by HCPs in between clinical visits, could be the use of billing codes that provide reimbursement for Remote Patient Monitoring (RPM), which covers evaluation and management of physiological data and Remote Therapeutic Monitoring (RTM), which covers review and monitoring of non-physiological data.[22] In these examples, the reimbursement is provided for the service that used the DHT, not for the technology itself – and the HCP would need to satisfy all of CMS's requirements for these billing codes.

One potential solution on the horizon, is the allocation of new funding for DHTs that meet the threshold for "breakthrough products" under the Ensuring Access to Breakthrough Products Act of 2024 (H.R. 1691).[23] This legislation will allow DHTs that qualify as breakthrough medical devices to receive four years of transitional reimbursement, with built-in requirements for CMS to create permanent reimbursement codes once FDA approval is granted.

CMS has similarly created a pilot for transitional coverage for breakthrough devices, under the Medicare Transitional Coverage for Emerging Technologies (TCET) program,[24] which was published in the Federal Register in August 2024. One helpful aspect of the TCET program is the creation of a process for submitting a non-binding letter of intent, alerting CMS 18-24 months in advance, that a DHT developer is seeking FDA approval for their product. This advance planning may allow more meaningful pre-launch planning and coordination between CMS, FDA, and DHT developers, to reduce regulatory and reimbursement uncertainty – which have proven to be key challenges for digital health.

History has shown that DHTs have not always been embraced until adoption is nurtured by regulatory reform or the availability of funding whether in the form of payor coverage, reimbursement, or incentive payments. In 2009, the American Recovery and Reinvestment Act provided of $27 billion in CMS funding payments for hospitals and clinics that adopted EHRs and could demonstrate satisfying certain criteria for "meaningful use" and attainment of related clinical quality measures.[25] This led to explosive growth in the deployment and use of EHR systems in the U.S., which according to one study, grew from 6.6% of U.S. hospitals in 2009 to 81.2% in 2019.[26] A similar effect was seen in the rapid growth of telemedicine during the COVID-19 pandemic, when CMS improved the ability to obtain reimbursement and waived a number of regulatory requirements that had effectively limited widespread adoption. To qualify for Medicare telehealth reimbursement, CMS temporarily: (i) waived requirements for pre-exiting established relationships with the billing HCP; (ii) waived certain patient and HCP location requirements for telemedicine; (iii) relaxed technology requirements for telehealth encounters, including permitting audio-only visits; and (iv) equalized reimbursement for telehealth visits to the same rate as in-person encounters.[27] One dataset showed that the number of telemedicine visits went from 0.1% of all billable encounters before the pandemic in 2019[28] to 4.86% in 2024.[29] While some of the CMS reforms that encouraged the growth of telehealth during the COVID pandemic will be sunset at the end of 2024, others have been made permanent.[30]

D. Regulation Under HIPAA

HHS-OCR is responsible for enforcing the Health Insurance Portability and Accountability Act (HIPAA).[31] Although HIPAA is commonly viewed synonymous with its most well-known section, the HIPAA Privacy Rule, which regulates the privacy of patients' health information, the original legislative intent of HIPAA, was broader and also included regulations focused on electronic health data access, interoperability, and portability. As health care and medical records become more digitized, these aspects of HIPAA have become more relevant. The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted in 2009 to promote the safe use of health information technology and strengthened the privacy laws set forth by HIPAA.[32] The HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information and contains provisions that strengthen the civil and criminal enforcement of the HIPAA rules.

Digital health technology developers must ensure that DHTs subject to the HIPAA Privacy Rule and the HIPAA Security Rule are HIPAA-compliant to ensure that a patient's EHR or other health information is inaccessible to anyone other than the patient or their health care provider.

Non-HIPAA covered entities that develop and market DHTs should assess whether they might be subject state-level regulations or to federal regulation by the FTC or FDA. The FDA recently released draft guidance related to quality management and cybersecurity requirements for FDA-regulated medical devices that qualify as "cyber devices."[33] The draft guidance stressed that the criteria for cyber devices includes technology that is connected to the internet, including medical devices that incorporate: (i) wireless connectivity such as wi-fi or cellular technology, Bluetooth, radiofrequency communication; or (ii) hardwired connectivity capable of con-

necting to the internet, such as USB, ethernet, serial port and network, connections. Once deemed a "cyber device," the manufacturer of such devices would need to submit to FDA "a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures" in premarket device approval applications.[34]

III. Existing Clinical Uses of DHTs

Though the regulatory frameworks governing the development and use of DHTs continues to evolve, many DHTs have been successfully integrated into the health care sector. These technologies serve as helpful case studies to understand how DHTs can play an invaluable role in maximizing efficiency, expanding access to high-quality health care, and optimizing health outcomes.

A. Telehealth Platforms

Telehealth is the use of telecommunications and information technology to provide access to health assessments, diagnosis, intervention, consultation, supervision, and information across distance.[35] Using telehealth platforms, health care providers and patients are able to meet remotely, either over the phone or over a video call, to discuss a patient's symptoms, make a diagnosis, and identify a treatment plan. In conjunction with the patient's Electronic Medical Record (EMR) and the use of Artificial Intelligence (AI) – each discussed in more detail below – a physician can harness technology to accurately analyze the patient's symptoms, diagnose the patient, and prescribe medication.

This technology-supported process offers meaningful benefits for increasing access to health care, particularly for underserved populations, including those in rural areas or areas with limited access to care, and for patients suffering from infectious diseases, weakened immune systems, or otherwise compromised health. Additionally, telehealth increases provider efficiency, in large part by reducing the time that the provider spends with the patient and thereby allowing the provider to see more patients each day.

B. Remote Patient Monitoring Devices

Wearable health care technologies, or "wearables," are devices that patients can attach to themselves to allow their health care providers to remotely monitor their health. The most popular example of this is the Apple Watch. The Apple Watch is a consumer health product with an increasing range of built-in digital heath capabilities, including biometric hardware and software that monitors individuals' heart rate, sinus rhythm, blood oxygen, tracks the menstrual cycle, and can even detect a fall. While this is the most common example of a wearable, there are many other types of wearables that are used to track patients' health care trends, including, but not limited to, CPAP machines, blood pressure monitors, glucose meters, and heart monitors. A study by KLAS has shown that remote patient monitoring has successfully reduced hospital visits, reduced hospital readmissions, improved patient health, and overall, increased patient satisfaction.[36]

As with telehealth, wearables and other remote patient monitoring devices have had significant impact on facilitating access to care for patients who have historically been underserved. Wearables have also provided invaluable benefits by permitting patients to track and manage their own health and wellness, increasing knowledge and efficiency of whether and when care should be sought. Finally, these tools have proven invaluable in offering opportunities to improve medical outcomes and enhance efficiencies in the provision of health care by collecting significantly more real-world data on patients that can offer providers a more holistic view of patient health and inform care decisions.

C. Electronic Health Records

EHRs also allow for efficient transfers of patient data between patients and providers. Requesting and receiving a copy of a medical record can often be a tedious task for both patients and providers, and the use of EHRs allow patients to access their entire medical record at the click of a button. EHRs often allow all of the patient's providers to see their medical history, allowing for a smooth transfer of the medical record from one provider to another. EHRs can also be very useful if a patient suffers a medical emergency. At the push of a button, an EHR linked to an electronic health data sharing exchange such as the Statewide Health Information Network for New York (SHIN-NY) can quickly provide essential details to emergency responders in an emergency, such as preexisting medical conditions, prescriptions, allergies, and the contact information of the patient's primary care physician.

D. AI-Enabled Clinical Software

The use of AI can also increase the efficiency of HCPs by allowing for technology-enabled remote patient monitoring and machine learning to support diagnostic decision-making and analyze health trends. Real-world examples of AI-enabled software used in clinical settings may include, among other things, imaging systems that use algorithms to give diagnostic information for skin cancer in patients, and smart sensor devices that estimate the probability of a heart attack based on vital sign monitoring.[37] While the FDA has issued 950 approvals or authorizations for AI-enabled medical devices to date,[38] all of those approvals relate to algorithms that are "locked," meaning that such algorithms provide the same result each time the same input is applied and does not change with use.[39] While interest in the use of generative or adaptive AI continues to grow in the health care industry, the FDA and

other regulators are grappling with how to provide continue assurances of safety and effectiveness of such technologies.

IV. Ongoing Challenges with Uptake of DHTs

Despite the widespread use of these and other DHTs, it remains challenging for novel technologies to find an initial foothold in the health care space. Among the biggest barriers to rapid uptake of novel DHTs are entrenched patient and provider preferences; while younger and more technology-savvy patients may be enthusiastic about substituting traditional in-person medical care for the convenience of remote telemedicine visits, remote in-home diagnostics, remote chronic disease monitoring, and in-home treatment, many older patients prefer the traditional in-person experience and crave the face time (as opposed to FaceTime) with their medical providers.

A lack of digital literacy and access to digital tools may also remain barriers to the widespread adoption of DHTs. CDRH is currently working to address these factors to further assist low-income patients. In June of 2023, CDRH sought public comment on how to increase patient access to at-home use medical technologies. Advancing health equity was made part of CDRH's 2022-2025 strategic priorities.[40]

Even when DHTs are widely adopted, various challenges remain. For example, DHTs may create some ambiguity regarding responsibility for monitoring remotely acquired health data. There is some risk that patients may unreasonably expect HCPs to be actively monitoring data obtained by remote monitoring devices and alerting them to potential health risks. Until clinical care workflow models and medical standards of care evolve, many HCPs will be reluctant to assume responsibility for using advanced technology to actively monitor acute incidents in real time, for fear of liability over missed diagnoses.

Another significant risk associated with implementing DHTs to remotely care for patients is ensuring the accuracy of diagnoses and care decisions. Patients may be skeptical about whether HCPs can accurately provide a diagnosis without engaging in a physical, in-person assessment. Such apprehension may be born in large part from concerns about the shortcomings of existing telecommunications technology, the inability of HCPs to physically examine patients engaged in remote monitoring or telehealth visits, and social/communication barriers from not being in the same room.

Beyond patient skepticism, regulators like the FDA have reiterated their commitment to ensuring that DHTs that enter the marketplace are sufficiently accurate, reliable, and safe. The FDA's pre-market notification and pre-approval processes are invaluable stopgaps to provide assurances of the effectiveness and safety of FDA-authorized DHTs, but the FDA and other regulators have struggled to grapple with how to provide continued assurances of accuracy and reliability for novel, evolving DHTs including adaptive AI-enabled technologies that "learn" from real-world experience. Not only do such technologies raise concerns about validating constantly evolving algorithms to ensure ongoing reliability, but they also run the risk of incorporating bias into the provision of care based off of previous diagnoses or patterns of symptoms. AI bias can also cause health care discrimination, especially in marginalized communities. Studies have shown AI "compounding existing inequities in socioeconomic status, race, ethnicity, religion, gender, disability, or sexual orientation. Bias particularly impacts disadvantaged populations, which can be subject to algorithmic predictions that are less accurate or underestimate the need for care."[41] For these reasons, combating AI bias and establishing targeted regulatory frameworks to grapple with generative or adaptive AI have become key projects for regulators like the FDA.[42]

V. Conclusion

The emergence and rapid growth of digital health products presents myriad potential health benefits. The integration of telehealth, remote monitoring device, EHRs, and other existing DHTs has proven that these technologies offer opportunities to enhance efficiency in the health care sector, including by making scheduling and attending appointments with HCPs, as well as communicating historical health data between HCPs and patients, easier and more efficient. Additionally, DHTs have demonstrated their potential to expand access to high-quality, reliable care and to improve health outcomes by offering patients and HCPs a more holistic view of patient health. The potential for innovation in the field seems endless.

However, the development of DHTs and their integration into health care services also present various complex challenges. Concerns over data privacy and data security remain paramount, along with liability risks and health care compliance issues that may be faced. Hesitation to embrace DHTs remains a challenge among some patients, payors, and providers. Additionally, disparities in access to technology and digital literacy may exacerbate existing health care inequalities, posing ethical challenges that demand careful consideration. Government commitments to advancing health equity will bridge this gap by further providing enhanced access to health care, especially for those who reside in rural or low-income communities.

Despite these challenges, the transformative potential of digital health is undeniable. By fostering collaboration between health care providers, technology developers, policymakers, and patients, these obstacles can be overcome. With continued research and commitment to patient care, digital

health has the power to revolutionize the way we approach health care delivery, ultimately improving outcomes and enhancing the well-being of patients everywhere.

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5. *See, e.g.,* FDA, *Digital Health Software Precertification (Pre-Cert) Pilot Program*, https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program.
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8. In 1976, the Medical Device Amendments Act was passed by Congress, which explicitly expanded FDA's authority to provide reasonable assurance of the safety and effectiveness of medical devices. *See* FDA, *A History of Medical Device Regulation & Oversight in the United States*, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states; *see also* FDA, *Overview of Device Regulation*, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation.
9. 21 U.S.C. § 321(h)
10. 21 U.S.C. § 360j(o). Specifically, the 21st Century Cures Act excluded from the definition of "device" any "software function that is intended—

    (A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

    (B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

    (C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart [subject to certain conditions] . . .;

    (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such

function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and (iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."

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