The State of Regulation of Medical Software and AI: Considerations for Clinicians and Providers

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Introduction

As we start a new decade, it is natural to think about the many advancements that have occurred in medicine over the past ten years. One such advancement that remains top of mind is the rapid evolution of digital health tools. "Digital health" has been used to refer to a wide variety of digital interventions in health care, ranging from the use of software algorithms to assist in diagnosis, to the use of digital tools to support interactions with patients through telemedicine, to the deployment of ingestible sensors to measure medication absorption. All of these aspects of digital health challenge traditional legal and regulatory frameworks, while simultaneously holding the potential to revolutionize the practice of medicine. Notably, providers themselves, as well as individual clinicians, are playing a significant role in the development of these digital tools, informed by the needs of their own practices. This paper focuses on the various uses of medical software, including the use of artificial intelligence (AI); how such software is currently regulated; and what providers and clinicians should understand as these tools proliferate and become more sophisticated.

During the last decade, the Food and Drug Administration (FDA), Congress, and other regulatory agencies began to confront in earnest how these software tools should be regulated. In particular, FDA and Congress sought to clarify which types of software tools would be regulated as a medical device and which would not. More recently, FDA has embarked on the next step: reconsidering *how* to regulate software that meets the medical device criteria. In particular, FDA is confronting the question of how to achieve the prevailing legal standard of a reasonable assurance of safety and effectiveness for software tools that: (1) may be more difficult to evaluate using the traditional mechanisms of assessing medical devices; (2) are being used by clinicians in a different way and may be less transparent in their mechanisms of action; and, (3) can evolve much more rapidly than traditional medical device hardware. While much of the discussion over the past decade has been focused on avoiding unnecessary regulation of promising digital technologies, the more recent focus on *how* to regulate these tools reaffirms the ongoing need to ensure that such tools are safe and beneficial to patients, and fully understood by the clinicians who will rely upon them. Ultimately, the appropriate regulatory oversight of medical software will depend on how such tools are integrated into health care delivery, and will require a sophisticated understanding of how clinicians and patients will relate to these technologies.

These important considerations ultimately lead to the question of how these increasingly powerful algorithms will reshape the practice of medicine itself, as providers and clinicians gain more experience with how these tools can best be deployed to improve health outcomes. In this paper, we provide an overview of the primary categories of medical software and how they are regulated, and analyze key overarching regulatory considerations for providers in both developing and deploying these tools.

I. Categories of Software Tools

In this section, we describe the regulatory landscape for five distinct categories of software used in medical practice: clinical decision support, wellness software, Medical Device Data Systems (MDDS), administrative software, and computer-assisted surgery software. Some of these software functionalities are patient-facing, while others are focused on the physician's practice or operations of a provider. All of them, however, promise to change the way medicine is practiced. Finally, we separately address artificial intelligence (AI) and machine learning (ML). AI and ML should not be thought of as a separate category of software, but instead as a means of developing and operating the software tools that could fall within virtually any of these categories.

Clinical Decision Support

Clinical decision support (CDS) software has been defined as a system that "provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care."[1] CDS is a broad category and can include everything from "computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information."[2] A CDS tool that actually provides a diagnosis, or directs a particular treatment regimen, is performing a function that has historically been regulated as a medical device. On the other hand, a CDS tool that merely organizes information for a clinician, along the lines of publicly disseminated treatment guidelines, has historically not been regulated as a medical device. Of course, there are almost infinite variations in between, and how clinicians incorporate these tools in their practices is rapidly evolving. Guided by the principle of protecting public health, FDA, and Congress, have attempted to delineate which types of CDS require FDA oversight—in other words, should be treated as medical devices—and which types of CDS do not.

CDS in Clinical Practice

The incorporation of CDS software into clinical practice is becoming almost ubiquitous. CDS complexity and uses vary significantly, however. For example, CDS can include something like a notification reminding physicians to provide recommended vaccinations that are missing from a patient's records.[3] Or, CDS can draw information from the records of many hospitals in a system to generate treatment recommendations based on previous patient outcomes. Generally, CDS tools can be divided into two categories: data mining systems and knowledge-based systems. The data mining tools "examine a patient's medical history in combination with trusted clinical

[1] *Clinical Decision Support,* HEALTHIT.GOV, https://www.healthit.gov/topic/safety/clinical-decision-support (last visited Dec 13, 2019).

[2] *Id.*

[3] *Vaccination Clinical Decision Support Reminders*, PRACTICE FUSION, https://knowledgebase.practicefusion.com/knowledgebase/articles/487117-vaccination-clinical-decision-support-reminders (last visited Dec. 13, 2019).

research," and can be used to predict negative outcomes like drug interactions.[4] Knowledge-based systems, on the other hand, "apply reasoning standards to analyze clinical data."[5]

The aim of CDS is generally to improve the "quality, safety and efficiency of healthcare."[6] In an ideal system, CDS tools provide physicians with a complete picture not only of the most up-to-date clinical guidelines, but with recommendations that reflect the patient's records as well. There are, of course, many barriers to reaching this idealized system, but the CDS tools currently at our disposal have proven effective in many areas of care.

Take, for example, quality of care: the National Academy of Medicine has noted that the availability and development of medical knowledge is increasing at such a rate that it is nearly impossible for clinicians to stay up to date. Some CDS tools have taken on this challenge, developing "the twenty-first century version of clinical practice guidelines (CPGs)—systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances…presented in real time within the context of a patient's EHR."[7] The integration of EHR and updated clinical guidance allows physicians "to rapidly move clinical knowledge from the scientific literature to the patient encounter," improving care as a result.[8] Furthermore, CDS tools can help physicians more quickly identify less common conditions that they may not have significant experience with, allowing the provider to begin an effective treatment regimen earlier than otherwise possible.

A well-integrated CDS function can also pull information from many places within a health care network. For example, the software could enable a physician to see patient information that was collected at a hospital's associated primary care facility, laboratories, or pharmacies.[9] While there are often significant hurdles in getting these various record systems to communicate, it is possible to use a standardized interface, like the HL7, within the CDS tool that allows it to draw from these sources and integrate the data.[10] This can save significant administrative time and allow physicians to have the full picture of a patient's condition during their visit.

In addition to supporting a physician's ability to make the most accurate diagnosis possible, CDS can also help practitioners ensure their patients' safety during treatment. CDS software can decrease rates of easily avoided errors by noting issues like contraindications or potentially

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[4] Allan Ridings, *Understanding the Current State of Clinical Decision Support Systems*, MED. ECON. (Nov. 30, 2016), https://www.medicaleconomics.com/medical-economics-blog/understanding-current-state-clinical-decision-support-systems.

[5] *Id.*

[6] Dean F. Sittig, et al, *Grand Challenges in Clinical Decision Support*, 41 J. OF BIOMEDICAL INFORMATICS 387 (2008), https://doi.org/10.1016/j.jbi.2007.09.003.

[7] NAT'L ACAD. OF MED., OPTIMIZING STRATEGIES FOR CLINICAL DECISION SUPPORT SUMMARY OF A MEETING SERIES 15 (2017), https://www.healthit.gov/sites/default/files/page/2018-04/Optimizing_Strategies_508.pdf.

[8] *Id.*

[9] Nancy Zimmerman, RN, BSN, *What Clinical Decision Support Can Offer*, PATIENT SAFETY & QUALITY HEALTHCARE (Jul. 6, 2016), https://www.psqh.com/analysis/what-clinical-decision-support-can-offer/.

[10] *Id.*

dangerous drug interactions.[11] CDS can also assist physicians by alerting them to signs of "silent deterioration" in their patients.[12]

The advantage of the CDS function in these situations lies in its ability to see the forest for the trees. As one commentator observed, "a clinician may note such changes in more routine care if actively seeking them, [but] the clinician who is already laser focused on treating appendicitis may not observe [these indicators] until the patient is suddenly septic and develops organ failure."[13]

As previously noted, CDS can also have a significant, positive impact on efficiency and cost. Unsurprisingly, a large part of this benefit is due to the streamlining effect of instantly available (and unprompted) data. If a provider does not have to go back to a physical journal or guideline, or conduct a separate search, it saves time. Additionally, reminder systems, like a vaccine prompt, can theoretically prevent patients from having to make additional appointments.

While CDS tools have a great deal of promise, their implementation has caused some frustration among providers. A frequently cited problem is that of notification burnout. This occurs when a CDS tool generates so many notifications, many of which are not well tailored to the treatment situation at hand, that physicians find themselves wasting time dismissing the notifications or overriding treatment suggestions. Not only does this result in lost time, but it often leads practitioners to ignore the system entirely.

Additionally, there are some basic technological hurdles that accompany these systems. First, there is a lack of consistency across EHR vendors regarding the placement of CDS trigger points. For example, "some systems… provide drug dose checking as soon as an order is entered, while others wait until a full session of multiple orders is ready to be signed."[14] There is sometimes a lack of congruity in the way that various organizations—even within one health system—store their EHR data. Without consistent data recording methods, a CDS tool may not be able to gather the data from all existing records without significant additional programming.[15] More broadly, as CDS becomes increasingly sophisticated, questions can emerge about the necessary level of training or familiarity a clinician needs to use the tool appropriately.

Finally, keeping CDS tools updated is also an enormous challenge and expense. While this is the case with most software, it is particularly true for a system tailored to unique health system requirements. And, as previously noted, medical advances may require frequent updating of these systems, depending on their function.

Regulatory Issues

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[11] AM. HOSP. ASS'N, TREND WATCH: ANNUAL SURVEY IT SUPPLEMENT BRIEF #3 (Jul. 2018), https://www.aha.org/system/files/2018-07/18-07-trendwatch-issue-brief3-patient-safety-quality-health-it.pdf.

[12] Zimmerman, *supra* note 9.

[13] *Id*.

[14] NAT'L ACAD. OF MED., supra note 7, 36.

[15] *Id.* at 28.

Whether a CDS tool is subject to federal regulation will have profound implications on how it is developed, used, disseminated, and modified. Depending on its function and purpose, CDS software will either be categorized as a device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), not qualify as a device, or fall into one of the various exempted categories established by the 21st Century Cures Act of 2016 (Cures Act). Under the FD&C Act, a "device" is defined 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—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) 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
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.[16]

The excluded functions include certain software that provides administrative support (billing, maintaining financial records, inventory management, etc.), wellness support, electronic health record capabilities, transfer and storage functions and CDS that meets a multi-part test.[17]

To qualify as a non-device, a CDS must meet the following four criteria:

> (1) not 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 (section 520(o)(1)(E) of the FD&C Act);
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> (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);
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> (3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition (section 70 520(o)(1)(E)(ii) of the FD&C Act); and

[16] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) (2019)

[17] *Id.* at 360j(o).

> (4) intended for the purpose of 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 (section 520(o)(1)(E)(iii) of the FD&C Act).[18]

In September 2019, FDA published revised draft guidance that aims to clarify how it draws the distinction between device and non-device CDS. The guidance also included language about CDS functions which FDA categorizes as a device but that do not present enough risk to require the same level of oversight.[19]

In addition to the statutory criteria for exemption, FDA has also proposed in its draft guidance that it intends to utilize the International Medical Device Regulatory Forum (IMDRF) Framework to evaluate the risk presented by various CDS functions. Within the framework, there are two factors that the agency examines: the "significance of information provided by a SaMD to the health care decision," and "the state of the health care situation or condition."[20] The "state" of the condition or situation is divided into three categories—critical, serious, or non-serious—while the significance of the information provided is stratified by its role of treating or diagnosing a condition, driving clinical management, or simply informing clinical management.[21] FDA stated in the draft guidance that software that either "drives clinical management" or that treats or diagnoses does not qualify as CDS under the Cures Act. These functions "go beyond supporting or providing recommendations to an HCP, patient, or caregiver (i.e., they do not meet criterion (3))."[22]

While these new terms need additional clarification, the crux of the analysis continues to turn on the provider's ability to review the basis for CDS recommendations. In its draft guidance, FDA has recommended that developers should describe CDS software functions in plain language.[23] Additionally, the source material for the data points—clinical practice guidelines, patient records, etc.—should be made available.[24] Naturally, the more advanced a CDS product becomes, the harder it will be for an individual provider to review the underlying basis for the CDS recommendation—both in terms of the volume of information and the complexity of the underlying process.

For example, in the context of artificial intelligence and machine learning, many providers may be unfamiliar with the underlying functions of these tools. However, the

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[18] *Id.*

[19] *Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software#ft1 (last visited Jan. 3, 2020).

[20] FDA, Clinical Decision Support Software, at 13 (Sept. 2019), *available at* https://www.fda.gov/media/109618/download.

[21] *Id.* at 13-14.

[22] *Id.* at 14.

[23] *Id.* at 12.

[24] *Id.*

agency has yet to clarify the level of understanding that would be required for the "logic" behind a recommendation to be sufficiently clear for the purposes of this regulation. It has also stated that the basis for a recommendation must be sufficiently explained "regardless of the complexity of the software and whether or not it is proprietary."[25] While it remains to be determined whether the agency will retain this language, it could establish a strange situation in which developers might be required to disclose information that other medical industries are able to protect by providing sufficient labeling and directions.

There is still a great deal that is unsettled in this area. Meanwhile, the sophistication of these tools is increasing rapidly. Hospital systems and individual clinicians that are involved in developing CDS software will have to pay special attention to forthcoming guidance to determine whether their functions fall outside of the exceptions. Moreover, providers should think carefully about how a particular CDS tool would best be used in a treatment environment. Because the intended use is crucial to assessing regulatory status, the same basic software function may or may not be a medical device based on whether the developer intends its output to provide a diagnosis or play a relatively significant role in clinical decision making, or alternatively, to serve more as an informational source for the clinician. In many cases, for a CDS tool to be used appropriately, it will need to be regulated as a medical device. While that status frequently results in the need to obtain marketing clearance or approval from FDA, this process also provides validation of the safety and efficacy of the software tool.

Wellness Products

From a consumer perspective, wellness-targeted software applications (apps) seem to be everywhere. Sleep trackers, food journals, step counters—all of these are advertised to help aid in maintaining a healthy lifestyle. While many of these products are aimed at consumers who want more ownership over their health, providers and insurers have also recognized the potential benefits of using these tools to improve patient outcomes. For example, looking through a patient's food log may help a physician instruct that patient on how to manage her diabetes. Increased steps may lead to a reduction in blood pressure and, likewise, in the medication needed to manage it. In addition to improving health and decreasing costs, health care providers are also responding to patients' increased interest in finding physicians who utilize these tools as part of their treatment protocols.[26]

At their most basic, these products can be used to address roadblocks that may have frustrated physicians' treatment plans in the past—namely by increasing patient engagement between appointments. For example, physicians often recommend changes to a patient's diet and exercise regime as a preventative measure or to treat symptoms of a condition. Studies have indicated that individuals using software to track their exercise or to record food and weight have greater

[25] *Id*.

[26] "About a third of consumers are interested in using apps for identifying symptoms and for health coaching." David Betts, Leslie Korenda, *Inside the Patient Journey: Three Key Touch Points for Consumer Engagement Strategies*, DELOITTE INSIGHTS (Sept. 25, 2018), https://www2.deloitte.com/us/en/insights/industry/health-care/patient-engagement-health-care-consumer-survey.html.

success in meeting their goals.[27] The theory is that by recommending wellness apps, physicians are giving patients tools to better understand and control their own health outcomes without more frequent intervention by the physician.

The variety and complexity of wellness products has expanded rapidly in the medical field in recent years. As technology has advanced and the public has become more adept with wearable technology, tech companies, hospitals, and providers have begun to use—and create—apps that allow patients to share their data in real time with their physicians. For example, the University of Virginia developed an app with Locus Health, and later partnered with Apple, to support a program that allows parents of infants who have recently been discharged from the neonatal intensive care unit (NICU) to use iPads to track and transmit important health metrics, allowing physicians to monitor an infant's health from afar.[28] In addition to providing parents with a greater sense of security, the program has allowed babies to go home sooner and has enabled staff to "treat high-risk kids…as if they were in the hospital."[29]

In addition to improving patient outcomes and engagement, many providers and regulators are hopeful that the availability of data, and the streamlining of the transfer of that data, will create efficiencies and improve the overall experience of receiving care. For example, if data from a patient's wellness app is downloaded and integrated into his medical records before he sets foot in the exam room, his physician may be able to better use their time together by asking more targeted questions about his symptoms.[30]

There is so much hope about the impact these products might have in fact, that various agencies have begun to include incentives for providers to use this technology in their practices. For example, "one of the 15 choices of measure for the Advancing Care Information score of the Merit-based Incentive Payment System (MIPS) states: '[p]atient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for at least one unique patient seen by the MIPS eligible clinician during the performance period."[31]

With such an array of wellness apps available and monetary incentives on the line, the possibilities may seem endless. However, providers should be aware of the risks and implications that come with these types of wellness apps. Even the choice between using a wellness product

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[27] John P. Higgins, MD, MBA, MPhil, *Smartphone Applications for Patients' Health and Fitness*, 129 THE AM. J. OF MED. 11, 12–13.

[28] The program was initially created to monitor high-risk cardiac pediatric patients and was later expanded to cover patients undergoing chemotherapy or suffering from cystic fibrosis. Jeffrey Vergales, MD & Brooke Vergales, MD, *Helping NICU Babies Get Home Faster: The iPad Program*, UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE: KIDS MATTER (Oct. 24, 2019), https://news.med.virginia.edu/kidsmatter/helping-nicu-babies-get-home-faster-the-ipad-program/; Laura Lovett, *UVA's Pediatric Remote Monitoring Program Building HOPE Sees Success in the NICU*, MOBIHEALTHNEWS (Mar. 7, 2019), https://www.mobihealthnews.com/content/uvas-pediatric-remote-monitoring-program-building-hope-sees-success-nicu.

[29] *Vergales*, supra note 28.

[30] Practical Guide, Office of the Nat'l Coordinator for Health Info. Tech., Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024 1, 2 (Jan. 2018), https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf.

[31] *What Are the PGHD-related Criteria in the Health IT Rules and Programs?* HEALTHIT.GOV, https://www.healthit.gov/topic/otherhot-topics/what-are-pghd-related-criteria-health-it-rules-and-programs (last visited Dec. 6, 2019).

that is already on the market, contracting with a developer to tailor a preexisting app to their specifications, or developing an app of their own can have different regulatory implications.

Regulatory Issues

Prior to the Cures Act, FDA had issued draft guidance that attempted to provide clarity on what types of apps could be offered to support wellness or to assist a person to "live well" with a disease or condition, which FDA would opt not to regulate as medical devices. In 2016, the Cures Act codified as one of five exempt functions, software for the "maintaining or encouraging a healthy lifestyle and [are] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."[32] Such a software product must also present minimal ("low") risk to the user and others, meaning that it is neither invasive nor implanted, and does not "involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied."[33]

In 2016, and again in 2019, the FDA issued guidance to provide further clarity on this exemption, and how it compared to the agency's earlier draft guidance on wellness functions. In this guidance, FDA clarifies that products can be geared towards different elements of healthy living. Wellness products that are meant to "maintain[] or encourag[e] a general state of health or a healthy activity," fall within the exception (provided they are also low risk). The exception also covers low-risk products that are meant to "reduce the risk or impact of certain chronic diseases or conditions… where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition."[34] If a wellness function does reference a specific disease or condition, its claims must be limited in scope, stating only that it "may help to reduce the risk of certain chronic disease or conditions" or that it targets certain behaviors or activities that "as part of a healthy lifestyle, may help living with certain chronic diseases or conditions."[35]

The concern, of course, is how to maximize the impact of these wellness tools while simultaneously keeping them within the scope of the exemption. For example, it may be difficult to maintain a claim that a product simply allows a patient to "live well" with his or her chronic condition when it is actually being used aggressively to manage the condition. An argument can easily be made that once a wellness tool is "too effective," it may slip into the category of "mitigating" or "curing" a disease or condition and therefore be subjected to regulation as a device—despite the fact that the ultimate determination is to be based on the use intended by the developer.

Wearable technology—like a heartrate monitor—is especially susceptible to this ambiguous status, because these products frequently hold potential "wellness" benefits as well as benefits relating to acute conditions. In its guidance for wellness products, FDA excludes a "portable product that is intended to monitor the pulse rate of users during exercise and hiking" from the

[32] FDA, General Wellness: Policy for Low Risk Devices, at 1 (Sept. 2019), https://www.fda.gov/media/90652/download.

[33] *Id.* at 5.

[34] *Id.* at 3.

[35] *Id.* at 4.

device category because its claims are only related to general health.[36] In contrast, in 2018, the heartrate monitoring feature on the Apple Watch, which can be used for a number of purposes including exercise, was cleared by FDA as a device for two uses (conducting an electrocardiogram [ECG] and analyzing for signs of atrial fibrillation [AF]). The ECG and AF software functions were deemed to be Class II, or "moderate risk," devices.[37] The crux of this difference lies in its intended uses and the risks presented by that use. This example also highlights, however, that developing a "wellness" tool for a medical device use purpose may nevertheless optimize the benefits of the tool.

Even with a product that manages to evade the stumbling blocks noted above and is clearly excepted from regulation as a device, it may still be subject to other regulations. The Federal Trade Commission Act, for example, is intended to protect consumers from "deceptive or unfair acts or practices in or affecting commerce, including those relating to privacy and data security, and those involving false or misleading claims about apps' safety or performance."[38] The Federal Trade Commission (FTC) has initiated actions against a number of apps in the past for unsubstantiated claims, like promising improved eyesight or the ability to identify the melanoma risk posed by a mole.[39] States like New York have also applied their own consumer protection provisions to certain wellness products.[40]

In addition to these established enforcement procedures, there are likely other regulatory changes on the horizon. For example, there are mounting concerns about the amount of data that these products are collecting with very little oversight. One proposed solution is to extend the Health Insurance Portability and Accountability Act (HIPAA) to reach wellness tools and similar products. Early last year, Senators Klobuchar and Murkowski introduced the Protecting Personal Health Data Act which would expand HIPAA to apply to products that collect genetic, biometric, or personal data.[41] Privacy is a concern that appears across many of the software applications and will be addressed further in Part II of this paper. Note that the FTC's jurisdiction is not limited to non-medical devices as it also has jurisdiction over the advertising of certain medical devices.

Medical Device Data Systems: Data Transfer and Storage Software

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[36] *Id.* at 8.

[37] Letter from Angela Krueger, Deputy Director, Engineering and Science Review, Office of Device Evaluation, Centers for Devices and Radiological Health, FDA, to Apple Inc. (Sept. 11 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

[38] *Mobile Health Apps Interactive Tool,* FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool. (last visited Jan. 3, 2020).

[39] Press Release, Fed. Trade Comm'n, FTC Charges Marketers of 'Vision Improvement' App with Deceptive Claims (Sept. 17, 2015), https://www.ftc.gov/news-events/press-releases/2015/09/ftc-charges-marketers-vision-improvement-app-deceptive-claims; Press Release, Fed. Trade Comm'n, FTC Cracks Down on Marketers of "Melanoma Detection" Apps (Feb. 23, 2015), https://www.ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps.

[40] Eric Wicklund, *mHealth Apps for Cardiac Care Sanctioned for Misleading Claims*, MHEALTH INTELLIGENCE (Mar. 24, 2017), https://mhealthintelligence.com/news/mhealth-apps-for-cardiac-care-sanctioned-for-misleading-claims.

[41] Tyrone Richardson, *Senate Privacy Bill Would Expand HIPAA, Restrict Health Apps*, BLOOMBERG LAW (Jun. 14, 2019), https://news.bloomberglaw.com/privacy-and-data-security/lawmakers-float-federal-wearable-devices-privacy-legislation; Protecting Personal Health Data Act of 2019, S. 1842, 116th Cong. (2019).

Medical Device Data Systems (MDDS) are functions that "transfer, store, convert formats, and display medical device data or results."[42] These may include "software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol."[43]

Regulatory Issues

While they were initially regulated as a Class III device (the default high-risk classification), MDDS were down-classified to Class I (low-risk) in 2011.[44] In 2015, FDA went further, releasing guidance stating that it did not "intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health."[45] The following year, the Cures Act amended the FD&C Act to exclude certain software functions from the definition of a medical device, including what FDA had defined as MDDS. As a result, software that transfers or stores medical device data is not itself a medical device.[46]

Under the agency's current approach, there are two categories of MDDS: device and non-device. This is similar to the language used in FDA's CDS guidance, essentially creating sub-categories within a general type of software function. Device-MDDS is defined as a "hardware function" that is "solely intended to transfer, store, convert formats, and display medical device data or results."[47] Non-device-MDDS are software functions with the same intended use as their device counterparts. While these definitions cover a wide array of applications, an MDDS product's interaction with data must be very limited in order to remain within this particular category.

The important question for parties using and developing this kind of technology—including making modifications to existing, general use IT— is whether they have gone beyond simply storing, transferring, displaying, or converting data. [48] For example, MDDS may not "modify the data," nor may it "control the functions or parameters of any connected medical device."[49] MDDS software may store a patient's electrocardiogram for later use by a physician but may not generate additional outputs for the physician's analysis.[50] In sum, the MDDS software does nothing more than receive the information and hold it within the system.

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[42] FDA, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, at 2 (Sept. 2019), *available at* https://www.fda.gov/media/88572/download.

[43] Medical Device Data System, 21 C.F.R. § 880.6310(a)(2) (2019).

[44] FDA, *supra* note 42, at 1.

[45] *Id.* at 1.

[46] *Id.* at 2.

[47] *Id.* at 2.

[48] *Requirements for Health Care Facilities and Manufacturers*, U.S. FOOD AND DRUG ADMIN. (Dec. 14, 2017), https://www.fda.gov/medical-devices/medical-device-data-systems/requirements-health-care-facilities-and-manufacturers.

[49] FDA, *supra* note 42, at 3.

[50] *Id.*

Additionally, MDDS must not analyze or interpret data.[51] As the agency pointed out in its recent guidance, this excludes many functions that are associated with active patient monitoring. [52] More broadly, any data transfer in situations requiring a "timely response" may have difficulty qualifying for the MDDS exemption. [53] For example, if the purpose of the software is to "generate alarms or alerts or prioritize patient-related information on multi-patient displays," the software is then categorized as a device because it must analyze the incoming data in order to perform its core function. [54] However, software that allows for monitoring but that is not meant to bring about "immediate clinical action," is still exempt as MDDS.[55]

Administrative Software

Another software exemption in the Cures Act is for administrative software, although it is unclear that administrative software would meet the definition of a device in the first instance. Under the amended Section 520(o) of the FD&C Act, the following software functions are not considered devices:

> (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…[56]

Administrative software can perform any number of functions, but it is typically thought of as encompassing programs that impact "general office operations."[57] FDA has provided examples that include "analyz[ing] insurance claims for fraud or abuse," "managing shifts," and "generat[ing] reminders for scheduled medical appointments…."[58] Physicians and, in particular, their staff may find these types of software helpful in lessening the workload in the back office. However, there are some interesting regulatory issues to consider.

The functions of many administrative software programs require large amounts of data in order to perform their established tasks. This often requires that the software be granted access to patient health records, typically stored in an electronic patient record system. Under the Health Insurance Portability and Accountability Act (HIPAA), covered entities—including "any health care providers who transmit[] health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA…"—must

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[51] *Id.* at 2, 5.

[52] Medical Device Data System, 21 C.F.R. § 880.6310(a)(2) (2019).

[53] FDA, *supra* note 42, at 4.

[54] *Id.* at 3-4.

[55] *Id.* at 3 n.3.

[56] Federal Food, Drug, and Cosmetic Act § 360j(o), 21 U.S.C, § 301 (2018).

[57] FDA, Policy for Device Software Functions and Mobile Medical Applications, at 17 (Sept. 2019), *available at* https://www.fda.gov/media/80958/download.

[58] *Id.* at 17-18.

"maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI."[59] This includes "protect[ing] against reasonably anticipated, impermissible uses or disclosures."[60] Presumably, granting additional software access to an EHR system could pose a "reasonably anticipated" threat to the security of e-PHI. As a result, physicians must carefully consider the validity of these programs before electing to include them as part of their practice.

Physicians must also deal with frustrations around interoperability. Many health information systems do not "talk to each other" and software may not be compatible with all EHR systems as a result. This can cause tremendous frustration not only on initial implementation but it can later prevent providers from using other EHR or administrative systems as they will not interact. Both ONC and CMS have recently published proposed rules intended to promote the adoption of interoperable systems.[61] Perhaps the most significant consideration for administrative software, from an FDA regulatory perspective, is the potential for administrative functions to be commingled with software functions that are medical devices. Federal law, and FDA policy, provide for each function to be assessed and regulated individually. Nevertheless, administrative software that is closely integrated with device software functionality can have implications for the device software.

Computer-Assisted Surgery

Computer-assisted surgical systems have experienced increased interest in recent years, particularly in relation to their use in robotic surgery.[62] These systems can be used for "pre-operative planning, surgical navigation and to assist in performing surgical procedures."[63] For example, some surgical software is used to create 3-D models that allow surgeons to fully explore the various paths a surgery could take. Robotic-assisted surgery uses software (and a robotic mechanism) to "control and move surgical instruments through one or more tiny incisions in the patient's body."[64] In turn, this "may help reduce pain, blood loss, scarring, infection, and recovery time after surgery in comparison to traditional surgical procedures."[65]

Unlike other types of software discussed in this paper, which are not necessarily FDA-regulated, the software used in computer-assisted surgery is commonly regulated by FDA. While it is not

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[59] *Summary of the HIPAA Security Rule*, U.S. DEP'T OF HEALTH AND HUMAN SERV., https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html (last visited Jan. 3, 2020).

[60] *Id.*

[61] *CMS Advances Interoperability & Patient Access to Health Data through New Proposals*, CMS NEWSROOM, https://www.cms.gov/newsroom/fact-sheets/cms-advances-interoperability-patient-access-health-data-through-new-proposals (last visited Dec. 30, 2019).

[62] Benjamin Schwartz, MD, *Is Computer-Assisted Surgery the Future of Orthopedics?* OP-MED (Oct. 18, 2019), https://opmed.doximity.com/articles/is-computer-assisted-surgery-the-future-of-orthopedics?_csrf_attempted=yes.

[63] *Computer-Assisted Surgical Systems*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems (last visited Dec. 30, 2019).

[64] *Id.*

[65] *Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication*, U.S. FOOD AND DRUG ADMIN. (Feb. 28, 2019),

always directly applied in a surgical setting, most uses fall within the category of "treatment or mitigation of disease," thereby excluding them from the non-device exemption. However, there are some situations in which FDA has elected to use its enforcement discretion not to regulate software that, while related to surgery, does not present a significant enough risk for the agency to regulate it as a device. One example is "[s]oftware functions that provide the surgeon with a list of recommended intraocular lens powers and recommended axis of implantation based on information inputted by the surgeon…."[66] Most software that can truly be considered surgery-assist software, however, bears too high of a risk not to be regulated as a device by FDA. (Put another way, one can think of many of these tools as falling *outside* the CDS exemption based on how they are used). Physicians who are interested in using this type of technology should carefully assess the regulatory status of any particular offering before incorporating it into their surgical procedures.

Artificial Intelligence and Machine Learning

References to Artificial Intelligence (AI) and Machine Learning (ML) have almost become synonymous with digital health. From a regulatory perspective, however, any device or tool is evaluated primarily based on its intended use; AI and ML are means to those intended ends. They are tools for developing and operating software algorithms. In piloting its "Pre-Cert" program for software as a medical device, FDA has AI and ML very much front of mind.

In April of last year, the FDA published an exploratory white paper proposing a framework for regulating AI and ML-based software.[67] The paper highlighted the particular challenges that AI and ML pose to FDA and acknowledged that the agency would need to make significant changes in order to keep up with the evolution of these technologies. In particular, FDA drew a distinction between a "locked" algorithm, which may be developed through AI or ML but is then deployed in a clinical setting as a static version, and an "adaptive" algorithm, which uses AI or ML for ongoing adaptation while in use. In short, the agency's current approach to medical device regulation can accommodate locked algorithms in a relatively straightforward manner, but it is not clear how the current regulatory paradigm would accommodate adaptive algorithms. While the details of the framework described in that white paper are beyond the scope of this article, it is nevertheless an important acknowledgement by the agency that we are at a crossroads regarding the way in which we regulate software.

II. Cross-Cutting Issues for Providers to Consider

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https://www.fda.gov/medical-devices/safety-communications/caution-when-using-robotically-assisted-surgical-devices-womens-health-including-mastectomy-and.

[66] *Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion (last visited Dec. 30, 2019).

[67] U.S. FOOD AND DRUG ADMIN., *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)* 1 (2019), https://www.fda.gov/media/122535/download.

Technological innovation and advancement is not a novel concept in the field of medicine. However, the nature of those advancements has changed drastically in the last twenty years. While clinicians and providers have always been involved in the research and development of new medical technologies, they are playing an even more integral role in the development of new software algorithms. This can be attributed to potentially lower "barriers to entry," the heavy reliance on patient and clinical data, and the fact that many of these tools have not been subjected to premarket regulatory review. FDA regulations provide an exemption from requirements for medical devices that are manufactured or altered by licensed practitioners for use in their own practices.[68] This creates some degree of latitude for clinicians to develop software tools for use in their own practices, even if such tools would otherwise qualify as regulated medical devices. At least for more sophisticated algorithms, however, it is likely that an actual software developer would need to be engaged. FDA does apply registration requirements to specification developers for medical devices.[69] These distinctions in regulatory classification highlight the importance of evaluating not only *what* a software tool would be intended to do, but also *how* it will be developed. The other key consideration for providers, which is the focus of the remainder of this section, is how software tools can most effectively be deployed in clinical practice.

Ethics and Transparency

There is increasing attention to the need for an ethical framework for applying advanced software in a medical setting. Software, and AI/ML, present potential ethical challenges for physicians and providers, whether they are developing or simply deploying these algorithms. For example, an assumption that many make about advanced algorithms, AI, and similar technologies is that they decrease bias by taking human influence out of the decision making process. However, recent studies have suggested that algorithms often replicate our biases.

Late last year, a study was published that found that an algorithm designed to flag patients with significant health needs for additional support from their health care providers (e.g. nursing teams, etc.) consistently produced results that inadequately represented the needs of black patients. [70] This particular algorithm uses predictions of future health costs as a way of estimating the patient's health needs. However, that process "had the effect of priming the system to replicate unevenness in access to healthcare in America."[71] Lower income individuals are less likely to have insurance coverage, transportation, or time to see a doctor, and their health costs may be lower as a result—even if their condition is severe. [72] This seemingly race-neutral algorithm created significant disparities between black and white patients.[73]

Rifat Atun, professor of global health systems at the Harvard Chan School, has suggested that diversity among developers is one necessary element to creating bias-less systems. He also noted that developers need access to "comprehensive data that doesn't ignore marginalized or high-risk

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[68] 21 C.F.R. § 807.65(d). This exemption is distinct from the special rules applied to "custom devices."

[69] *Id.* § 807.20.

[70] Tom Simonite, *A Health Care Algorithm Offered Less Care to Black Patients*, WIRED (Oct. 24, 2019), https://www.wired.com/story/how-algorithm-favored-whites-over-blacks-health-care/.

[71] *Id.*

[72] *Id.*

[73] *Id.*

groups that may not be included in certain data sets."[74] Others have expressed a desire for increased oversight of the underlying algorithms.

Algorithmic transparency and bias have also appeared in several bills that are currently under consideration in Congress. The Algorithmic Accountability Act, which has been introduced in both the House and Senate, aims to authorize the FTC to create rules requiring companies to complete studies that assess the "impact[] on accuracy, fairness, bias, discrimination, privacy, and security…" that automated decision systems might have.[75] The Artificial Intelligence Initiative Act would direct NIST to evaluate AI algorithms and minimize bias, among other things.[76]

In the alternative, some organizations have attempted to create—or modify—algorithms to skirt proprietary roadblocks to transparency. One example of this, taken from outside the medical realm, is that of the Allegheny Family Screening Tool. In an effort to solve understaffing issues, some child-welfare agencies have turned to AI software to predict potential negative outcomes for children in their systems.[77] Instead of purchasing software from developers who were unwilling to share the inner workings of their algorithms, Allegheny County adopted a system that allowed it to own the screening tool and make all of its inner workings public.[78] A fundamental flaw, the County soon learned, was that the AI software requires data in order to form predictions. Naturally, in this case, the available data were the reports of past case workers. Ultimately, this resulted in the AI learning patterns from previous social workers, including their biases, resulting in AI-powered software that had bias "baked" into it.[79]

While the solution to correcting underlying biases is not clear, the need for some degree of transparency in and scrutiny of the algorithms that power these systems is evident. Indeed, lack of transparency may lead to additional ethical dilemmas for providers as they attempt to weigh the benefits and risks of using these tools in their practices.[80]

Oversight and Practice of Medicine

FDA's current regulatory approach places great significance on the clinician as a gatekeeper between a CDS tool, wellness product, or other non-device software, and the patient. This approach may not be realistic as algorithms grow in complexity, evolve more rapidly, and

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[74] *Could Artificial Intelligence Transform Health Systems?* HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH (Nov. 13, 2018), https://www.hsph.harvard.edu/news/features/could-artificial-intelligence-transform-health-systems/.

[75] H.R. 2231, 116th Cong. (2019); S. 1108, 116th Cong. (2019).

[76] S. 1558, 116th Cong. (2019).

[77] Ulu Mills, *'Less Bad' Bias: An Analysis of the Allegheny Family Screening Tool*, MEDIUM (Feb 5, 2019), https://medium.com/mps-seminar-one/less-bad-bias-an-analysis-of-the-allegheny-family-screening-tool-ef6ffa8a56fb.

[78] Dan Hurley, *Can an Algorithm Tell When Kids Are in Danger?* N.Y. TIMES (Jan. 2, 2018), https://www.nytimes.com/2018/01/02/magazine/can-an-algorithm-tell-when-kids-are-in-danger.html.

[79] Dylan Matthews, *Why the Left Should Worry More About AI*, VOX (Nov. 7, 2019), https://www.vox.com/future-perfect/2019/11/7/20897531/artificial-intelligence-left-socialist-google-deepmind.

[80] Michael J. Rigby, *From the Editor: Ethical Dimensions of Using Artificial Intelligence in Health Care*, 21 AMA J. OF ETHICS E121-124 (2019).

become increasingly relied upon by clinicians, providers, and insurers to make definitive diagnosis and treatment decision. As previously mentioned, sufficient review of the logic and inputs involved in these algorithms may become impossible from practical standpoint—or, at the very least, so onerous that it undercuts any efficiencies produced by those tools. Furthermore, if machine learning can, as predicted, significantly reduce clinical errors, we may reach a point in medicine where using these tools is considered best practice in certain specialties. [81]

A 2018 study published by researchers used a set of machine learning algorithms to comb through de-identified patient data to "predict and diagnose diseases," which they did with "extraordinary accuracy."[82] In fact, "within 24 hours of a patient's hospitalization… the algorithms were able to predict with over 90% accuracy the patient's odds of dying."[83] The results are astounding, yet "[t]hese predictions… were based on patterns in the data that the researchers could not fully explain."[84] Without this explanation, these tools might have difficulties qualifying for an exemption under current CDS rules; at the same time, a similar tool, such as a more traditional diagnostic test, would need to have validated results and an assessment of limitations before its output could be relied upon for treatment decisions.

As it currently stands, we do not yet have a clear picture of exactly how much understanding about a software algorithm FDA will require health care providers to have in order for the algorithm to be exempt from medical device regulation. As these tools evolve, it is impossible to predict how clinicians will interact with them, and the degree to which they will decide to "look behind" an algorithm's recommendations. Nor is it clear whether the understanding of these algorithms should fall on the individual clinician, the institutional provider, or even the patient. As regulatory authorities strive to adapt to digital health, providers and clinicians should also play an active role in shaping the future dynamic between health care professionals, their patients, and digital health technology.

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[81] Ekaterina Psheva, *The Doctor and the Machine*, HARVARD MEDICAL SCHOOL RESEARCH (Apr. 3, 2019), https://hms.harvard.edu/news/doctor-machine.

[82] Andrew Burt, Samuel Volchenboum, *How Health Care Changes When Algorithms Start Making Diagnoses*, HARVARD BUSINESS REVIEW (May 8, 2018), https://hbr.org/2018/05/how-health-care-changes-when-algorithms-start-making-diagnoses.

[83] *Id.*

[84] *Id.*