

DIGITAL HEALTH REPORT

FDA Regulation of Wellness Devices

By Georgia Ravitz, Jamie Ravitz, Paul Gadiock, and Mary O'Brien

In the midst of an ongoing pandemic—with stay-at-home orders being issued and lifted rapid fire, and working from home becoming the status quo for the foreseeable future—the challenge of staying fit and active has become all too real for consumers.

Nevertheless, the market clearly reflects the desire of consumers to stay active during these times. Sales of fitness products, such as the Apple Watch, have increased. Fitbit's aggregated user data from March to September 2020 indicated that fitness activities have spiked—including hiking, running, kickboxing, and other outdoor activities. Meditation alone experienced



In This Issue

FDA Regulation of Wellness Devices Pages 1-3

Commercial Contracting Hygiene for Digital Health Start-Ups: Considerations for Investments, Acquisitions, and Other Strategic Events Pages 4-5

Recent Enforcement Actions Against Electronic Health Records (EHR) Technology Vendors..... Pages 6-7

HIPAA for Digital Health Entrepreneurs: Proposed Changes to Improve Individual Access to PHI Pages 7-9

a 2,900 percent increase.¹ Somewhat unsurprisingly, the health and wellness market size is ballooning, expected to be worth \$657.8 billion by 2025.²

How are wellness devices regulated?

Historically, the U.S. Food and Drug Administration (FDA) had the authority to regulate general wellness products under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Up until recently, these devices were not distinguished from medical devices,

which generally require FDA review prior to marketing.

However, the FDA and legislators have since recognized that general wellness devices do not warrant the same level of regulatory scrutiny. In 2016, Congress passed the 21st Cures Act (Cures Act) which was implemented to accelerate medical product development and innovation.³ In 2019, the FDA released revised guidelines specifically excluding software functions that are intended for

¹ Fitbit Staff, "Finding Your Pandemic Flow: New Fitbit Data Reveals Your New Favorite Activities" (Oct. 20, 2020), <https://blog.fitbit.com/finding-your-pandemic-flow/>.

² Press Release, AnalystView, "Connected Health & Wellness Devices Market Size Worth \$657.8 Billion by 2025" (Sept. 17, 2013), <https://www.analystviewmarketinsights.com/press-release-connected-health-wellness-devices-market/>.

³ 21st Century Cures Act, FDA (Jan. 31, 2020), <https://www.fda.gov/regulatory-information/select-ed-amendments-fdc-act/21st-century-cures-act>.

FDA Regulation of Wellness Devices (Continued from page 1)

maintaining or encouraging a healthy lifestyle from the definition of a “medical device.”⁴

Further, the Center for Devices and Radiological Health (CDRH) under the FDA has indicated that it does not intend to examine low-risk general wellness products to determine whether they are devices within the FD&C Act, or if they are devices, whether they comply with pre-market review and post-market regulatory requirements for devices.

Under the current regulatory guidance, the FDA has defined a general wellness product under two criteria:⁵

- (1) the device has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
- (2) the device has an intended use that relates to the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease and condition.

Wellness devices which fall in the first category cannot make any reference to diseases or conditions—only general wellness claims. For example, a wellness device under this category could claim that it promotes or maintains a healthy weight or manage stress levels. However, it could not claim that it will treat an

eating disorder, such as anorexia.

Wellness devices which fall into the second category may indicate their intended uses are to promote, track, and/or encourage choices, which as part of a healthy lifestyle, may either 1) help reduce the risk or 2) help living well with certain chronic diseases or conditions, such as heart disease, high blood pressure, and type 2 diabetes.

Unlike the wellness devices that fall in the first category, devices in the second category can make reference to diseases and conditions. It is important that the consumer understands that healthy lifestyle choices play an important role in their health outcomes.⁶

If any answer to the below questions is yes, then the device is not low risk, and it would not be covered by FDA’s current issued guidance for wellness devices. Denial of one of these questions could trigger additional requirement under the FDA, including a 510(k) premarket review, to review the device as a medical device.

- 1. Is the product invasive?⁷
- 2. Is the product implanted?
- 3. Does the product involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are

	Allowed to mention disease/condition?	Permitted Claim	Impermissible Claim
First Category of Intended Use	Yes	Claims to promote physical fitness, such as to help log, track, or trend exercise activity	A claim that a product will treat or diagnose obesity
Second Category of Intended Use	No	Product promotes physical activity, which, as part of a healthy lifestyle, <i>may help reduce the risk</i> of high blood pressure	A claim that a product will <i>treat</i> muscle atrophy or erectile dysfunction

How is risk level determined?

After determining under which category a wellness device qualifies, the manufacturer would then need to assess whether the device qualifies as low risk. The FDA has posited three questions to determine the risk-level of a device.

not applied, such as risks from lasers or radiation exposure?

The FDA has provided guidance in the form of a non-exhaustive list on products which would not qualify as “low risk” devices:

⁴ Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act, FDA (Sept. 27, 2019), <https://www.fda.gov/media/109622/download>.

⁵ General Wellness: Policy for Low Risk Devices, FDA (Sept. 27, 2019), <https://www.fda.gov/media/90652/download>.

⁶ Webinar: General Wellness Guidance: Policy for Low Risk Devices, FDA (Sept. 1, 2016), <https://www.fda.gov/media/99809/download>.

⁷ The FDA defines “invasive” as “penetrat[ing] or pierc[ing] the skin or mucous membranes of the body.” Policy for Low Risk Devices, *supra* note 5.

FDA Regulation of Wellness Devices *(Continued from page 2)*

Device	Promoted Claim	Why it isn't classified as low-risk
Sunlamp	tanning purposes	risks to a user's safety from the ultraviolet radiation, including, without limitation, an increased risk of skin cancer
Implants	improved self-image or enhanced sexual function	Implants pose risks to users such as rupture or adverse reaction to implant materials and risks associated with the implantation procedure
A laser product	improve confidence in user's appearance by rejuvenating the skin	While the claims of rejuvenating the skin and improving confidence in user's appearance are general wellness claims, laser technology presents risks of skin and eye burns
A neurostimulation product	Improve memory	risks to a user's safety from electrical stimulation

How narrow is the distinction between what qualifies as a medical device versus a wellness device?

Sometimes the distinction of a wellness device versus a medical device can be a fine line, so much so, in fact that the FDA released guidance on "Multiple Function Device Products" in 2020. The FDA released this guidance specifically because medical products could contain several function, some of which would fall under the FDA's purview, and others wouldn't. Products which contain some functions which don't qualify under the FD&C Act, but have functions which would, are still subject to FDA review. However, the FDA would not assess the exempted functions as the subject of their review, but only their impact when

assessing the safety and effectiveness of the device function which is under review.⁸

In October 2020, Apple launched its Apple Watch Series 6, which advertised two distinct features for users: a pulse oximeter (also called a blood oxygen monitor) and an electrocardiogram (EKG) feature. The EKG feature, which originally was developed in 2018,⁹ needed FDA approval whereas the pulse oximeter did not. The key difference was the intended use of each feature. The EKG feature, which flags irregular heart rhythm, serves a specific medical purpose. The FDA approved the EKG feature in the Apple Watches as a Class II medical device. Apple claims that their pulse oximeter, on the other hand,

only provides information and is not monitoring or diagnosing the user with that data, which qualifies it as a wellness device.

Should wellness devices be trusted when making medical decisions?

In 2016, a study in Ireland revealed that wellness devices can come attached to some valid concerns. One of the largest concerns is that consumers trust the validity of the device, perhaps a little too much.¹⁰ NPR published an article where doctors commented that patients were bringing their wellness devices to appointments, asking the doctor to digest the information from that device.¹¹ The University of Illinois at Chicago concurred that wellness devices can provide inaccurate information, leading to an erroneous understanding of the data.¹²

This doesn't mean wellness devices are inaccurate. Indeed, a separate study revealed that, in general, wellness devices can accurately measure some features such as heart rate, number of steps, distance, and sleep duration.¹³

Now more than ever, appropriate product claims are critical for managing regulatory oversight, promoting user understanding and satisfaction, and thriving as a wellness business.

⁸ *Multiple Function Device Products: Policy and Considerations*, FDA (July 29, 2020), <https://www.fda.gov/media/112671/download>.

⁹ Letter from Angela C. Krueger, Deputy Director, Center for Devices and Radiological Health, to Donna-Bea Tillman (Sept. 11, 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf.

¹⁰ M. Schukat, et al., "Unintended Consequences of Wearable Sensor Use in Healthcare," 1 Yearbook Med. Info. 73 (Nov. 2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5171570/>.

¹¹ Patti Neighmond, "Fitness Trackers: Good at Measuring Heart Rate, Not So Good At Measuring Calories," NPR (May 24, 2017), <https://www.npr.org/sections/health-shots/2017/05/24/529839681/fitness-trackers-good-at-measuring-heart-rate-not-so-good-at-measuring-calories>.

¹² "Ethics of Wearables: How Health Providers Use Health Data Insights from Wellness Technology," University of Illinois Chicago, <https://healthinformatics.uic.edu/blog/ethics-of-wearables/>.

¹³ Junoing Xie, et al., "Evaluating the Validity of Current Mainstream Wearable Devices in Fitness Tracking Under Various Physical Activities: Comparative Study," 6(4) *JMIR mHealth and uHealth* e94 (Apr. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5920198/>.

Commercial Contracting Hygiene for Digital Health Start-Ups: Considerations for Investments, Acquisitions, and Other Strategic Events

By Subha Patibanda and Nayha Lang

For the same reasons that doctors laud preventive healthcare, we advise our digital health clients (especially those that plan to engage with investors, acquirers, or other strategic partners) to practice good commercial contracting hygiene throughout their life cycle. It is not uncommon for strategic events to be held up because of problematic contract provisions that are perceived to hinder the value of the deal. In this article, we outline some common commercial contracting considerations that digital health companies should keep in mind as they consider an investment, acquisition, or other strategic event in their life cycle:

Intellectual Property and Confidentiality Protections

- Because a company's intellectual property portfolio is often one of its most important assets, potential investors and acquirers often closely evaluate the intellectual property-related provisions (or lack thereof) in commercial contracts. At a high level, investors and acquirers want to ensure that a company truly owns the intellectual property rights that it believes it owns, has obtained sufficient licenses for any third-party dependencies, and has not transferred or granted overbroad rights and licenses to third parties.
- For example, if your company has engaged a third party to develop its flagship product, ensure that the agreement includes carefully drafted inbound assignment provisions that effectuate a transfer of intellectual property rights to the company. This



language should be drafted in the present tense (e.g., the counterparty “hereby assigns”) rather than worded as a future obligation (e.g., “agrees to assign” or “shall assign”).

- On the other hand, be especially cautious of any obligations to transfer out or exclusively license any intellectual property rights to a third party. Such provisions, if agreed to at all, must be drafted very carefully to ensure that the company's proprietary rights are protected. Further, any disclosure, license, or escrow obligations with respect to the company's source code are likely to be very carefully analyzed (especially to make sure that a particular transaction does not trigger release).
- Whenever your company is disclosing confidential information, ensure that appropriate written confidentiality obligations are in place.

Significant Business Constraints

- Potential investors or acquirers often want to understand whether a company has agreed to restrictions

that would materially limit the company's (or a potential acquirer's) ability to conduct business. Such restrictions may impact an investor's perception of a company's future profitability or an acquirer's future integration plans. Examples of significant business restrictions may include non-competition/non-solicitation restrictions, “most-favored nations” or other terms related to preferential pricing or supply, covenants not to sue, exclusivities, and rights of first refusal/negotiation. Keep a close eye out for any such provisions that could potentially bind an acquirer (e.g., if a non-competition restriction is intended to bind a company and its future affiliates), as these provisions may especially magnify concerns.

Assignability and Other Transactional Effects

- Though often looped in with other “boilerplate” provisions, assignment (or anti-assignment) clauses are often one of the most consequential and, as a result, most carefully diligenced clauses in the

Commercial Contracting Hygiene for Digital Health Start-Ups . . . *(Continued from page 4)*

context of mergers and acquisitions. Assignment provisions set forth the situations in which a party may (or may not) assign the agreement to a third party, and may also set forth certain requirements, obligations, or other “effects” that may be triggered as a result of a particular transaction (e.g., consent and notice requirements, termination rights, springing payment, license, or other obligations). These types of provisions will likely be considered when determining whether a potential acquirer is likely to see certain contracts as roadblocks to closing, and so carefully drafting assignability and related provisions to preserve your flexibility (especially in the event of a merger, acquisition, or other change of control) can help minimize issues on this front down the line.

Termination Rights

- When negotiating with material vendors or customers, consider how easy or difficult it will be for either party to walk away from the arrangement.
- Potential investors and acquirers often diligence how “sticky” a company’s agreements with material vendors and customers are, and may be concerned about future bottom line and stability if these vendors and customers can easily walk away from the company. For example, a potential investor or acquirer may be wary about a company’s future profit stability if 90 percent of revenue stems from one customer that has the right to terminate the agreement at any time with no penalty. Similarly, if a hard-to-replace material vendor can easily terminate an agreement with little

or no notice, a potential investor or acquirer may be concerned about the company’s operational stability.

- On the flip side, also keep in mind the company’s own rights to terminate an agreement, because potential acquirers could be looking to buy a particular company for a number of reasons that may or may not include the company’s existing relationships. For example, if the acquirer’s sole reason for acquiring your company is your patent portfolio, 10-year binding commitments to supply your product to customers may raise some concerns.

Other Considerations

- At a high level, potential investors and acquirers may wish to assess a company’s general risk profile by analyzing the risk allocation provisions in a company’s commercial contracts (e.g., if a company takes on significant risk in many of its agreements by not capping liability, offering non-standard outbound warranties and indemnification obligations).
- Consider whether your product (software or hardware) is subject to any regulatory approval, permit, registration, or authorization, including by the FDA or any other federal, state, or foreign equivalent. In addition to obtaining any required authorizations from regulatory agencies or governmental authorities, the claims you make about your product should be truthful, evidence-based, and not misleading, consistent with applicable federal, state, and foreign laws and regulations (e.g., FDA and FTC regulations).

- If you are contracting with any licensed (or government-regulated) healthcare professionals or entities, or government entities, or if the contracts involve healthcare products and services or FDA-regulated products, there are additional regulatory considerations involved in evaluating whether such transaction is permissible under applicable laws and regulations (e.g., healthcare fraud and abuse laws) or otherwise imposes a material risk to your company. For transactions that involve FDA-regulated products, licensed healthcare professionals, or healthcare services or items subject to federal and/or state regulations, it is helpful to consider regulatory implications and risks associated with proposed business models and fee structures before diving into contract drafting or negotiations.
- Understand your company’s position as to whether it is subject to HIPAA, and the basis for this position. Ensure that your company’s contracting practices are consistent with this position (e.g., does your company sign business associate agreements with customers and with downstream vendors?).
- Ensure that your company’s contracting practices align with the company’s actual inward- and outward-facing privacy policies and procedures, and that the company’s practices, policies, and procedures are consistent with applicable laws (e.g., CCPA and GDPR).

Please do not hesitate to contact your attorneys at Wilson Sonsini Goodrich & Rosati if you need assistance with drafting, reviewing, or negotiating your commercial contracts.

Recent Enforcement Actions Against Electronic Health Records (EHR) Technology Vendors

By Eva Yin

With the expansion of the digital health and telemedicine markets, electronic health records (EHR) vendors should take note of recent enforcement actions by the Department of Justice (DOJ) and the Department of Health and Human Services, Office of Inspector General (HHS-OIG). Many start-up companies new to the healthcare industry often think that healthcare fraud and abuse laws do not apply to health records software or related technologies and make the mistake of thinking that they only need to be concerned with privacy laws. Recent enforcement actions in this space serve as a reminder that EHR technology companies that contract with healthcare professionals or entities, or collaborate with pharmaceutical or biotechnology companies, are subject to broad healthcare fraud and abuse laws, and that marketing programs that involve referrals or lead generation arrangements, or other incentives that induce or influence the selection of the EHR platform, can result in lawsuits, government investigations, and millions of dollars in settlements.

Two broad healthcare fraud and abuse laws that the federal government can use to go after any player in the healthcare supply chain, from physicians and distributors to technology developers and manufacturers, are the federal Anti-Kickback Statute (AKS) and the False Claims Act (FCA).

The AKS is a criminal law that generally prohibits the knowing and willful payment of any remuneration to induce, reward, or incentivize patient referrals or business generated between parties involving any healthcare item or service payable by a federal healthcare program, such as Medicare or Medicaid. Remuneration can include anything of value, including revenue-sharing arrangements, commission or referral fees, provision of free services or products, expensive hotel stays or meals, and excessive compensation. The civil FCA makes it illegal for any person or entity to knowingly submit, or cause the submission of, a false or fraudulent claim to the federal government for payment. Further, a claim that results from an illegal kickback under the AKS can create liability under the civil FCA in addition to the AKS liability. What this means in practice is illustrated by the following examples:

- January 2021 – athenahealth, Inc. (Athena), a national EHR vendor based in Massachusetts, agreed to pay \$18.25 million to resolve FCA and AKS violations related to its marketing programs that provided unlawful kickbacks to customers in exchange for sales of its EHR product.¹ Illegal kickbacks provided to customers included free tickets and amenities to entertainment and recreational events, complimentary travel and luxury accommodations, payments up to \$3,000 to existing customers for identifying and referring new customers who sign

up for Athena's products or services, and deals with competing vendors to discontinue competing product offerings and to refer their clients to Athena, including payments made to competitors based on the value and the volume of clients who successfully converted from competitors to Athena.

- January 2020 – Practice Fusion Inc. (Practice Fusion), a health information technology developer based in California, agreed to pay \$145 million to resolve criminal and civil investigations related to its EHR software, including soliciting and receiving illegal kickbacks from pharmaceutical companies in exchange for implementing clinical decision support (CDS) alerts in its EHR software designed to increase prescriptions for their drug products.² In particular, in exchange for "sponsorship" payments from pharmaceutical companies, Practice Fusion allowed pharmaceutical companies to influence the design and the implementation of the CDS alerts, including setting the criteria that triggered an alert to healthcare providers.

These recent enforcement actions highlight the importance of healthcare regulatory compliance for EHR companies, as well as pharmaceutical and biotechnology companies that collaborate or contract with EHR companies to provide certain services or products to healthcare providers, healthcare organizations, or patients.

¹ DOJ, News Release, "Electronic Health Records Technology Vendor to Pay \$18.25 Million to Resolve Kickback Allegations" (January 28, 2021), available at <https://www.justice.gov/opa/pr/electronic-health-records-technology-vendor-pay-1825-million-resolve-kickback-allegations>.

² DOJ, News Release, "Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations" (January 27, 2020), available at <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0>.

Recent Enforcement Actions Against Electronic Health Records . . . (Continued from page 6)

Since 2016, the government has reported a significant increase in telefraud schemes and has increased its scrutiny of the telehealth and telemedicine markets—and digital health companies, including EHR vendors, are no exception. Accordingly, EHR vendors and companies that contract with EHR vendors should address key regulatory risks under healthcare fraud and abuse laws as part of their compliance programs, as well as in financial arrangements, including marketing programs, involving healthcare professionals or organizations.

On February 26, 2021, in an open letter, HHS-OIG Principal Deputy Inspector General Grimm noted that, while the government recognizes the importance of telehealth services in improving care coordination and health outcomes, a year after the COVID-19 public health emergency, the government is assessing telehealth services, including concerns raised in various enforcement actions. New policies and regulations in this space are anticipated in the coming years.

“It is important that new policies and technologies with potential

*to improve care and enhance convenience achieve these goals and are not compromised by fraud, abuse, or misuse. **OIG is conducting significant oversight work assessing telehealth services during the public health emergency.** Once complete, these reviews will provide objective findings and recommendations that can further inform policymakers and other stakeholders considering what telehealth flexibilities should be permanent.”³*

³ HHS, Principal Deputy Inspector General Grimm on Telehealth (February 26, 2021), available at <https://oig.hhs.gov/coronavirus/letter-grimm-02262021.asp>.

HIPAA for Digital Health Entrepreneurs: Proposed Changes to Improve Individual Access to PHI

By Haley Bavasi

Welcome to the next installment in our series exploring the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for entrepreneurs. This series focuses on HIPAA topics impacting our digital health clients, particularly those who may be newly encountering health privacy. In this installment, we detour from navigating the ins-and-outs of HIPAA as it stands today to highlight proposed changes that aim to expand individuals’ access to PHI and improve the overall coordination of care. These changes are part of a broader, multi-pronged initiative by

the Department of Health and Human Services (HHS) to move from a fee-for-service model to value-based care, in what HHS calls the “Regulatory Sprint to Coordinated Care.” As part of this effort, on December 10, 2020, the HHS Office for Civil Rights (OCR) announced proposed changes to HIPAA through a Notice of Proposed Rulemaking¹ (Proposed Rule), which changes aim to enhance value-based, coordinated care while maintaining the privacy and security of PHI. These proposed changes open the door to significant opportunities for entrepreneurs developing innovative services and products that further the goal of

individual empowerment over their health and enhanced continuum of care.

Background

When we talk about “expanding access,” what exactly does that mean? What rights do patients already have in and to our medical information? If your medical information is “protected health information” (PHI) subject to HIPAA, your rights include the right to access, inspect, copy, and request an accounting of disclosures of your PHI kept in a “designated record set” (which is, in short, a group of medical and billing records). Individuals also have the right to direct a covered entity to transmit

¹ The Proposed Rule can be viewed at <https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf>.

Continued on page 8...

HIPAA for Digital Health Entrepreneurs . . . (Continued from page 7)

PHI to another entity or individual, such as a new provider or family member.² While these rights are granted by law, historically they've been difficult to exercise, especially as many of us have become accustomed to information being literally available at our fingertips.

Take, for instance, the relatable scenario of needing to transfer medical records to a new provider. You may have felt a little bewildered when told *you* would need to track down all your previous records, and maybe you were even more shocked when told these records would need to be faxed or delivered via snail mail (yes, this still happens). It's not uncommon for providers, particularly specialists, to refuse to put new patients on the schedule until all your previous records are in hand. If you've ever had this experience, it may have led to a myriad of relatively unpleasant encounters navigating patient portals, provider websites, printing and faxing forms, email and calls to the front office, among other vexing hurdles. This user experience is very much a symptom of clunky means of accessing or otherwise exercising our rights to PHI. While HIPAA prohibits covered entities from creating barriers or unreasonably delaying access to PHI, in practice, when dealing with healthcare bureaucracy, the process tends to be anything but seamless, resulting in more negative experiences for patients and their caregivers.

The Proposal

HHS OCR acknowledged in publishing the Proposed Rule that “individuals

frequently face barriers to obtaining timely access to their PHI, in the form and format requested, and at a reasonable, cost-based fee.” To combat these issues, the Proposed Rule, among other things: 1) enhances individuals' rights to PHI, including the right to direct information to third parties, 2) changes the scope of permitted disclosures by covered entities in order to improve care coordination and case management, 3) permits more flexible disclosures in emergency circumstances or based on a provider's professional judgment, and 4) changes requirements relating to covered entities' notice of privacy practices.

Right of Access to PHI

Proposed changes expanding individuals' rights of access arguably presents the greatest opportunities for those in the digital health field, in part because it enables individuals to use third-party applications to access medical information and requires covered entities to generally respect these new means of disclosure. Specifically, the Proposed Rule:

- enables individuals to leverage their own devices to capture PHI without charge, such as taking notes or capturing images of their chart on a phone camera;
- clarifies that an individual's right of access can be satisfied by sharing PHI through a personal health application;
- requires covered entities to respond to requests by individuals within 15 calendar days instead of 30 days;

- eliminates the fee covered entities may currently charge for electronically transmitted PHI, such that PHI must be provided free of charge to individuals requesting it through electronic means;
- requires covered entities to post a fee schedule on their website for providing PHI that would still be subject to a fee;
- clarifies the format in which covered entities must respond to individuals' requests for their PHI; and
- prohibits covered entities from imposing unreasonable identify verification measures when individual's request access to PHI.

Right to Direct PHI to Third Parties

The Proposed Rule would distinguish between an individual's right to access, inspect, and copy PHI, versus an individual's right to direct covered entities to share PHI among themselves through electronic health record (EHR) systems. At an individual's direction, a covered entity would now be required to submit requests for medical records from another healthcare provider's EHR. On the flip side, the Proposed Rule would require covered entities receiving those requests to respond when directed by the individual, whether the request is made orally or in writing. This change would have a direct impact on that relatable scenario outlined above—instead of putting the onus on patients to collect and transmit their records, covered entities would be required to make and respond to requests for PHI at the individual's direction.

² See [hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html) for more information about individuals' rights related to PHI.

HIPAA for Digital Health Entrepreneurs . . . *(Continued from page 8)*

Disclosures for Care Coordination and Case Management

Under the current rules, covered entities are permitted to disclose PHI for treatment and healthcare operations purposes without obtaining patient authorization. The Proposed Rule expands the scope of these disclosures by clarifying covered entities may disclose PHI to home- and community-based organizations and service providers, social service agencies, and other similar third parties that provide health-related services in order to improve the coordination of care and case management for individuals. Importantly, the disclosures do not need to be made to entities that are healthcare providers or covered entities, giving providers covered by HIPAA greater latitude to coordinate individuals' care across a continuum of services.

Disclosures in Emergency Situations

The Proposed Rule would change when covered entities can disclose PHI in emergency situations. Currently, these disclosures can be made to avoid harm

to health and safety only if the harm is "serious and imminent." Under the Proposed Rule, disclosures could be made if in the reasonable judgment of the provider, the harm is "serious and reasonably foreseeable." The impetus for this change is to give providers greater latitude to exercise their professional judgment for cases that have been considered "close calls" in the absence of any clear line in the first place, such as when an individual appears suicidal but has not expressed an "imminent" plan to harm themselves. On a related point, the Proposed Rule would allow providers to disclose PHI when, based on their professional judgment, it is in the best interest of the patient, even absent emergent circumstances.

Notice of Privacy Practices

Covered entities currently are required to provide patients with a notice of privacy practices and obtain written acknowledgment that the patient has received and read this notice. This requirement has proven administratively onerous on healthcare providers, arguably without doing much to educate

individuals about the contents of the notice or their rights. The Proposed Rule would replace the written acknowledgement requirement with an individual right to discuss the notice with a person designated by the covered entity, among other modifications that aim to make it easier for patients to understand their rights in a meaningful way.

Next Steps

The notice and comment period for the Proposed Rule was recently extended through May 6, 2021 due to public interest in the proposed changes. While there currently is no timeline for finalizing the Proposed Rule, when a final rule eventually emerges, we will report back on the final changes with a more specific focus on what these changes mean for our digital health entrepreneurs.

Please contact your Wilson Sonsini attorney for more information and further assistance on HIPAA topics.

The Digital Health Report is developed and reviewed by a team of attorneys from the firm's corporate, intellectual property, litigation, and regulatory departments, including the individuals listed below.

Ali R. Alemozafar
Partner
Intellectual Property
415-947-2054
aalemozafar@wsgr.com

Haley N. Bavasi
Associate
Privacy and Cybersecurity
206-883-2662
hbavasi@wsgr.com

Farah Gerdes
Partner
Technology Transactions
617-598-7821
fgerdes@wsgr.com

David Hoffmeister
Partner
Corporate
650-354-4246
dhoffmeister@wsgr.com

Michael Hostetler
Partner
Patents and Innovations
858-350-2306
mhostetler@wsgr.com

James Huie
Partner
Corporate
650-565-3981
jhuie@wsgr.com

Manja Sachet
Partner
Technology Transactions
206-883-2521
msachet@wsgr.com

Kathleen Snyder
Of Counsel
Technology Transactions
617-598-7857
ksnyder@wsgr.com

WILSON SONSINI

650 Page Mill Road, Palo Alto, California 94304-1050 | Phone 650-493-9300 | Fax 650-493-6811 | www.wsgr.com

Austin Beijing Boston Brussels Hong Kong London Los Angeles New York Palo Alto San Diego San Francisco Seattle Shanghai Washington, DC Wilmington, DE

This communication is provided as a service to our clients and friends and is for informational purposes only. It is not intended to create an attorney-client relationship or constitute an advertisement, a solicitation, or professional advice as to any particular situation.

© 2021 Wilson Sonsini Goodrich & Rosati, Professional Corporation. All rights reserved.