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WILSON SONSINI

# DIGITAL HEALTH REPORT

## Real-World Evidence and Digital Health

*By David Hoffmeister, Vern Norviel, and Charles Andres*

**Introduction**

The 21st Century Cures Act added section 505F to the Federal Food, Drug, and Cosmetic Act (FDCA). Section 505F requires that the U.S. Food and Drug Administration (FDA) "establish a program to evaluate the potential use of real-world evidence" to "help support approval of a new indication for a drug . . ." and to "help support or satisfy post approval study requirements."

Real-world evidence can be an important component of satisfying drug approval and post-approval study requirements and also, can provide other tangible advantages to drug sponsors. What's more, the generation and use of real-world evidence is anticipated to

experience significant growth over the next decade. But what is real-world evidence? What data can be used to establish real-world evidence? What is the relative importance of real-world evidence? And how does digital health intersect with real-word evidence? We address these questions, and others, in this article.

**What is Real-World Evidence (RWE)?**

Real-world evidence (RWE) means "*data* regarding the *usage*, or the *potential benefits* or *risks*, *of a drug* derived *from sources other than traditional clinical trials*." (Emphasis added.) RWE is based on real-world data.

**What is Real-World Data (RWD)?**

Real-world data (RWD) is used to generate RWE. The FDA defines real-world data, according to a draft guidance, as "data relating to patient health status and/or delivery of health care that are routinely collected from a variety of sources." These data can include: data derived from electronic health records, medical claims and billing data, data from product and disease registries, *patient generated data, and data gathered from other sources that can inform on health status, such as mobile devices*. (Emphasis added.)

**What are RWE and RWD used for?**

RWE and RWD can *support* investigational new drug applications (INDs); new drug applications (NDAs); and biologics license applications (BLAs). RWE and RWD can be used to support regulatory decisions regarding safety, effectiveness, or both. The keyword is support.

The data that will primarily influence approval or licensing will continue to

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be data generated from clinical trials—preferably "gold standard" clinical trials that are randomized, blinded, placebo-controlled trials with sufficient patient enrollment to demonstrate statistically significant efficacy (e.g., phase 3 clinical trials).

Thus, RWE and RWD will not, on their own, provide sufficient basis to demonstrate substantial evidence of drug safety and efficacy for drug approval or licensing. Rather, RWE and RWD can act in an ancillary, supportive role to the clinical trial data contained in an NDA or BLA.

**How are RWE and RWD submitted to the FDA?**

In a cover letter accompanying the submission, the sponsor "should identify the submission as containing RWE" by including the following information:

1) *The purpose of the RWE*, which can include:

- Providing evidence supporting safety or efficacy for a drug approval;
- Providing evidence supporting a label change for an approved drug; and
- Part of a post marketing requirement to support a regulatory decision.

2) *The study design using the RWE*, which can include: a randomized clinical trial; single arm trial; or observational study; and

3) *RWE Sources Used to Generate the RWE*, for example, data collected from mobile technologies and patient generate data.

**What are some potential advantages of generating and submitting RWE?**

RWE has the potential to increase patient engagement in the clinical trial—especially if the RWE is gathered using a mobile device and patients can view and share their own health information in real time. Additionally, RWE may provide significant reductions in clinical trial time and cost through, e.g., new clinical trial designs (e.g., adaptive clinical trials). Further, RWE can support a patient-centric shift in clinical trial research, which may in turn, increase the number and diversity of patients who enroll in clinical trials. Traditionally, for example, the percentage of the population that participates in a clinical trial is estimated to be about 3 percent. RWE can enable larger scale research than could otherwise be conducted. And, importantly, there is precedent for using RWE in place of a control arm of a clinical trial. We expect to see continued growth in this area.

Below is an example of a table that can be submitted in an FDA submission:

**Purpose(s) of Using RWE as Part of the Submission (Select all that apply)**

- ☐ To provide evidence in support of effectiveness or safety for a new product approval
- ☐ To provide evidence in of support labeling changes for an approved drug, including:
  - ☐ Add or modify an indication
  - ☐ Change in dose, does regimen, or route of administration
  - ☐ Use in a new population
  - ☐ Add comparative effectiveness information
  - ☐ Add safety information
  - ☐ Other labeling change. Specify:
- ☐ To be used as a part of a postmarketing requirement to support a regulatory decision

**Study Design(s) Using RWE (Select all that apply)**

- ☐ Randomized clinical trial
- ☐ Single arm trial
- ☐ Observational study
- ☐ Other study design. Specify:

**RWD Source(s) Used to Generate RWE (Select all that apply)**

- ☐ Data derived from electronic health records
- ☐ Medical claims and/or billing data
- ☐ Product and/or disease registry data
- ☐ Other data source that can inform on health status. Specify:

**What are some potential disadvantages of generating and submitting RWE?**

The use of RWE, for example, to increase patient engagement, could potentially impact the ability to obtain patent protection for new patents arising from the clinical trial data. For example, suppose RWE identifies a potential drug-drug interaction, which could result in a label change. Also suppose that a patent or patients share the data publicly and

prematurely. Such sharing may result in the loss of the right to patent in some jurisdictions.

Also, while RWE can enable larger scale research, patients may not be prompt in inputting their health information into mobile devices, data may not be readily available from other real world sources, like insurance companies, which could result in a large amount of missing data during the course of the research. In other words, although a large amount of data can be collected using RWE study designs, the data may not be usable or useful if large amounts of data are missing. In the absence of a standardized, automated, data collection and reporting format, using RWE may entail time consuming, human reviews on the part of the drug sponsor. Finally, it is possible that, when RWE is used in place of a control arm of a clinical trial, the FDA, in evaluating a new drug application or biologics license application, could determine that the RWE-based control arm was deficient or inadequate, possibly necessitating collection of additional clinical trial data.

**What can RWE inform?**

RWE can inform drug sponsors and the FDA, for example, on treatment response duration, the difference between response and comparator or placebo, drug candidate side effects, patient emotional state, patient quality of life, patient lifestyle (e.g., the amount, intensity, and duration of exercise), patient adherence to a treatment regimen, and patient satisfaction with the drug or drug candidate treatment. Some of this data, by definition, is subjective, but would appear to be important, for at least the following reasons.

First, insurers and governments are increasingly demanding evidence that a drug's price is justified by the drug's benefits (e.g., drug efficacy pricing). RWE can support a sponsor's argument that a drug provides value beyond the standard of care. Second, the FDA (and other regulatory agencies) are in the process of shifting toward a patient-centered focus, where the agencies want to understand how patients experience disease and treatment (for example, in the areas of depression and cancer). That subjective information must come from patients, and can be met, at least in part, by RWE. Further, RWE can help sponsors better understand the challenges facing patients who have been diagnosed with a specific disease or condition.

**How does RWE intersect with digital health?**

Protected health information (PHI) from electronic health records (EHRs) can be used, for example, to augment or replace data from a control arm of a clinical trial. This is a powerful intersection of digital health and RWE.

Mobile phones and other mobile digital health devices (e.g., Fitbits, Apple Watches) have become commonplace in both developed and emerging countries. This can provide the opportunity to gather RWE information across populations, demographics, and age groups.

Mobile devices increase the opportunity to accurately capture RWD. In the instance where data are transferred automatically from a mobile device to a database, manual data entry error is potentially minimized.

Patients can easily complete questionnaires on mobile devices. Along these lines, RWE can increase patient engagement throughout the lifetime of a product.

Mobile devices can be used to increase the probability of patient compliance by providing timely prompts, facilitating communication with healthcare providers, and rewarding desired patient actions. We expect this last area to see tremendous growth in platforms, hardware, and the patents supporting these.

Protocols to collect RWE and RWD can be rapidly deployed and nearly simultaneously updated. This, in turn, can result in faster rollout of clinical research and help ensure that the research, regardless of where conducted, is done to the same standard.

RWE and RWD can be used to help understand subjective patient data. For example, if the patient subjectively reports feeling hot or flushed, ambient temperature data can help inform how the environment, if at all, contributed to the patient's subjective feeling.

**What about other digital health gathering hardware and software?**

In the face of a COVID-19 pandemic, and thereafter, remote, always-on patient monitoring devices may allow for conducting clinical trials that otherwise would not be conducted, or would start, if at all, at a later point in time. These remote study subject monitoring devices, which are configured to continuously collect patient data, will perhaps give researchers the most accurate, real-time window into a patient's moment-to-moment condition, and can help inform telemedicine discussions and trial site visits.

**What are some examples of the use of RWE?**

STAT recently reported on three uses of RWE, one instance in a drug first approval, and two other instances for an additional indication of an approved drug. An emerging and contentious area is the use of RWE as a "synthetic"

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control arm to reduce or eliminate the need for placebo arms in clinical trials. Synthetic control arms, for example, can occur when sets of health records replace placebo groups. In the area of oncology, for example, this can pit patient advocates—who do not think cancer patients in clinical trials should ever be given placebo or a treatment that is perceived as being less effective—against clinicians, who trust "gold standard" clinical trials.

**Conclusion**

RWE will be a growing area because it is important to patients, insurers, governments, and drug sponsors. Carefully planning clinical trials to gather useful RWE and RWD can increase a drug or drug candidates' probability of allowance or license and increase competitive advantage in the marketplace. Successfully doing this involves understanding digital health devices, platforms, databases, and software, how to best integrate these into clinical trials, and how to best extract valuable information from the acquired data.

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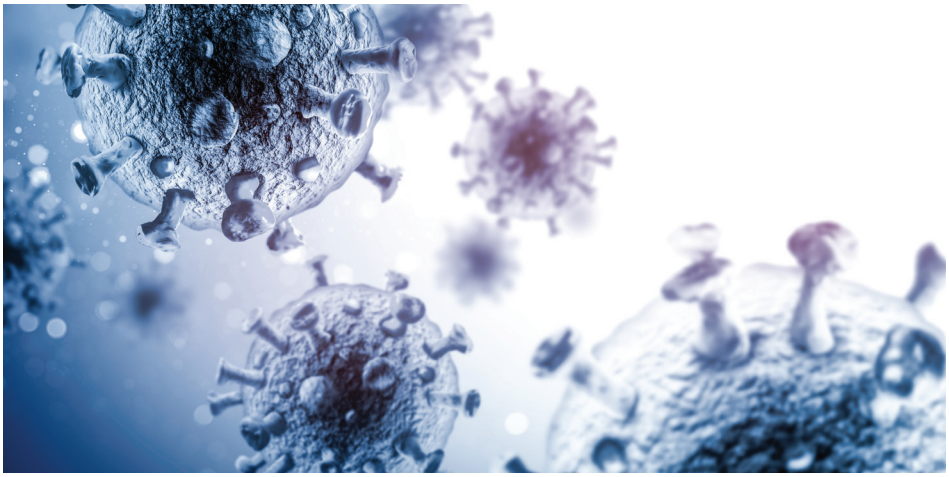
# COVID-19 May Prove Medicare's Tipping Point on Telehealth

*By Jeff Weinstein and Melissa Hudzik*

**Introduction**

The Medicare Program, the U.S.'s largest and foremost health insurer, has proven very slow at changing restrictive standards and limited coverage for telehealth.[1] Historically, Medicare has restricted reimbursement of telehealth to beneficiaries in rural areas and does not reimburse services received at home. These and varied other coverage limitations are widely regarded as having deterred adoption of telehealth by Medicare providers and beneficiaries.[2] In response to the COVID-19 pandemic, the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) greatly loosened constraints on Medicare telehealth in the context of the public health emergency (the Emergency). This article looks at some aspects of the



dramatic opening up of telehealth in "ordinary Medicare" (i.e., Parts A and B fee-for-service) during the Emergency and speculates about the possibility for permanent change.

**Responding to COVID-19**

Since the HHS Secretary declared the Emergency under section 319 of the Public Health Service Act on January 31, 2020, state and local authorities have directed more than 310 million Americans to shelter-in-place. Such orders likely caused many to defer elective and even necessary medical treatment, as have factors such as fear of contagion; lack of personal protective equipment; and difficult inconvenience

[1] Nicol Turner Lee, Jack Karsten, and Jordan Roberts, "Removing regulatory barriers to telehealth before and after COVID-19", Brookings Institution (May 6, 2020).

[2] *Ibid*. The Centers for Medicare and Medicaid Services (CMS) reported that telehealth services were accessed only by one-quarter of a percent (0.25 percent) of more than 35 million fee-for-service Medicare beneficiaries whose claims for 2016 were reviewed. CMS, "Report to Congress about Information on Medicare Telehealth" (March 2018).

arising from social distancing.[3] Federal policy makers and many stakeholders—including professional associations, specialty societies, and patient advocacy groups—have responded to this disruption of traditional face-to-face healthcare with renewed enthusiasm for telehealth.

The Coronavirus Preparedness and Response Supplemental Appropriations Act[4] (and the subsequent CARES Act[5]) along with long-standing emergency authority granted HHS under section 1135 of the Social Security Act (the Act), have afforded an opportunity to dramatically reorient Medicare policy for the duration of the Emergency. They have empowered HHS to waive many restrictions—including basic ones—and otherwise open up new areas of telehealth coverage.

**Opening Up Telehealth Coverage**

HHS and CMS have responded boldly, not only with regard to COVID-19 related services, but across Medicare telehealth. CMS has greatly expanded the varieties of telehealth that Medicare will reimburse—some 85 new codes were added on a temporary basis by April. The agency has announced that it intends to continue doing so in response to appropriate stakeholder requests. For the duration of the Emergency, the agency has adopted an expedited sub-regulatory process for amending the list of covered services.

A frequently updated list of Medicare covered telehealth codes can be found here: https://www.cms.gov/files/zip/covid-19-telehealth-services-phe.zip.

HHS has waived categorical restrictions so that all Medicare providers are eligible to perform reimbursed telehealth services. For the first time, physical therapists, occupational therapists, licensed clinical social workers, clinical psychologists, and speech language pathologists can receive payment from Medicare for telehealth.

**Lifting Basic Constraints**

Basic constraints on telehealth arrangements have been temporarily lifted. These include:

- Beneficiaries need no longer reside in rural areas in order to receive covered telehealth services. Beneficiaries in any geographic region are eligible.
- A beneficiary's home may now qualify as an "originating site" from which he or she can access telehealth visits; he or she need not physically present at an eligible medical facility.
- Telehealth visits may be conducted on ordinary telephones instead of dedicated special equipment.
- Providers may initiate telehealth services for beneficiaries whom they have not personally treated in the last three years.

HHS has violated some Medicare taboos. For example, Medicare has for the first time offered coverage for remote services provided via audio-only telephony.[6] In its March 2020 Interim Final Rule, CMS stated that it would allow providers to perform medical evaluations of beneficiaries who have audio phones only. CMS then broadened this coverage to include audio-only behavioral health and patient education services.[7] The late arrival of Medicare coverage for audio-only phone services, however narrow in relation to audio/visual services, represents a basic change long sought out by stakeholders. Little about this, or the expansion more broadly, appear dictated by recent or imminent technological breakthroughs (e.g., widespread adoption of 5G and rapidly multiplying web-based health platforms). Instead, HHS and CMS appear using flexibilities afforded in the Emergency to make a generalized response to stakeholders' putative needs and expressed demands during the current crises in public health and the healthcare economy.

**Less Obvious, but Significant Changes**

Beyond basic changes of the sort listed above, CMS and its sisters at HHS have temporarily pared back other less obvious policies variously perceived as impeding adoption of telehealth.

[3] In the first quarter of 2020, the Department of Commerce reported that almost half of the national decline in gross domestic product was attributed to a slowdown in the health care sector. During the months of April and May, the Bureau of Labor Statistics reported that the health care sector lost a net total of 1.1 million jobs." Reported in *Health Affairs Blog*, July 9, 2020.

[4] *Public Law* 116-123 (2020).

[5] *Public Law* 116-136 (2020).

[6] Specifically, under the CARES Act CMS waived provisions of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) that required that telecommunications systems incorporating video technology be used to furnish certain telehealth services.

[7] *Medicare and Medicaid Interim Final Rule and Request for Comments: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* [CMS-5531 IFC] (4/30/20).

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Such actions include:

- CMS instituted telehealth pay parity for audio/visual telehealth visits with services provided in-person (fee-for-service rate).
- The HHS Office of Inspector General, the agency charged with law enforcement relating to federal healthcare programs, has refrained from policing providers who reduce or waive otherwise applicable patient cost-sharing for remote services, including telehealth visits.[8]
- CMS put aside caps that limited how frequently Medicare beneficiaries can obtain telehealth services. For example: inpatient visits need no longer be spaced three days apart; skilled nursing facility visits need no longer be spaced 30 days apart; and critical care consult codes may be furnished to a Medicare beneficiary more than once per day.
- CMS allowed "direct physician supervision"—which ordinarily require physical proximity—to be provided virtually using real-time audio/video technology.
- CMS waived the Medicare requirement that providers be licensed in the state they are delivering telemedicine services when practicing across state lines, if a list of conditions are met. (This change does not exempt providers from state licensure requirements.)

**Prospects for Permanently Opening Up Medicare Telehealth**

What will come of these dramatic—if temporary—shifts in policy? They will very likely remain in place for at least several more months. Under section 319 of the Public Health Service Act, the Secretary may renew a public health emergency declaration every 90 days. The current renewal was set to expire on July 25, 2020. HHS recently signaled its intention to renew the determination again. It will likely remain in place through late October. Although it is unclear whether HHS will then undertake an additional renewal, it seems rather unlikely that the administration would permit these (and many other) Emergency policies, favorable for providers and beneficiaries alike, to lapse shortly preceding a crucial Presidential election.

HHS may be cueing up a permanent opening up of Medicare telehealth. On June 25, 2020, CMS issued its proposed Home Health Prospective Payment System rule for calendar year 2021. Under the proposed rule, home health agencies would be able to continue to utilize new telehealth benefits after the Emergency under certain conditions.[9] It remains to be seen if HHS finalizes this home health proposal or if comparable efforts will be made to make permanent more expansive telehealth coverage in other areas of ordinary Medicare (e.g., outpatient, ASCs, hospitals and SNFs, and hospice).

When the Emergency does end in any case, providers and beneficiaries will have enjoyed months of a much more expansive and generous approach to telehealth. Return to Medicare's old restrictive standards and coverage will likely seem anachronistic and—given intense campaigning by professional and patient interest groups—may prove politically impossible. We cannot speak with certainty about the long-term outcome of HHS's experiment in opening up Medicare telehealth during the Emergency. Many aspects of the recent course shift, including its pervasive and thoroughgoing nature, suggest that federal policymakers never intended a return to the status quo.

[8] OIG, "FAQs—OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak" available at: https://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2020/telehealth-waiver-faq-2020.pdf.

[9] Among other things, the telehealth must be related to the skilled services being furnished; must be outlined on the plan of care; and must be tied to a specific goal indicating how such use would facilitate treatment outcomes. The use of telehealth may not substitute for an in-person home visit that is ordered on the plan of care and cannot be considered a visit for the purpose of patient eligibility or payment. Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, 85 Fed. Reg. 39408, 39427-28 (June 30, 2020).

# HIPAA for Digital Health Entrepreneurs: Business Associate? Comply with HIPAA, BAA or Not

*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 that impact our digital health clients, particularly those who may be newly encountering health privacy. In a past installment we explored what it means to be a "business associate" by focusing on the type of services a company provides and who it provides them to.

Sometimes the analysis of whether a company is acting as a business associate is straightforward, sometimes it's complicated. Today's installment focuses on *when* your company should do be asking the question, "am I a business associate?" The answer is early and often. In reality, though, the first conversation I have with a client about HIPAA usually isn't proactively assessing their status as a business associate, but more typically in reaction to coming into contact with a business associate agreement (BAA). Do they need one? Can we provide one? Should they sign this one a potential customer sent?

This happens so frequently, in fact, that the purpose of this article is to press pause and say let's forget the BAA for a minute. If your company meets the definition of a "business associate" under HIPAA, you must comply with HIPAA once you know or should know you are processing protected health information (PHI), regardless of whether a BAA is in place.[1] This is because business associate status attaches by legal definition, not by any act of contracting. In other words, by the time a company is contemplating their status as a business associate, the HIPAA train may have already left the station. If a company is not aware of whether its service technically renders it a business associate under HIPAA, or if it knows it is a business associate but is not performing in a HIPAA-compliant manner, it is running a regulatory and business risk.

In this installment we dig a little more deeply into the implications of providing services that meet the definition of "business associate services."

**Refresher: What Constitutes Business Associate Services?**

Before diving in, a brief refresher on what constitutes business associate services is helpful to level-set. Not all services provided to a customer in the healthcare space will render you a business associate. If your product or service is only marketed to individual users, or your customer is involved in healthcare, but is not a covered entity, then, as a general rule, HIPAA is not implicated. A "business associate" is any person (broadly defined to include a natural person or organization) who, on behalf of a covered entity:

1) Creates, maintains, receives, or transmits protected health information (PHI) for a function or activity that is regulated by HIPAA, or
2) Provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for such covered entity, and the provision of such service involves the disclosure of PHI.[2]

A helpful way to approach this analysis may be to ask:

1) Is my target customer a "covered entity"?
2) If yes, will I create, maintain, receive, or transmit PHI, or will my product or services otherwise involve the disclosure of PHI?
3) If still yes, then does the service itself fit within the definition of a business associate service?

**If You Are a Business Associate, You Must Comply with HIPAA—BAA, Or Not**

Many digital health companies may also be business associates due to the simple fact that healthcare providers and health plans (both covered entities) are core to the healthcare ecosystem. This interaction often (but not always) creates a business associate relationship because the definition of PHI and business associate services are broad—in other words, it isn't hard to get from point A to "BA." (Some HIPAA humor…)

From a HIPAA perspective, the most important question digital health companies should be asking early and

[1] See 78 Fed. Reg. 5565, 5598 (January 25, 2013) ("The final rule establishes that a person becomes a business associate by definition, not by the act of contracting with a covered entity or otherwise.").
[2] See definition of "business associate" at 45 C.F.R. 160.103.

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## HIPAA for Digital Health Entrepreneurs: Business Associate? . . . *(Continued from page 7)*

frequently is do the services you provide or want to provide render you a business associate? Whether a BAA is in place is not dispositive: If your service meets the definition of a business associate service, you are a business associate with respect to that service and must comply with HIPAA, or else stop providing the service that makes you a business associate.

If you provide services that involve healthcare providers or health plans and haven't considered the HIPAA implications of your services, you may have ongoing regulatory obligations that you're not aware of (and therefore are likely not meeting). These obligations attach at any time the services meeting the definition are rendered, not when you're asked to sign a BAA. We see plenty of instances where covered entities who should be asking for BAAs simply don't, which unfortunately does not relieve the service provider of these obligations under HIPAA once they know, or should know, they are processing PHI.

You may be thinking, what if I don't *know* my product or service is being used by a covered entity to create, maintain, store, or transmit PHI? If I don't know that, then how could I possibly know if I'm hosting PHI? Great question, and the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has provided guidance on the matter. Below are three scenarios that illustrate why understanding how HIPAA applies to you is critical to your business.

**Scenario 1 – [Actual] Ignorance Is Bliss**

OCR recognizes there are certain instances where a company would not reasonably know their product or service was being used by a covered entity to maintain PHI, such that they are unwittingly performing a business associate service.[3] For example, if an industry-agnostic cloud service provider simply offers data storage services and doesn't market to any particular customer or advertise any special compliance abilities (unlike, e.g., AWS HIPAA-compliant cloud service provider (CSP) products), it likely isn't "reasonable" to assume the company knows or should know if PHI is being stored on its platform.

But what if PHI is actually being stored on your platform and you find out? Can you just ignore it? No. Unfortunately, you are no longer living in the realm of actual ignorance is bliss. In this situation, HIPAA provides an affirmative defense *if* a company acts to correct the "non-compliance" (disclosure of PHI without a business associate agreement in place) within **30 days** from the time it "knew, or by exercising reasonable diligence would have known" of the violation. But, according to OCR, there is *no defense* if the business associate was not aware of the violation is not due to its own "willful neglect."[4]

According to OCR, once you know you are processing PHI, you have three options:

- Comply with HIPAA (as a business associate)
- Securely return the PHI
- Securely destroy the PHI, with the covered entities permission

**Scenario 2 – All Other Ignorance, Likely No Excuse**

In this modified scenario, what if you don't "actually" know for sure whether your users include covered entities? For example, you have a peer-to-peer messaging app that's industry-agnostic (anyone can use it) but you proactively target market the app to doctors at hospitals, among other user groups, as being a secure, easy-to-use way to communicate with other providers about patients under your common care. The company considers this marketing a particular use case, but doesn't collect information that would identify a certain user as a physician—to them, all users look the same. Physicians at a particular hospital download the app and use it to communicate about their patients. Should the company know it would be used to transmit PHI? Does it have "constructive" knowledge of this fact? If a company reaps the benefit of successfully targeting certain covered entity customers, is it reasonable to later assert it didn't have reason to know these customers were using the service?

OCR's position appears to be that constructive knowledge is enough to determine a company is providing business associate services if it "should have known" PHI was being transmitted to the app (in our example) without the appropriate business associate relationship. At that point, the company

[3] See HHS OCR FAQ, What if a HIPAA covered entity (or business associate) uses a CSP to maintain ePHI without first executing a business associate agreement with that CSP? https://www.hhs.gov/hipaa/for-professionals/faq/2079/what-if-a-hipaa-covered-entity-or-business-associate-uses-a-csp-to-maintain-ephi-without-first-executing-a-business-associate-agreement-with-that-csp/index.html.

[4] See FAQ; 45 CFR 160.410.

has the same three options outlined above. OCR is very clear that a company cannot avoid this obligation if the PHI has not been discovered due to the company's own "willful neglect."

If you *know* you have PHI and do not have a BAA in place, you should be aware that the lack of BAA does not excuse you from HIPAA compliance with respect to that PHI for so long as you maintain it.

**Enforcement Overview**

At least for now, OCR's enforcement in this area appears to be low. Only data regarding resolution agreements are made public (where fines and remediation plans are agreed to), and this data does not indicate a trend toward sanctioning business associates who are not under BAAs and out of compliance with HIPAA.

To date, there has been no resolution agreement with a business associate for failing to enter into a business associate agreement with a covered entity customer. This aligns with the regulations: HIPAA puts the obligation on the covered entity to obtain "reasonable assurances" from its vendors who provide business associate services that the vendor will comply with HIPAA, not the other way around. Notwithstanding that fact, there is risk for companies who do not know where they stand vis-à-vis HIPAA. On the other hand, to date, OCR has entered into six resolution agreements (a settlement agreement in which the covered entity or business associate agrees to perform certain obligations and make reports to OCR, generally for a period of three years, and may include the payment of a resolution amount) with fines of up to $1.55 million for failure of covered entities to execute business associate agreements with vendors.[5] This does not mean, however, with the proliferation of digital health companies in the healthcare industry, that OCR would not prioritize this issue in the future.

Aside from the enforcement risk, there is a business risk for failing to evaluate your status as a business associate early. If a company has developed its services model in such a way that would subject it to HIPAA, but has not built HIPAA compliance into its framework or roadmap, having to do so abruptly is never a fun development. We often see this come in the course of diligence for a next funding round, or while trying to execute a deal with a large healthcare customer. It's never a good time. There are many compelling reasons why it's vital for companies providing services in the digital health space to understand their obligations under HIPAA.

**Up Next**

Complying with HIPAA may seem a daunting task. Luckily, HIPAA is a deliberately flexible, technology-agnostic framework that fits the size, scale, and scope of the company—it's not intended to be one-size-fits-all in order to allow entities of all types to comply. The challenge is surmountable. In the coming installments, we will explore the very question of "how do I become HIPAA compliant?" to help companies envision how HIPAA could be integrated into their privacy and security environments.

[5] HHS OCR, Resolution Agreements, https://www.hhs.gov/hipaa/newsroom/index.html.

# The Bayh-Dole Act Turns 40

*By Kathy Ku*

Over the past 40 years, the Bayh-Dole Act has given rise to some of the most revolutionary innovations in the United States. In 2002, *The Economist* trumpeted the Bayh-Dole Act as "possibly the most inspired piece of legislation to be enacted in America over the past half-century." Today, the federal government continues its efforts to unleash American innovation to enable a greater return on the federal government's investment in R&D.

Prior to 1980, the federal government took title to all inventions developed under federal funding. Under this system, few federally funded inventions were brought to market. Simply put, the federal government was inefficient at transferring novel technologies to the private sector. In 1980, the Bayh-Dole Act was signed into law and changed how ownership of inventions that arise out of federally funded contracts and grants, including SBIR and STTR grants, were apportioned. Under the Bayh-Dole Act, federal grant recipients are allowed to retain title to inventions developed under the related federal grant. Further, federal grant recipients are able to negotiate license terms and therefore efficiently develop and market novel technologies. These changes ushered in by the Bayh-Dole Act has and continues to incentivize universities and companies to develop cutting-edge technologies.

Many start-ups are built around intellectual property invented at universities. Others have received SBIR or STTR grants to help move technologies from one phase of development to the next. For these digital health companies, intellectual property protection can come in the form of patents, copyrights, trade dress, and/or trade secrets. The Bayh-Dole Act covers potentially patentable inventions, including software patents, as well as hardware and medical device patents.

Under the Bayh-Dole Act, the federal government allows federal grant recipients to retain title to inventions and the resulting patents funded by federal dollars, however, there are strings attached. Clients should be aware of these strings and aim to comply with all Bayh-Dole Act requirements because not meeting these requirements may lead to loss of valuable intellectual property rights. Fundamentally, the federal government wants: to know what inventions are being created under its funding, to receive recognition for its support of these inventions, and to be kept informed about the commercialization of the technology. Therefore, in order to retain title to a federally funded invention, the federal grant recipient must:

1. Disclose all inventions to the federal government;
2. Elect to retain title of the inventions;
3. Report all patent applications filed; and
4. Provide information on how the federal grant recipient is developing the technology.

There are specific timelines and detailed compliance obligations that must be met in order to have and maintain clear rights in an invention. If these obligations are not met:

1. The government may restrict or eliminate the federal grant recipient's right to retain ownership of the subject invention such that the government obtains title to the subject invention.
2. It is unclear whether the federal grant recipient can cure a failure to disclose. As such, it is important to comply with the requirements.
3. Failing to comply with disclosure and other Bayh-Dole requirements can lead to a cloud on the title of the resulting patent.
4. Non-compliance will be a material fact that may need to be disclosed in transactions and to investors.
5. Sophisticated investors and potential partners will conduct due diligence on this issue.

Consult your Wilson Sonsini attorney for more information about the Bayh-Dole law and obligations.

# Limited Public Guidance Available Regarding COVID-19 Related Apps

*By Rosalind Schonwald, Haley Bavasi, Manja Sachet, and Tracey Rubin*

Many companies, including some clients, are seeing their COVID-19-related apps rejected from Amazon, Google. and Apple app stores. In the case of Apple, there is currently no formal rule. The public guidance provided by Apple to date is the following language from a March 14, 2020 press release:

"[W]e're evaluating apps critically to ensure data sources are reputable and that developers presenting these apps are from recognized entities such as government organizations, health-focused NGOs, companies deeply credentialed in health issues, and medical or educational institutions. **Only developers from one of these recognized entities should submit an app related to COVID-19.** Entertainment or game apps with COVID-19 as their theme will not be allowed." (Emphasis added.)

Apple has reserved broad discretion to accept or reject apps, and there does not appear to be any bright-line rule regarding which apps will be approved. Given the limited entities described in Apple's guidance regarding COVID-19-related apps, to increase chances of having a COVID-19-related app approved, companies should consider how best to present themselves and their app, which may include: 1) emphasizing the company's qualifications as one of the enumerated entity types, such as a company "deeply credentialed in health issues," 2) emphasizing the company's institutional ties or affiliations with the enumerated entity types, 3) emphasizing the app's more general purpose that could also be used to address COVID-19, or 4) if options 1-3 aren't available, and if applicable, positioning the company as another form of "recognized entity" worthy of public trust.

Please contact your Wilson Sonsini attorney for further assistance.

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