



THE PETRIE-FLOM CENTER
FOR HEALTH LAW POLICY, BIOTECHNOLOGY,
AND BIOETHICS AT HARVARD LAW SCHOOL



Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Home Health

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I. Executive Summary

This report surveys the primary federal laws and regulations that affect or could affect in-home digital diagnostics. It aims to provide an informational resource for clinicians, researchers, developers, and policymakers interested in the regulation of in-home digital diagnostics.

Given its focus, this report should be used to identify key federal regulatory issues of interest to policymakers, manufacturers, attorneys, physicians, and regulators. Each section contains an explanation of the primary area of focus with both a description of any important subissues in the area and tables that identify and summarize relevant federal laws or regulations that are likely to have the greatest impact on in-home digital diagnostics regulation.

The report is not meant to be exhaustive. Other federal and state laws apply to in-home digital diagnostics, such as the Genetic Information Nondiscrimination Act of 2008 (GINA),⁶ which covers genetic information that an in-home digital diagnostic could collect. Additionally, in-home digital diagnostic manufacturers will confront issues relating to state law, such as contract law, which governs how parties allocate risk using agreements, such as device user agreements between manufacturers and hospitals. Additionally, in-home digital diagnostics may malfunction or in some other way cause harm to an individual. Here, state tort law may operate to allocate liability for harms arising from the use of in-home digital diagnostics.

While in-home digital diagnostic manufacturers and users must be aware that these issues exist, they are beyond the scope of this report (except where noted that federal laws can directly influence whether state law applies). Our goal instead is to provide a succinct overview of the primary laws and regulations in-home digital diagnostics implicate. As such, the report is meant to inform the reader of the most important regulatory considerations and provide a jumping off point for deeper exploration, if needed, rather than an exhaustive encyclopedia of all laws and regulations that touch this product category.

⁶ Genetic Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified at 42 U.S.C. §§ 2000ff to 2000ff-11). Another example is the Federal Policy for the Protection of Human Subjects Research, also known as the “Common Rule,” which sets mandatory guidelines for research “involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.” 45 C.F.R. part 46.

II. Overview

New and accelerated technological innovations have the potential to transform diagnosis by changing the location and process for diagnosing diseases or conditions. One subset of these technologies involves tools used to diagnose patients outside the traditional confines of the clinic: in-home digital diagnostics.

Examples cut across a wide range of diagnostic techniques:

- Magnetic Resonance Imaging (MRI) technology now allows certain scans to take place directly in the patient's home rather than in a hospital or dedicated MRI facility.⁷
- The smartphone app Miiskin allows users to take photos of moles and track them over time, and has begun partnering with providers to integrate these photos and other information into diagnostic decisions by physicians.⁸
- Sleep studies, which used to be conducted exclusively in special hospital rooms, can now be performed at home using portable monitors like the WatchPAT Home Sleep Apnea Test, manufactured by Itamar Medical.⁹
- Even a device like an electrocardiogram (ECG) is now available on smartwatches like FitBit¹⁰ and Apple Watch,¹¹ and implantable devices like pacemakers may be used to collect other information that can diagnose, prevent, or treat both cardiac-related and non-cardiac-related diseases.¹²

⁷ Francis X. Shen et al., *Emerging Ethical Issues Raised by Highly Portable MRI Research in Remote and Resource-Limited International Settings*, NEUROIMAGE 118210 (2021).

⁸ Miiskin: Teledermatology Platform and Skin Tracking App, MIISKIN, <https://miiskin.com> (last visited Jun 27, 2022).

⁹ WatchPAT® Home Sleep Study Device, ITAMAR MEDICAL, <https://www.itamar-medical.com/patients/watchpat-home-sleep-testing> (last visited Jun 27, 2022).

¹⁰ Irregular Rhythm, FITBIT, <https://www.fitbit.com/global/us/technology/irregular-rhythm> (last visited Jun 27, 2022).

¹¹ Take an ECG with the ECG app on Apple Watch, APPLE, <https://support.apple.com/en-us/HT208955> (last visited Jun 27, 2022).

¹² Caroline Billings & David E. Anderson, *Role of Implantable Drug Delivery Devices with Dual Platform Capabilities in the Prevention and Treatment of Bacterial Osteomyelitis*, 9 BIOENGINEERING 65 (2022). James F. Meschia, *Pacemakers as Atrial Fibrillation Detectors: Finding Racial Differences and Opportunities for Preventing Stroke*, 5 JOURNAL OF THE AMERICAN HEART ASSOCIATION e003090 (2016).

In some cases, the in-home digital diagnostics may enable new care relationships, either by engaging the patient earlier in the disease lifecycle or structuring the healthcare encounter differently.¹³

Digital diagnostics are unique because they integrate existing and new technologies alike outside the hospital, doctor's office, or imaging facility—often in the patient's home. Because in-home digital diagnostics do not occupy a discrete area of either medicine or technology, they also implicate a wide range of regulatory frameworks. This regulatory blurriness is part of what motivates this report, which seeks to clarify potential schema within which in-home digital diagnostics may fit.

The report therefore focuses on four areas of law that have the greatest significance for in-home digital diagnostics.

1) Federal Regulation of in-home digital diagnostics by the U.S. Food and Drug Administration

Federal laws that regulate devices, for example, regulate when and how some in-home digital diagnostics reach consumers. While in-home digital diagnostics include “devices” regulated by FDA, they also include so-called “General Wellness Products” (“GWPs”) (defined in Part IV.A.ii.). Examples of GWPs include:

- fitness trackers (like FitBit and Apple Watch, which track activity);
- cough-tracking applications (like Hyfe, which ambiently monitors user coughs);¹⁴
- skin lesion tracking tools (like Miiskin's skin check app, which can keep track of skin lesions);¹⁵
- some seizure diary apps (like Nile);¹⁶
- metabolism measurement products (like Lumen);¹⁷ and
- mental-health-oriented applications (like Headspace).¹⁸

¹³ Sleep Apnea Diagnosis & Management Program, ITAMAR MEDICAL, <https://www.itamar-medical.com/professionals/total-sleep-solution> (last visited Jun 27, 2022). Unified digital therapy and care delivery, HAPPIFY HEALTH, <https://www.happifyhealth.com/overview> (last visited Jun 27, 2022).

¹⁴ Measure cough as an objective clinical finding, HYFE AI, <https://www.hyfe.ai> (last visited Jun 27, 2022).

¹⁵ Miiskin Is Your Personal Skin Check App, MIISKIN, <https://miiskin.com/app> (last visited Jun 27, 2022).

¹⁶ Seizure Diary App, EPILEPSY FOUNDATION, <https://www.epilepsy.com/tools-resources/seizure-diary-app> (last visited Aug 16, 2022).

¹⁷ Hack your metabolism, LUMEN, <https://lumen.me> (last visited Aug 15, 2022).

¹⁸ SeizAlarm Homepage, SEIZALARM, <http://seizalarm.com> (last visited Jun 27, 2022).

In this report we explain how products¹⁹ are categorized as “devices” or GWPs, what restrictions apply to both, and where products like in vitro diagnostics fit into this picture.

2) Reimbursement of in-home digital diagnostics by the U.S. federal government

The federal government insures primarily four population subgroups:

- the elderly and the disabled;
- low-income adults and children;
- certain military personnel; and
- certain persons associated with federal agency units (such as employees).

In this report we explore the two most important public insurance programs—Medicare and Medicaid—which cover the first two of these groups. We discuss how the federal government reimburses for in-home digital diagnostics within these two programs, and the effects of such reimbursement on investment decisions as well as individuals.

3) U.S. federal legal intellectual property protection of in-home digital diagnostics

Federal law (and some state law) can protect the underlying technology of in-home digital diagnostics through intellectual property law, which generally falls into four categories:

- patents;
- copyrights;
- trademarks; and
- trade secrets.

Each intellectual property regime can provide protection over different aspects of in-home digital diagnostics. Patents may protect the underlying “invention” while trademarks may protect the name or logo that the manufacturer uses to market and sell the device to consumers. In this report, we explain that intellectual property laws can provide important economic incentives to in-home digital diagnostic developers, allowing them in some circumstances to exclude others from making or selling the same or a similar product, or a similar product under a confusingly similar name, logo, or design.

4) U.S. federal privacy protections applicable to in-home digital diagnostics

¹⁹ The report refers to in-home digital diagnostics as “products.” Some in-home digital diagnostics may be better described as “services.” The report does not take a position on when in-home digital diagnostics are products or services. Instead, it simply uses the term “product” for convenience.

Finally, consumers who use in-home digital diagnostics have varying privacy protections under federal law. The primary federal laws that protect consumer privacy are the

- Health Insurance Portability and Accountability Act (HIPAA); and
- Federal Trade Commission Act (FTCA).

This report explains the substantive protections provided by each statute, as well as how their application to in-home digital diagnostics may be limited.

III. Defining In-Home Digital Diagnostics

There is no settled definition for “in-home digital diagnostics,” and yet it is important to demarcate the scope of the inquiry. While others might arrive at slightly different definitions, for the purposes of this report, the term “in-home digital diagnostics” is interpreted broadly, with each constituent part understood in the following way:

In-Home: outside of traditional healthcare settings.

- Traditional healthcare settings include, for example, physician offices, brick-and-mortar hospitals, medical centers, and stand-alone testing facilities. When the diagnostic is used primarily or only in these settings or locations, the definition excludes it. An at-home sleep study device would, by contrast, qualify as “in-home,” as would a smartphone application, like Hyfe, which produces a cough report by tracking user cough patterns whenever initiated by the user. At the same time, as we use the term, “in-home” might also include a traditional healthcare service, such as an office visit, if performed remotely through video or telephone.

Diagnostics: any device that can aid in the identification of a particular disease or condition, or event associated with that disease or condition.

- This definition covers not just an initial diagnosis of a particular disease or condition, but also the “diagnosis” (or identification) of events caused by a particular disease or condition. Glucose monitors, for example, would fit within this definition because they can aid in the diagnosis of low blood sugar, even though a patient typically uses one only after an initial diabetes diagnosis.

Digital: significantly incorporates a novel, technology-enabled component not traditionally found in diagnostic devices.

- A self-testing kit that allows users to view their results online would not satisfy this definition of “digital,” since the digital component does not significantly alter the analog self-test. By contrast, a self-testing kit that enables the user to run the tissue sample through a machine-learning application on a phone or tablet to process the results, or to assist the user in understanding and interpreting the results, would fall within this definition. This flexible definition captures the breadth of technologies where the digital component significantly changes the nature of the device.

IV. Federal Regulation

The landscape of potential federal laws that regulate in-home digital diagnostics is immense. This report focuses on four areas of law that have the greatest significance for in-home digital diagnostics:

- device safety and effectiveness;
- reimbursement;
- federal intellectual property protection; and
- privacy.

A. Device Safety & Effectiveness

The Food, Drug, & Cosmetic Act (FDCA)²⁰ is the federal law most pertinent to in-home digital diagnostics safety and effectiveness. For our purposes, one important aspect of its coverage is its focus on devices (Box 1).

Box 1. Definition of Device Under the FDCA

“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 . . . intended to diagnose or treat a disease or condition or to cure, mitigate, treat, or prevent disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals.”²¹

Devices are classified into three categories depending on the risk of their “intended use” and regulated accordingly. The concept of “intended use” is crucial to determining whether a product is a device and, if so, into what category it falls. Promotion and advertising, which are also important for determining intended use, are also governed by the FDCA and FDA, which has issued guidance about its views on the subject. While its guidance documents do not have the force of law, they do provide a window into FDA’s current thinking on given topics and its propensity to bring enforcement actions.²² Once devices are on the market, they are also subject to various postmarket requirements, such as manufacturing and information collection requirements.

While the FDCA regulates devices, not all in-home digital diagnostics are devices. That is partly because in 2016 Congress excluded certain software functions from the definition of “device” by enacting the 21st Century Cures Act.

²⁰ 21 U.S.C. § 301.

²¹ 21 U.S.C. § 321(h)(1)(B)-(C).

²² For example, based on this guidance and the law, a product like SeizAlarm, though disclaiming diagnostic functions, could be considered a device based on a determination by FDA that the “intended use” of the product was diagnostic.

Importantly, then, the type of in-home digital diagnostic and its intended use(s) are crucial to determining whether and which federal laws and regulations apply to it. In some cases, products may not be devices at all, or they may present a low enough risk that FDA will not bring enforcement actions against the manufacturers. Finally, FDA does not have the resources to bring enforcement actions against every manufacturer whose product may violate the FDCA, meaning some devices will never be evaluated by FDA despite the risks they pose.

The regulatory classification of a product has implications beyond FDA review (or lack thereof). For example, federal law eliminates certain state law claims for injuries caused by certain kinds of defective devices.²³ This would foreclose product liability for some types of in-home digital diagnostics, so long as they were classified as a device (and generally speaking that the device complied with FDA requirements, e.g., special controls for some Class II devices). Device manufacturers also have a duty to monitor their products once they enter the marketplace. And some devices, like tests developed and used within a single laboratory, may not be regulated only by FDA under FDCA, but also (or rather) by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).²⁴ For reasons explained below, however, this latter regulatory regime may be unlikely to apply to most in-home digital diagnostics.

The remainder of this Section explains in more detail device classification, including a discussion of general wellness products, advertising and promotion, and state law claims for injuries caused by devices. It then reviews postmarket requirements for devices and the regulatory requirements that apply to in vitro diagnostics. Each of these issues affects how the product in question will be regulated, the type of products manufacturers may develop, as well as their obligations once a product is on the market.

i. Pre-Market Device Classification

Any in-home digital diagnostic that meets the definition of a “device” is not legally allowed in the marketplace unless it satisfies the standards set forth by the Food, Drug, & Cosmetic Act, which is implemented and enforced by FDA. In doing so, one of FDA’s goals is to ensure that devices are safe and effective for their intended use.

²³ Charlotte A. Tschider, *Medical Device Artificial Intelligence: The New Tort Frontier*, 46 BYU L. REV. 1551 (2020).

²⁴ In addition to the definitional issues posed by the FDCA, there is another federal law that governs a variety of so-called “lab-developed” tests (LDTs). In theory, FDA can regulate LDTs as devices; in practice, however, CMS has exercised dominant regulatory authority. Since some in-home digital diagnostics may be classified as LDTs, both the FDCA and the statute that governs LDTs—the Clinical Laboratory Improvement Amendments—are relevant to this report. LDTs are discussed in Section V.A.vi.

FDA employs a risk-based framework that stratifies devices into three classes (I, II, and III) in its evaluation—the riskier the device, the higher the classification and more regulatory hurdles it must clear to get to market. Class I devices are the lowest risk and generally reach the market without review by FDA, with the mandated statutory requirements (“general controls”) providing “reasonable assurance” of safety and efficacy.²⁵ Class II devices are considered moderate-risk and generally require review by FDA to demonstrate “substantial equivalence” to a device that is currently marketed or to a device that has previously demonstrated substantial equivalence to a legally marketed device (and so on). This route to market is known as the “510(k)” pathway (Table 1).²⁶ While Class II devices may be subject to intermediate review under several different FDA pathways (501(k), de novo),²⁷ the majority of devices (most Class I and some Class II) reach the market without review, and the bulk of those reviewed by FDA reach the market through the 510(k) pathway.

Class III devices generally reach the market only after a Premarket Approval (PMA) review.²⁸ The PMA pathway, by contrast to the pathways used for Class I and II devices, accounts for only approximately 1% of all devices that reach the market each year.²⁹ Table 1 depicts in general terms how a device classification affects the type of FDA review required. Each pathway is depicted in Figure 1 below.

²⁵ Some Class I devices also must go through this pathway. If the new device cannot be shown to be substantially equivalent to another legally marketed Class I or II device, then the device is automatically considered to be a Class III device, which comprises the highest risk devices. If the manufacturer believes the device is not high risk, however, then it may submit a “de novo” request for classification into Class I or II.

²⁶ Some Class II devices are “exempt” and do not require any form of FDA review.

²⁷ IOM report at 3 (“More than 80% of 510(k)-cleared devices are categorized as Class II device types.”)

²⁸ PMA devices may be modified through additional review, typically approved as PMA “supplements.” Benjamin N. Rome, Daniel B. Kramer & Aaron S. Kesselheim, *FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979-2012*, 311 JAMA 385 (2014).

²⁹ The Investigational Device Exemption also accounts for around 1% of all new devices.

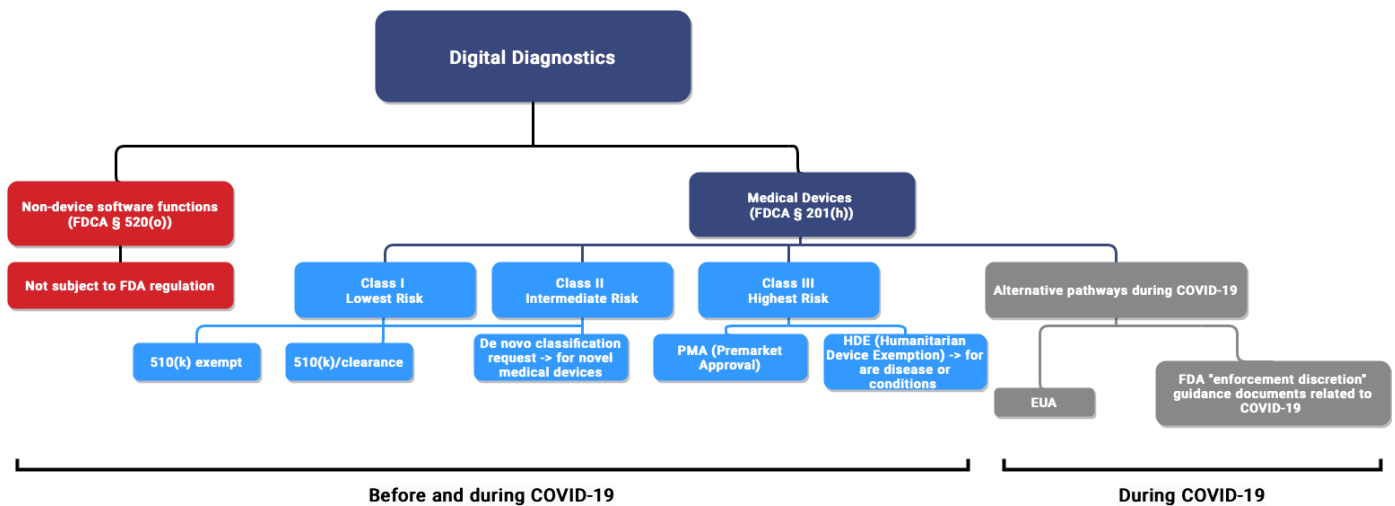


Figure 1. Device Classification

Low- to moderate-risk devices typically reach the market through the 510(k) pathway, which requires the manufacturer submit information to the FDA demonstrating that the device in question is substantially equivalent to a legally marketed device. Some low and moderate risk devices are 510(k) exempt, meaning they can reach the market without premarket review. High risk devices, however, must undergo a more rigorous review process known as Premarket Approval. High risk-devices that target a small disease population and are used in limited settings may also reach the market through the Humanitarian Device Exemption. During the COVID-19 pandemic public health emergency, devices also reached the market through Emergency Use Authorization. Some devices also were subject to “enforcement discretion,” meaning the FDA used its discretion not to enforce federal law against certain devices. This latter tack is also used with respect to some low-risk general wellness products that may also be devices. Those low-risk general wellness products may also fall within the non-device software functions exception in federal law, making them outside the purview of FDA regulation. This figure is adapted from Sara Gerke, Carmel Shachar, Peter R. Chai, and I. Glenn Cohen, *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 Nat. Med. 1176 (2020).

Table 1: FDA Review of GWPs and Devices

Product Class	Level of Risk	Level of Review	Examples
GWP	Low	None	Hyfe, Miiskin skin check app
Class I	Low	Usually No Review, Sometimes 510(k)	Tongue depressors, cotton swabs
Class II	Moderate	Often 510(k), Sometimes De Novo, Sometimes No Review	Electrocardiograms (ECG) like the ECG function on Apple Watch, certain genetic diagnostic tests, and glucose monitors
Class III	High	PMA	Implantable devices like cardioverter defibrillators ³⁰ and spinal cord stimulators ³¹

Some in-home digital diagnostic devices that reach the market may do so as Class I or Class II devices without review by FDA. And many potential in-home digital diagnostics, like Hyfe and Seizure Diary App, have gone to market not as devices but as GWPs, as discussed below. Furthermore, some in-home digital diagnostics that fall within Class II will require only that the manufacturer demonstrate substantial equivalence to an existing device on the market—or by some other regulatory pathway. While many Class II devices have historically been used under physician supervision, newer digital diagnostics (like the ECG function on the Apple Watch) may be operated without such supervision. Finally, FDA can reclassify devices after market entry based on new information.

³⁰ Defibrillator, Automatic Implantable Cardioverter, With Cardiac Resynchronization (Crt-D), PMA Number P010031.

³¹ Itrel, Synergy And Intellis Spinal Cord Stimulation Systems And Pisces, Specify, And Vectris Spinal Cord Stimulation Lea, PMA Number P840001.

Takeaways:

- FDA has jurisdiction to regulate devices based on risk, ranging from requirements to meet certain standards subject to FDA enforcement (most Class I or some Class II) to express review and clearance or approval by FDA before a product can enter the market (some Class I, most Class II, or all Class III).
- Digital diagnostics may fall into or outside of any of the categories, making them subject to potentially no regulation or very stringent regulation.
- Whether and how FDA reviews in-home digital diagnostics will depend on their intended use and the risks posed by those uses.
- Some in-home digital diagnostic devices that reach the market do so as Class I or Class II devices without premarket review by FDA and others are GWPs that have not undergone FDA review.
- Some devices may be used without traditional physician supervision, raising questions about how to evaluate their risk.

Table 2: Further Information on Federal Device Regulation

Topic/Law	Citation	Other Sources	Summary
Laws and Regulations on Device Classifications	21 U.S.C. § 360c [Device Classification] 21 C.F.R. §§ 860-895	FDA Guidance on Device and Drug Classification	Devices are regulated based on risk and are classified as <ul style="list-style-type: none"> • Class I (low risk); • Class II (moderate risk); or • Class III (high risk).
Premarket Approval – Most Stringent FDA Pathway to Market	21 U.S.C. §§ 351, 352, 353, 360, 360c-360j, 360bbb-8b, 371, 372, 373, 374, 375, 379, 379e, 379k-1, 381 21 C.F.R. pt. 814	FDA Webpage on PMA FDA Guidance Documents on PMA Process and Procedures	The PMA pathway <ul style="list-style-type: none"> • applies to Class III devices; • is the most stringent form of review; • requires clinical trials; and • provides the most liability protection from state law claims.
510(k) Pathway – Intermediate Pathway	21 U.S.C. §§ 360(k), (n), 360c(b), 360d 21 C.F.R. § 807	FDA Guidance on <ul style="list-style-type: none"> • Substantial equivalence • Abbreviated 510(k) Program • Threshold Standards for 510(k) 	The 510(k) pathway <ul style="list-style-type: none"> • requires a “predicate device”; • prevents automatic classification as Class III device; • enables reclassification as Class II device; and • generally does not require clinical trials.
De Novo Classification	21 U.S.C. §§ 360c(a), (f)(2) 21 C.F.R. § 860	FDA Final Rule FDA Guidance on Acceptance Review for De Novo Classification Requests De Novo Classification	De novo classification applies to <ul style="list-style-type: none"> • low-to-moderate risk devices with no predicate; and • otherwise automatically classified into Class III. De novo devices reach market

		Process (Automatic Class III)	<ul style="list-style-type: none"> through less stringent review than PMA; and with or without clinical data.
Breakthrough Device Designation	21 U.S.C. § 360e-3	FDA Guidance on Breakthrough Devices FDA Webpage on Breakthrough Devices	<p>“Breakthrough” device is a designation that</p> <ul style="list-style-type: none"> applies to new devices for life-threatening or debilitating conditions; entitles the device to resources that facilitate expedited development and review; and requires postmarket data collection.
Humanitarian Devices	21 U.S.C. § 360j(m) 21 C.F.R. § 814(H)	FDA Guidance on Humanitarian Device Exemption	<p>Humanitarian Use Devices</p> <ul style="list-style-type: none"> are designed to benefit patients with a disease affecting ≤8,000 per year in US; cannot be unreasonably risky; have shorter time to market than traditional devices; and can be used only in limited settings, which includes supervision by an institutional review board.
Pediatric Use of Devices	21 U.S.C. § 360e-1 21 C.F.R. §§ 814.20(b)(13), 814.37(b)(2), (c)(2)(ii), 814.44(e)(ii), 814.100(c), 814.104(b)(6), 814.116(c)(2)	FDA Guidance on <ul style="list-style-type: none"> Pediatric Expertise for Advisory Panels Using Existing Clinical Data for Extrapolation Providing Information about Pediatric Uses of 	<p>This data requirement is for devices that are seeking marketing under an HDE or a product development protocol used by individuals <21 years that</p> <ul style="list-style-type: none"> may be designed for children or adapted from devices used for adults; raise special access and safety concerns; and

		Medical Devices to FDA <ul style="list-style-type: none"> • Premarket Assessment of Pediatric Medical Devices 	<ul style="list-style-type: none"> • often require specialized expertise during development and postmarket surveillance.
Investigational Devices	21 U.S.C. § 360j(g) 21 C.F.R. § 812 et seq.	FDA Webpage on Investigational Device Exemption FDA Guidance Early Collaboration Meetings	Investigational Devices <ul style="list-style-type: none"> • are generally exempted from premarket review requirements for the limited purposes of studying the device, and are subject to other restrictions.

ii. Low-Risk General Wellness Products

In-home digital diagnostics that fall outside the above-mentioned definition of “devices” are not regulated by FDA. The scope of devices, or products regulable by FDA, was narrowed in 2016 when Congress passed the 21st Century Cures Act.³²

Specifically, the 21st Century Cures Act excludes certain software functions from the category of “devices.” These software functions include:

- administrative support;
- electronic records processing and services;
- storing and formatting laboratory test or device information; and
- clinical decision support (CDS) software (excluding image or certain data processing) that allows a healthcare professional to independently review the basis for recommendations and is not intended to be the primary diagnostic tool.

Perhaps even more importantly, the 21st Century Cures Act also excludes from the definition of “device” software functions

- intended “for maintaining or encouraging a healthy lifestyle and [...] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.”³³

The FDA has also described such software as falling within what it calls “low-risk general wellness” products (GWPs). In its guidance documents, FDA notes that some GWPs may fall outside the statutory definition of “device” and hence may be exempt from FDA regulation while other GWPs may fall within it. For those GWPs that are classified as devices, FDA intends to exercise enforcement discretion where the risk presented by the product is low. Thus, a product may be either excluded from the definition of “device” under the 21st Century Cures Act and hence outside of FDA’s jurisdiction, or included in the definition of “device” but, because the risks are low enough, FDA has determined it will exercise enforcement discretion. One criterion for making this determination is whether FDA already regulates similar devices.³⁴ Examples include computer, tablet, or smartphone applications (used on products like FitBit, Apple Watch, Android products, and the iPhone) that track steps, heartrate, weight, and eating habits, as well as mobile apps that provide daily mindfulness exercises. While the FDCA covers and FDA regulates devices, not every in-home digital diagnostic is a device.

Examples of such low-risk general wellness products include:

³² 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

³³ 21 U.S.C. § 360j(0)(1)(B).

³⁴ FDA has issued regulations for various devices under 21 C.F.R. §§ 860-898.

- computer, tablet, or smartphone applications (used on products like FitBit, Apple Watch, and the iPhone) that track steps, heartrate, weight, and eating habits; and
- mobile apps that allow the user to record their own eating habits or medical conditions.

Examples of products that were classified as devices and treated by the FDA as needing review include:

- Apple's ECG app (which obtained 510(k) clearance);³⁵
- ZOLL LifeVest (which obtained PMA);³⁶ and
- MonoPrep Pap Test (which obtained PMA).³⁷

A product's status as a low-risk GWP is important because it exempts the product in question from FDA regulation. Manufacturers, however, must be careful not to jeopardize that status by marketing their products with uses that would necessitate FDA review (e.g., uses that would classify them as certain kinds of devices). This determination will turn on a variety of factors, including how the product is marketed, the risk it poses to users, and the current regulation of similar products by FDA as devices.

³⁵ Electrocardiograph Software For Over-The-Counter Use, 510(k) Number K201525.

³⁶ ZOLL LifeVest Wearable Defibrillator, ZOLL MEDICAL CORPORATION, <https://lifevest.zoll.com> (last visited Aug 15, 2022).

³⁷ MONOPREP PAP TEST, Processor, Cervical Cytology Slide, Automated, PMA Number P040052.

Takeaways:

- By passing the 21st Century Cures Act, Congress specifically exempted from the definition of “device” certain types of products, including some in-home digital diagnostics, that FDA has interpreted to include “low risk general wellness products.”
- FDA has the ability to regulate some low-risk GWPs that are also devices under the FDCA but has chosen to use enforcement discretion and not be active in this space.
- Some in-home digital diagnostics will be excluded from the definition of “device” and hence be outside FDA jurisdiction while others will meet the definition of “device” but will otherwise be sufficiently low risk that FDA does not intend to enforce the FDCA against the devices’ manufacturers.
- A variety of in-home digital diagnostics products are regulated by FDA as devices, including some types of CDS.

Table 3: Further Information on Product Exemption from FDA Regulation

Topic/Law	Citation	Other Sources	Summary
Products Exempt from FDA Regulation	<p>42 U.S.C. § 360j(o) [21st Century Cures Act]</p> <p>21 C.F.R. §§ 880, 884, 892</p>	<p>FDA Guidance on</p> <ul style="list-style-type: none"> • Software Functions • GWP • Software as Medical Device • CDS <p>FDA Final Rule on</p> <ul style="list-style-type: none"> • When Software Functions Are Devices 	<p>The following are NOT devices:</p> <ul style="list-style-type: none"> • some GWPs; • certain software functions related to data transfer and storage; and • some CDS, such as those subject to independent physician review. <p>The following ARE devices:</p> <ul style="list-style-type: none"> • some GWPs; and • some low-risk CDS used by patients' caregivers.

iii. Advertising and Promotion

The distinction between “device” and GWP has important implications for advertising and promoting a product. Though the distinction between advertising and promoting sometimes collapses,³⁸ generally speaking: Advertising refers to one-way communication of product information to consumers through media, such as television, the internet, or social media. Promotion is a broader category that can encompass advertising, but also includes other communications by a manufacturer regarding their product, such as providing information to individuals (such as physicians) or entities (such as hospitals or payors) about a product. It may include excerpts of studies, case reports, fact sheets, device schematics, or other materials that provide information about the function or benefits of a product.

FDA and the Federal Trade Commission (FTC) regulate different aspects of device marketing, with FDA regulating promotional labeling (“misbranding”) under the FDCA³⁹ and FTC regulating “the truth or falsity of all advertising (other than labeling)” under the Federal Trade Commission Act (FTCA). Although their jurisdictions sometimes overlap, FDA plays the primary role in regulating the advertising marketplace for devices.

Devices are subject to federal law and FDA’s rules regarding the promotion of devices.⁴⁰ Promotional labeling of devices must not be false or misleading. It must also disclose important facts about the device’s use and risks and present information about its effectiveness. The central question for FDA is whether, on the whole, device promotional labeling satisfies these criteria. For this, it uses a variety of factors, including consistent use of appropriate language and the framing of risk information.

On the other hand, products treated as exempt under the 21st Century Cures Act—such as GWPs—are not subject to the FDA promotion guidance,⁴¹ because they are not

³⁸ Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, FEDERAL TRADE COMMISSION (2016), <http://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration> (last visited Jun 16, 2022).

³⁹ FDA also has authority to regulate advertisements of “restricted devices.” 21 U.S.C. §§ 352(r), 360j(e), 360e(d)(1)(B)(ii).

⁴⁰ FDA defines “promotion” to include advertising: “The terms promotional piece, promotional materials, and promotional communications are used in this guidance to refer generally to both advertising and promotional labeling, regardless of format. Promotional materials include, among others, television ads, brochures, booklets, detailing pieces, internet web sites, print ads, exhibits, and sound recordings or radio ads. As noted in the introduction, this guidance applies to all types of promotion for prescription drugs, advertisements for restricted devices and promotional labeling for all devices.” U.S. FOOD & DRUG ADMINISTRATION, Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (2009), <http://www.liebertpub.com/doi/10.1089/blr.2009.9936> (last visited Jun 18, 2021).

⁴¹ Guidance documents are not law and are not legally binding, though FDA has often used them this way, raising questions about the scope of FDA’s authority. E.g., Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures) Symposium: U.S. Food and Drug Regulation in Its First Century and Beyond*, 93 CORNELL L. REV. 901 (2007).

devices. So, while manufacturers of GWP's can advertise freely, they must be careful not to advertise in certain ways or make claims that could evidence an objective intent on the part of the manufacturer to bring their products within the definition "devices" as set forth in the FDCA. In other words, because whether something is a device depends on its "intended use," and because the product's intended use is determined in part by what the manufacturer says, advertising a product as a device brings it within the FDCA (and, hence, FDA jurisdiction).

FDA has issued detailed guidance regarding the kind of claims acceptable for GWP's. Under FDA's guidance, for example, a smartphone app that tracks and analyzes weight, sleep, and eating habits and claims to diagnose or treat obesity is a device and not a GWP. But a similar product is more likely to be a GWP, and not a device, if it only "promotes making healthy lifestyle choices such as getting enough sleep, eating a balanced diet, and maintaining a healthy weight, which may help living well with type 2 diabetes." If the manufacturer makes the former kind of claim, FDA may pursue an enforcement action to prohibit the marketing or sale of the product in question. In one recent example, FDA sent a warning letter to a firm marketing a series of products designed to improve skin without clearance or approval from FDA.⁴²

Some product manufacturers may try to avoid regulatory scrutiny by using marketing language and disclaimers to frame their products as GWP's instead of devices.⁴³ These include Miiskin's skin check app and SeizAlarm's seizure detection app. Other products are expressly marketed as devices, such as Apple's ECG function (which was cleared through the 510(k) pathway) and Biotronik's implantable pacemaker (which was approved through the PMA pathway). On SeizAlarm's website, for example, it explains that "SeizAlarm does not prevent seizures, should not be used for diagnosis and [sic] is not a substitute for medical care. Use of SeizAlarm should be a supplement to other medical treatments you are already using."⁴⁴ In determining whether a product is correctly characterized as a GWP—or a low-risk device that is also a GWP—such disclaimer language is not irrelevant, but it is also not sufficient.⁴⁵ To make a final determination, FDA would likely evaluate how the product is marketed. Based on this evaluation, it might conclude that the product is a device and is subject to FDA jurisdiction, in violation of the FDCA, and, therefore, worthy of an enforcement action.

Regardless of whether the product is classified as a device, federal and state advertising laws still apply to protect consumers even for products that are not

⁴² Warning Letter: Skin Sheek - MARCS-CMS 612682 - 01/28/2022, FDA: CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (2022), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/skin-sheek-612682-01282022> (last visited Jun 27, 2022).

⁴³ David A. Simon, Carmel Shachar, & I. Glenn Cohen, Skating the Line Between Wellness Products and Regulated Devices: Strategies and Implications, 9 J. L. & Biosciences 1 (2022).

⁴⁴ SeizAlarm Homepage, *supra* note 17.

⁴⁵ David A. Simon, Carmel Shachar, & I. Glenn Cohen, *Unsettled Liability Issues for "Prediagnostic" Wearables and Health-Related Products*, 328 JAMA 1391 (2022).

“devices” within the meaning of that statute. For example, the FTCA, the main federal law governing unfair and deceptive practices, can be used to penalize manufacturers that make false claims about their products that are not devices. For example, FTC recently brought an action against a company that used false labeling on its goods to market them as made in the USA when they were not.⁴⁶

FTC can also bring claims against device manufacturers. Recently, for instance, FTC sued a device manufacturer for making false and misleading claims that the device was “clinically proven” to treat pain.⁴⁷ Another federal law, the Lanham Act, allows for competitor firms to bring lawsuits alleging that a particular advertisement is false or misleading, affected consumer decision making, and harmed the competitor firm.

In sum, advertising makes its way into the regulatory analysis in two ways. On the one hand, it can help to establish whether a product is a device. On the other hand, manufacturers face tighter restrictions on advertising when the product is a device. Thus, if a manufacturer, without undergoing FDA review, advertises its product as having the capability to diagnose, treat, or mitigate a disease, the advertisement may help to establish both that the product is a device and that it violates FDCA advertising regulations that apply to devices.

⁴⁶ FTC Takes Action Against Lions Not Sheep and Owner for Slapping Bogus Made in USA Labels on Clothing Imported from China, FEDERAL TRADE COMMISSION (2022), <http://www.ftc.gov/news-events/news/press-releases/2022/05/ftc-takes-action-against-lions-not-sheep-owner-slapping-bogus-made-usa-labels-clothing-imported> (last visited Jun 27, 2022).

⁴⁷ Refunds Coming to Consumers Who Bought Deceptively Marketed Willow Curve Device, FEDERAL TRADE COMMISSION (2021), <http://www.ftc.gov/news-events/news/press-releases/2021/08/refunds-coming-consumers-who-bought-deceptively-marketed-willow-curve-device> (last visited Jun 16, 2022).

Takeaways:

- FDA has jurisdiction to regulate promotional labeling of in-home digital diagnostics when they are devices.
- In-home digital diagnostics that are marketed as having an ability to diagnose or mitigate conditions likely fall within FDA's jurisdiction to regulate labeling of devices.⁴⁸
- In-home digital diagnostics that promote general wellness functions, such as sleep and step tracking, are unlikely to be considered devices absent other advertising, promotional labeling, or actions that evince an objective intent that the device is to be used to diagnose, treat, or mitigate a condition.
- FTC regulates advertising more generally, and can bring enforcement actions against in-home digital diagnostic manufacturers (regardless of whether they manufacture a device, a GWP, or neither) when they engage in unfair or deceptive practices, including claims about the effectiveness or usefulness of devices regulated by FDA.
- While FDA does not regulate the advertising of GWPs, FTC might.
- Digital diagnostic manufacturers or their competitors may be able to sue one another for false advertising under the Lanham Act.

⁴⁸ Warning Letter: Skin Sheek - MARCS-CMS 612682 - 01/28/2022, *supra* note 42.

Table 4: Further Information on Advertising and Promotion of Medical Devices

Topic Law	Citations	Other Sources	Summary
Federal Law on Labeling (FDCA)	21 U.S.C. §§ 352(a), 352(f)(1), 352(o), 355(b), 352(r), 360j, 360e, 360(k)	FDA Webpage on FDCA	FDCA's labeling and misbranding provisions cover: <ul style="list-style-type: none"> • promotional labeling of devices.
Labeling Regulations	21 C.F.R. § 1.21 [Failure to Reveal Material Facts] 21 C.F.R. §§ 801.1-18, 801.109-128, 801.405-437	FDA Guidance on <ul style="list-style-type: none"> • Presenting Risk Information in Promotion of Prescription Devices • Social Media Promotion with Character Limits • Correcting Misinformation Online • All Other Advertising and Promotion Topics 	FDA enforces FDCA, which requires that device labeling <ul style="list-style-type: none"> • not be "false or misleading in any particular"; • not contain information inconsistent with drug labeling; and • requires warning statements for "restricted devices" and enables FDA to regulate advertisements thereof.
Federal Law on Competition (Federal Trade Commission Act (FTCA))	15 U.S.C. § 5	FTC Webpage on FTCA FTC Webpage with Guidance Documents	FTC <ul style="list-style-type: none"> • enforces the FTCA; • has jurisdiction over advertising of medical devices; and • regulates "unfair and deceptive" trade practices, including

			advertising of devices and non-devices.
Federal Law on Trademarks and False Advertising (Lanham Act)	15 U.S.C. § 1125(a)(1)(b)	Academic Article Explaining False Advertising and Trademark Law	<p>Lanham Act's false advertising provision</p> <ul style="list-style-type: none"> • allows competitors to sue for false or misleading advertisements that injure the competitor firm; and • does not allow private citizens to sue firms for false advertising.

iv. State Law Preemption for Injuries Caused by Digital Diagnostics

Device classification affects not just how a product or service is regulated and marketed, but also whether a manufacturer of the device, product, or service can be held liable under state law for injuries caused by their device. While this report does not focus on state law, federal law has an important role to play in determining whether a state law claim may be brought by those harmed by in-home digital diagnostics. For example, the Medical Device Amendments of 1976 expressly foreclose certain state law claims that might otherwise proceed.⁴⁹ When federal law displaces state law claims in this manner, federal law is said to “preempt” state law. A device like HeartMate 3™ Left Ventricular Assist System (LVAS) that received a PMA, for example, would not be subject to state tort claims based on product defects.⁵⁰

Federal law may also impliedly preempt state law claims, which occurs when federal law and state law conflict in irreconcilable ways.⁵¹ State law claims are impliedly preempted when they are not based in a state law cause of action but simply allege violation of federal law or regulation.⁵² Thus, a claim against Apple alleging a defect in its ECG function could proceed if it was based on a state law product defect or strict liability tort claim, but not if it was based solely on Apple’s failure to comply with FDA regulations.

There are many complex questions as to the scope of such preemption. There are three clear takeaways from the current case law:

- Federal law expressly preempts state law claims against devices that have undergone the most stringent regulatory review (PMA) and comply with federal requirements;
- Federal law can impliedly preempt state law claims that undergo less stringent review (510(k) clearance); and
- Federal law will not preempt state law claims against low-risk GWP that have not undergone any review by FDA.

⁴⁹ 21 U.S.C. § 360k.

⁵⁰ PMA No. P160054 (Aug. 23, 2017).

⁵¹ E.g., *Kubicki on behalf of Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 173 (D.D.C. 2018) (“Implied preemption in the medical-device context prohibits a plaintiff from enforcing FDCA requirements in the absence of a preexisting state law claim that addresses those same duties, irrespective of whether the device was approved through the PMA process . . . or the § 510(k) substantial equivalence process . . .”).

⁵² *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017) (“So when a claim challenges a representation the FDA blessed in the approval process, it is preempted.”); *In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, 537 F. Supp. 3d 679, 706 (D.N.J. 2021) (“The implied preemption issue is explained in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), where the Supreme Court ‘under the auspices of the MDA’ foreclosed a state common law fraud-on-the-FDA tort claim.”) (quoting *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 535 (D.N.J. 2009) (citing *Buckman*, 531 U.S. 341)).

Most devices that enter the market do so with less stringent or no review. Express preemption will, therefore, be limited to only the small subset of devices that undergo PMA review. Implied preemption will preempt certain state law claims for some Class II devices that receive 510(k) clearance. Issues of state tort law liability, therefore, will likely arise for in-home digital diagnostics. Digital diagnostic developers, therefore, should pay close attention to both how their devices come to market and the state laws that govern liability, which are primarily, though not exclusively, state contract, tort, and unfair and deceptive practices laws.

Takeaways:

- Device classification can influence liability determinations when in-home digital diagnostics cause individuals harm.
- Federal law preempts some state law claims for devices approved through Premarket Approval or the 510(k) clearance (and likely the de novo pathway as well).⁵³
- Devices undergoing no review and GWP are not immune from state law claims under federal law.

⁵³ Technically the law is not settled on whether devices brought to market under the de novo pathway trigger the preemption provision of the Medical Device Amendments of 1976.

Table 4: Further Information on Preemption of State Law Claims

Law/Topic	Citations	Other Sources	Summary
Preemption Provision of the Medical Device Amendments of 1976	21 U.S.C. § 360k	<p>The Supreme Court has issued several important preemption decisions:</p> <ul style="list-style-type: none"> • Medtronic, Inc. v. Lohr, 518 U.S. 470, 471 (1996) • Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) • Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) 	<p>Congress</p> <ul style="list-style-type: none"> • preempted certain state law claims against manufacturers of devices that successfully reach the market through the PMA pathway; but • did not expressly preempt state law claims for exempt or 510(k)-cleared devices; and • left open the preemption of other state law claims through judicially-created doctrines such as implied preemption.

v. Postmarket Requirements & Powers

Once devices enter the market, the FDCA imposes various “postmarketing” requirements on device manufacturers.⁵⁴ These can include tracking and reporting systems for serious adverse events, device malfunctions, and cybersecurity threats. Manufacturers also have to register where devices are produced or distributed. FDA may require manufacturers to engage in further “surveillance” studies of the device, at any point in the lifecycle of the device, where the device is moderate to high risk (Class II or III) and

- would be reasonably likely to have a serious adverse health consequence if it failed;
- is expected to have “significant use” in populations younger than 22 years of age;
- is implantable or the premarket review of which was based on proxies for disease improvement (i.e., “surrogate endpoints”);
- is life-sustaining or life-supporting and used outside of a hospital, ambulatory surgical center, nursing home, outpatient diagnostic facility, or outpatient treatment facility that is not a doctor’s office.

Manufacturers may also face remedial action by FDA, including notifying physicians of a risk posed by a device, recalling a device, and banning a device.

For example, FDA could mandate postmarket surveillance for an in-home digital diagnostic like an implantable cardiac monitor (e.g., serious consequences if failed, implantable, life-sustaining) or a mobile concussion-detection device for youth athletics (e.g., serious consequences if failed, significant use in pediatric populations), or an automated insulin monitor that simultaneously measures and administers insulin to the user (e.g., serious consequences if failed, life-sustaining, life-supporting).

Further, if FDA suspects that a device may be involved in adverse events in the published literature, it may order additional surveillance to understand the device’s risks.⁵⁵ Suppose, for example, that a new contact lens that can detect and measure the progression of glaucoma over a period of years enters the market. If case reports emerge in the literature about the contact lens causing temporary blindness or working intermittently, FDA may order postmarket surveillance to assess the performance of the device as well as its association with adverse events. Based on the information it receives from surveillance, FDA may reclassify a device making it subject to new statutory requirements.⁵⁶ Congress requires FDA to post information about the number

⁵⁴ 21 C.F.R. pt. 806; *id.* at pt. 822.

⁵⁵ Alexander Everhart & Ariel D. Stern, *Post-Market Surveillance of Software Medical Devices: Evidence from Regulatory Data*, in *DIGITAL AT HOME DIAGNOSTICS: ETHICAL, LEGAL, AND REGULATORY ISSUES* (Julia Adler-Milstein, I. Glenn Cohen, Daniel Kramer, & Carmel Shachar eds., Cambridge University Press forthcoming 2023).

⁵⁶ 21 U.S.C. § 360e; 11021 U.S.C. § 360c(e)(1)(A)(i); 21 C.F.R. § 860.130.

and type of devices it reclassifies every year.⁵⁷ Additionally, the 21st Century Cures Act requires FDA to consider whether “postmarket controls,” such as data collection, can reduce the need for premarket data that would otherwise be required for a PMA.⁵⁸ This, along with the requirement that FDA take the “least burdensome approach to medical device premarket evaluation,”⁵⁹ postmarket data collection is a component of many PMAs.⁶⁰

Takeaways:

- Digital diagnostics that are moderate or high risk may be subject to monitoring requirements by FDA either as a condition of market entry or after market entry.
- FDA may order monitoring for risks posed by the device, including how well the device functions and its association with any reported adverse events.
- Digital diagnostics may be required to undergo additional surveillance if they reach the market after FDA review of proxies, such as surrogate endpoints.
- FDA may reclassify a device into a different risk category based on information it receives after market entry.
- FDA is obligated to consider postmarket data collection when evaluating a PMA and, hence, may use data collection to reduce the premarket data collection required for a PMA.

⁵⁷ 21 U.S.C. § 360c-1.

⁵⁸ 21 U.S.C. § 360c(a)(3)(C). It is not clear whether this provision of the 21st Century Cures Act had any effect on the requirement of postmarket studies. E.g., Danelle Hidano, Sanket S. Dhruva, & Rita F. Redberg, *US Food and Drug Administration—Mandated Postmarketing Studies for High-risk Cardiovascular Devices Approved 2015-2019*, 182 JAMA INTERNAL MEDICINE 556 (2022).

⁵⁹ U.S. FOOD AND DRUG ADMINISTRATION, Center for Devices and Radiological Health, *The Least Burdensome Provisions: Concept and Principles* (2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles> (last visited Aug 15, 2022).

⁶⁰ This requirement was enacted as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

Table 5: Further Information on Postmarket Device Regulation

Law/Topic	Citations	Other Sources	Summary
Federal Laws and Regulations Covering Device Reporting, Monitoring, Manufacturing, Recalls, and Records	<p>21 U.S.C. §§ 360c, 360e, 360i, 360h, 360l</p> <p>21 C.F.R. §§ 810 et seq., 803 et seq., 806 et seq., 820-22, 860 Subpart C, 895 et seq.</p>	<p>FDA Webpage on</p> <ul style="list-style-type: none"> • Reporting Medical Device Problems • Comprehensive Regulatory Assistance • Quality System Regulation and Good Manufacturing Practices • Device Recalls • Postmarket Requirements • Device Safety <p>FDA Guidance on</p> <ul style="list-style-type: none"> • Medical Device Reporting for Manufacturers (current) • Medical Device Reporting for Manufacturers (draft) • Manufacturer Inspections • Quality System Information for Certain PMA Review • Mandated Postmarket Surveillance • Postmarket Data Collection for PMA Devices • Least Burdensome Approach to Regulatory Review • Other Issues for Devices 	<p>Congress gives FDA power to</p> <ul style="list-style-type: none"> • impose mandatory reporting on manufacturers and facilities that use devices; • require reporting deaths and serious injuries, as well as certain defects; • require manufacturers develop and implement an FDA-approved postmarket surveillance plan for certain Class II and III devices; • require record keeping; • require quality control systems; • enable FDA to monitor, issue

			<p>warnings to physicians, and recall a device from the market; and</p> <ul style="list-style-type: none"> • reclassify devices after market entry in response to safety and efficacy information.
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vi. In Vitro & Lab Developed Tests

Certain diagnostic devices that interact with human specimens, such as COVID-19 diagnostic tests, also are subject to the FDCA and, hence, FDA regulation.

Special rules apply to so-called “lab-developed tests” (LDTs), which are “designed, manufactured, and used within a single laboratory,” and are regulated by a separate legal regime. LDTs can be developed for a variety of conditions, ranging from infectious diseases (such as vitro diagnostics for COVID-19 or Lyme disease) to genetic conditions. While FDA has previously expressed a desire to promulgate specific regulation of LDTs, as of 2022 it has not yet done so in earnest.⁶¹

The most direct regulation of LDTs comes from a different agency, CMS, under a different statute, CLIA, which regulates the laboratories that devise and use those LDTs. Before an LDT can be developed, the laboratory must be certified as CLIA-compliant. The CLIA certification process runs through a government-approved accreditor. Once certified, a laboratory may use an LDT only when it meets certain analytical validity requirements. Analytical validity requirements ensure only that the test measures what it claims to measure. But they do not guarantee that the test has clinical validity—assurance that the information can be used in clinical practice to detect or predict a disease or condition.

For example, a diagnostic LDT designed to detect acute Lyme disease infection that does not accurately measure the presence of antibodies produced in response to infection by *B. burgdorferi*, the bacteria that causes Lyme disease, would fail CLIA’s analytical validity requirement.⁶² Likewise, a test that purported to measure a certain white blood cell count (CD57 lymphocyte) and did so accurately would meet CLIA’s requirement for analytical validity but would not be clinically validated to diagnose chronic Lyme (though it may ultimately be useful for that purpose).⁶³

Most at-home diagnostic tests that use human specimens are regulated by FDA, including diagnostic tests for diseases like COVID-19 and HIV and conditions like pregnancy. Because CLIA applies only to situations where a test is “designed, manufactured, and used within a single laboratory,”⁶⁴ it is unlikely to apply to at-home self-testing kits.

⁶¹ Some have expressed skepticism that FDA even has the authority to regulate LDTs without further Congressional action. See Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA’s Role in America’s COVID-Testing Debacle*, 130 YALE L.J. F. 78 (2020).

⁶² Maria E. Agüero-Rosenfeld & Gary P. Wormser, *Lyme disease: diagnostic issues and controversies*, 15 EXPERT REVIEW OF MOLECULAR DIAGNOSTICS 1 (2015).

⁶³ Raphael B. Stricker & Edward E. Winger, *Decreased CD57 lymphocyte subset in patients with chronic Lyme disease*, 76 IMMUNOLOGY LETTERS 43 (2001).

⁶⁴ Laboratory is further defined as a “facility,” which is not defined except by functional language that describes what the laboratory does. 42 C.F.R. § 493.2.

That said, there are some situations where an in-home diagnostic test using human specimens can implicate CLIA. For example, some direct-to-consumer genetic tests are regulated under CLIA and not FDA.⁶⁵ Additionally, CLIA applies whenever a test is “either performed by someone other than the individual being tested (e.g., other staff, employee health personnel), or the results are interpreted or reported by someone other than the individual.”⁶⁶ This raises a question of whether the “someone” “interpret[ing]” or “report[ing]” the results can be a computer. For example, a consumer may order or pick up a test kit, take a sample, and then run the diagnostic test using either the test developer’s new wireless technology or computer software on a phone.⁶⁷ While an analog “kit” may not be considered an LDT, a digital kit that “sends” the sample for analysis could, conceivably, be treated as a “laboratory”—in such cases, the manufacturer would need a CLIA certificate. Presently, however, it seems that the FDCA, and not CLIA, will govern most in-home diagnostic tests involving human specimens.

Takeaways:

- Digital diagnostics that use human tissue may be regulated by either FDA or CMS under different statutes with different requirements.
- Manufacturers of in-home digital diagnostics may consider the business and legal implications of having a “lab-developed test” versus a “device” when developing and marketing their product.
- There is uncertainty about how and under what circumstances CLIA would apply to certain in-home digital diagnostics.

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⁶⁶ Waivers are available for “simple laboratory examinations and procedures” cleared by FDA for home use and pose no reasonable risk to the patient if the test is performed incorrectly. 42 C.F.R. § 493.15, <https://www.cms.gov/files/document/over-counter-otc-home-testing-and-clia-applicability.pdf>.

⁶⁷ Christopher T. Ertsgaard et al., *Open-channel microfluidics via resonant wireless power transfer*, 13 NAT COMMUN 1869 (2022).

Table 6: Further Information on Regulation of LDTs

Topic/Law	Citations	Other Sources	Summary
Federal Laws and Regulations Governing Devices and In Vitro Diagnostics for Human Use	21 U.S.C. § 321(h)(1)(B) 21 C.F.R. § 809 et seq.	FDA Guidance on <ul style="list-style-type: none"> In Vitro Diagnostic Studies Framework for Regulating LDTs Procedures for Categorizing LDTs Under CLIA FDA Discussion Paper on LDTs 	FDA has power to regulate <ul style="list-style-type: none"> in vitro diagnostics that are “devices”; and in vitro diagnostics that include LDTs, which FDA has suggested in a discussion paper it would regulate but has not yet done so.
Federal Laws Governing Laboratory Standards and Techniques	42 U.S.C. § 263a 42 C.F.R. § 493 et seq.	Centers for Medicare & Medicaid Services (CMS) Webpage on Clinical Laboratory Improvement Amendments (CLIA)	Most testing is regulated not by FDA but rather by the Secretary of Health and Human Services (HHS) under CLIA, which <ul style="list-style-type: none"> sets requirements, including certification requirements, for all labs that perform clinical diagnostic tests on human specimens; is designed to ensure that laboratories perform

			<p>accurate and reliable tests;</p> <ul style="list-style-type: none"> • empowers the HHS Secretary to enforce CLIA, which HHS does through CMS by inspecting, certifying, and sanctioning labs; and • usually requires compliance for reimbursement under federal healthcare programs.
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B. Reimbursement

Reimbursement for in-home digital diagnostics will be a critical factor in their development and adoption. Insurance coverage for in-home digital diagnostics, for example, will create incentives for the development and use of the covered product.⁶⁸ Proper reimbursement incentives for new digital diagnostics may lead to technologies that improve patient outcomes at overall lower costs than existing technologies. At the same time, reimbursement and the lack thereof raise access issues. Some low-income consumers may, via insurance reimbursement, access the technology, but those without insurance will be excluded.

Additionally, in-home digital diagnostics must be billed and documented appropriately to obtain payment for them. As described below, billing and coding rules are the primary way that the federal government typically seeks to hold providers (and others) accountable for ensuring that healthcare resources are allocated appropriately and not wasted on unnecessary care or treatment.

In this Section we explore these issues by focusing on the largest single insurer in the U.S.: the Federal Government. It insures over 130 million individuals through

- Medicare Parts A, B, & C (which cover mostly elderly and disabled individuals), including Medicare Advantage (Part C);⁶⁹
- Medicaid (which covers low-income individuals and children);⁷⁰
- Department of Defense (TRICARE); and
- Department of Veteran's Affairs (VA Care).⁷¹

Medicare and Medicaid are governed by the Social Security Act. TRICARE and VA Care are governed by separate laws. This report will focus on Medicare and Medicaid reimbursement, as they are two of the largest health payor programs and heavily influence the private insurance markets.

Items or services, including in-home digital diagnostics, that are not reimbursed by federal insurance programs such as Medicare and Medicaid may still be reimbursed by private insurance companies. As such, they may be subject to coverage rules under

⁶⁸ Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75 (2020).

⁶⁹ Medicare Beneficiaries at a Glance, CMS, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot (last visited Jun 27, 2022). Medicare Part D covers drugs. It is possible for Medicare Part D issues to arise in the device context, but we do not discuss them here.

⁷⁰ February 2022 Medicaid & CHIP Enrollment Data Highlights, MEDICAID, <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html> (last visited Jun 27, 2022).

⁷¹ In Focus: U.S. Health Care Coverage and Spending, CONGRESSIONAL RESEARCH SERVICE (Apr. 1, 2022), <https://sgp.fas.org/crs/misc/IF10830.pdf> (last accessed June 27, 2022).

laws such as the Employee Retirement Income Security Act (ERISA)⁷² and the Affordable Care Act (ACA).⁷³ Although these laws and private insurance companies are important, their wide application and variability by state is beyond the scope of this report.

⁷² 29 U.S.C. §§ 1001-1461, Pub. L. 93-406, 88 Stat. 829 (Sept. 2, 1974).

⁷³ Patient Protection and Affordable Care Act (Affordable Care Act) ("Obamacare"), Pub. L. 111-148, 124 Stat. 119 (Mar. 23, 2010).

i. Medicare

Many in-home digital diagnostics may be delivered by a healthcare provider but used at home or outside the clinician's office. For example, a cardiac device that also monitors heart function may be implanted at the hospital but used almost exclusively outside the traditional healthcare setting. Other times the device may be prescribed in the clinic but delivered to the patient at the patient's home, such as a remote patient monitoring "sticker" that is applied to the skin. In still other cases the device may be ordered and obtained directly by the patient as an over-the-counter (OTC) product, like some mental health applications or self-testing kits.

Each of these scenarios may pose challenges for the reimbursement of novel technologies. OTC in-home digital diagnostics, for example, may not be reimbursed by any insurance, raising issues of access and equity for low-income groups. Even for devices available on prescription, reimbursement challenges remain for enrollees of programs like Medicare.

To be reimbursable, Medicare first requires that the item or service be "reasonable and necessary" as defined by the Social Security Act and CMS.⁷⁴ Medicare largely covers and reimburses devices as part of services administered in a hospital (Part A) or in an outpatient setting or physician's office (Part B). In some instances, it may also cover a standalone device, such as durable medical equipment.

Medicare reimbursement is complex. There are at least three key issues to understand for any item or service paid for by the Medicare program:

- coverage, which CMS determines by asking whether the device is "reasonable and necessary";
- coding, which requires providers to make their claim for payment for a covered device using "codes" that correspond to treatments; and
- reimbursement, which CMS sets through a complex cost and data driven process embodied generally in the Medicare Physician Fee Schedule (for physicians) or the Prospective Payment System (for hospitals).

Coverage. Because the Social Security Act generally does not list specific items or services but instead defines benefit categories, CMS often must decide whether a particular device falls within a benefit category and is not excluded by law. The fictitious glaucoma-related contact lens, mentioned above, could be "reasonable and necessary" to diagnose or treat glaucoma. But because the product is new, CMS may need to determine coverage for it. Here it has several tools to do so:

⁷⁴ 42 U.S.C. § 1395y. CMS recently promulgated regulations defining "reasonable and necessary" for the first time. 21 C.F.R. § 405.201. But it repealed its regulations shortly thereafter. 86 FED. REG. 62944, Nov. 15, 2021.

- a national coverage determination (NCD), which is a determination by CMS to cover a device for all beneficiaries;
- a local coverage determination (LCD), which is a determination by a Medicare Administrative Contractor (MAC) to cover a device for beneficiaries in a specific geographical region;
- a case-by-case adjudication (CBC), which is a determination by a MAC to cover a device for a specific beneficiary;
- the clinical trial policy (CTP), which is a CMS policy to cover devices in certain clinical trials; or
- parallel review (PR), which is a CMS program that reviews evidence of device safety and efficacy for reimbursement purposes at the same time FDA considers clearance or approval.

CMS makes the vast majority of its decisions through MACs using LCDs; only a small percentage of decisions occur using NCDs.⁷⁵ Thus, while national coverage is possible for novel devices like the contact lens mentioned above, it is more likely that the local contractors will individually decide whether to cover the new contact lens within the particular geographic location they cover. This means there may be inconsistencies in coverage depending where a consumer lives.

⁷⁵ Michele Schoonmaker, Grant P. Bagley, & M. Kay Scanlan, *Coordination of Federal Regulation and Payment for New Diagnostic Tests: A Proposed New Approach*, 57 FOOD & DRUG L.J. 195 (2002).

Table 7: Reimbursement Pathways Used by CMS

Reimbursement Pathway	Device Type	Determination Body	Applies to
NCD	Any	CMS	All beneficiaries
LCD	Any	MAC	Beneficiaries in contractor region
CBC	Any	MAC	Specific beneficiary
CPT	Routine items and services in clinical trials	CMS	Beneficiaries in clinical trial
PR	Any	CMS	All beneficiaries
"Innovative Technology"*	Breakthrough devices	CMS	All beneficiaries

*On January 14, 2021, CMS issued a final rule defining "reasonable and necessary" and implementing a specific expedited coverage pathway for so-called "innovative technology."⁷⁶ After public comment, however, CMS rescinded the rule on November 15, 2021.⁷⁷

If, however, CMS decides (or a third-party petitions CMS to decide) that the device may be important enough (as defined by various factors), it will initiate an NCD.⁷⁸ The NCD—which includes draft publication, public comment, and response—may require an external technology assessment or a meeting of a specialized Medicare body that considers how and under what conditions to cover the device.⁷⁹ For example, on March 9, 2021, the Foundation for Lung Cancer, the Society of Thoracic Surgeons, and the American College of Radiology requested a NCD for screening of non-small cell lung cancer.⁸⁰ After the review process, on February 10, 2022, CMS announced an NCD expanding coverage of early screening of non-small cell lung cancer, lowering the eligibility age from 55 to 50.⁸¹ After the NCD, Medicare would cover all Medicare

⁷⁶ 86 Fed. Reg. 2987, January 14, 2021.

⁷⁷ 86 Fed. Reg. 62944, November 15, 2021.

⁷⁸ 78 Fed. Reg. 48164, 48167, August 7, 2013. CMS lists the following examples as cases where it might decide to initiate a NCD: practitioners or the public have raised concerns about health outcomes related to the device; new evidence or interpretation of evidence has come to light; LCDs may vary in when and how they cover a device; the technology represents a "substantial clinical advance and is likely to result in a significant improvement in patient health outcomes or positive impact on the Medicare program"; and when rapid diffusion is expected that raises questions about effect on Medicare. *Id.*

⁷⁹ CMS may consult with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), which is a specialized body that is designed to provide guidance to CMS on various issues.

⁸⁰ Formal Reconsideration Request for National Coverage Determination on Screening for Lung Cancer with Low Dose CT – CAG-00439N, available at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id304.pdf>.

⁸¹ CMS Expands Coverage of Lung Cancer Screening with Low Dose Computed Tomography, CMS, <https://www.cms.gov/newsroom/press-releases/cms-expands-coverage-lung-cancer-screening-low-dose-computed->

beneficiaries age 50 and over for the specialized computed tomography (CT) scan to detect early non-small cell lung cancer. The additional time it takes CMS to make a coverage decision can also affect the value proposition for firms seeking to bring new products to market: they must account for this delay, and potential failure, to enter the market when developing, marketing, and selling products.

Coding & Reimbursement. Once a device is covered, it must be reimbursed. To be reimbursed, the covered device must have an associated billing code—of which there are three types: Current Procedural Terminology (CPT) codes, International Classification of Diseases, 10th rev. (ICD-10) codes (and soon ICD-11), and Healthcare Common Procedural Coding System (HCPCS) codes—that can be used to bill Medicare.⁸² Coding is the language that CMS and healthcare providers use to communicate their use of covered devices or products to CMS so that the providers can be reimbursed appropriately for the service. CMS reimbursement is often dependent upon the coding that is used in connection with the claim for payment.

For existing technologies, coding may be relatively simple. But newer devices face greater challenges, because the coverage and coding process takes between 18 months to 5 years.⁸³ The contact lens mentioned above, for example, might face difficulty obtaining new codes if existing codes are inadequate to capture the new technology.⁸⁴ The same may be true for an at-home COVID-19 diagnostic test that analyzes tissue samples directly through a smartphone application algorithm using artificial intelligence.

Obtaining new reimbursement codes can be important because existing codes may reimburse at a rate tied to the old technology. Thus, both the fictional contact lens and the at-home digitized COVID-19 test mentioned above may use older, existing codes and receive a reimbursement rate tied to those codes. Yet this rate may be lower than the rate required to generate a return on the investment to develop these newer products. And a delay to market caused by a need to obtain new codes could, especially for a time-sensitive technology such as a COVID-19 test, create additional challenges for the firm seeking to bring the new product to market. This may curb investment or, if investment has already been made, increase out-of-pocket costs for consumers.

tomography (last visited Aug 17, 2022). National Coverage Determination Decision Memo, CAG-00439R, Screening for Lung Cancer with Low Dose Computed Tomography (LDCT).

⁸² G. Gregory Raab & David H. Parr, *From Medical Invention to Clinical Practice: The Reimbursement Challenge Facing New Device Procedures and Technology—Part 1: Issues in Medical Device Assessment*, 3 JOURNAL OF THE AMERICAN COLLEGE OF RADIOLOGY 694 (2006).

⁸³ *Id.*

⁸⁴ E.g., Medicare Claims Processing Manual Chapter 4 - Part B Hospital, 1, 4. § 60.1.

Codes can also affect reimbursement depending on where the device is used, which can change which reimbursement system CMS uses to pay for the device.⁸⁵ A COVID-19 test that is administered to an inpatient will be reimbursed differently than one administered at a physician's office. Tests performed at home without a physician risk not being reimbursed at all. What's more, CMS may use "pass-through" payments to reimburse some devices based on the cost of acquiring the device. Using data from this process, CMS may change the reimbursement rate for a procedure by factoring into the reimbursement the cost of information it obtained during the pass-through payment stage.⁸⁶ In other words, the payments for the particular service may go up or down depending on how much CMS thinks it costs to use the device. While this may work well with relatively inexpensive innovations, such as the digitized COVID-19 at-home test, it may not work as well for very expensive products where the time horizons for return on investment are much longer.

Takeaways:

- Medicare payment for use of in-home digital diagnostics will depend on decisions relating to coverage, coding, and reimbursement.
- Coverage may be determined either nationally by CMS or locally by Medicare contractors, though LCDs are the most common.
- Medicare will reimburse only some in-home digital diagnostics, and reimbursement is usually calculated as part of the prospective payment to hospitals or the fee schedule for physicians.
- For the in-home digital diagnostics Medicare reimburses, it will do so based on a variety of factors, including billing codes and the setting in which reimbursement is requested.
- Reimbursement for in-home digital diagnostics, particularly novel in-home digital diagnostics, is by no means guaranteed and can affect incentives to bring the product to market.

⁸⁵ G. Gregory Raab & David H. Parr, *From Medical Invention to Clinical Practice: The Reimbursement Challenge Facing New Device Procedures and Technology—Part 3: Payment*, 3 JOURNAL OF THE AMERICAN COLLEGE OF RADIOLOGY 842 (2006). The two main systems are Ambulatory Payment Classifications (APC) and Diagnosis-Related Group Reimbursement (DRG).

⁸⁶ *Id.*

Table 8: Further Information on Medicare Reimbursement

Law/Topic	Citations	Other Sources	Summary
Federal Law Governing Reimbursement for Federal Healthcare Programs Medicare and Medicaid (Social Security Act)	42 U.S.C. §§ [Part A:]1395c to 1395i-5, 1395x, [Part B:] 1395j to 1395w-6, 1395x, [Part C:] 1395w-21 to 1395w-29, [Part D:] 1395w-101 to 1395w-154	CMS Webpage on Medicare CMS Revised Process for Making National Coverage Determinations Medicare Benefit Manual	Medicare is the federal insurance program that covers most elderly and disabled beneficiaries, and it includes: <ul style="list-style-type: none"> • Part A, which covers hospital care that covers certain diagnostics; • Part B, which covers mostly outpatient services, like physician visits and some preventative services, and durable medical equipment (e.g., wheelchairs, walkers); • Part C, which covers a variety of services in Parts A, B, and D that are provided by private plans that must abide by Medicare-set rules; and • Part D, which covers prescription drugs typically filled at a retail pharmacy.

ii. Medicare Advantage

Medicare Advantage—also known as Medicare Part C—is offered to Medicare beneficiaries as an alternative to original Medicare Parts A and B. In 2021, Medicare Advantage enrolled 42 percent of the total Medicare population (around 26 million individuals), a figure that is projected to grow.⁸⁷ Because of its size, Medicare Advantage exerts significant influence over the development of in-home digital devices. Because of its structure, Medicare Advantage can be structured in ways Medicare and Medicaid cannot be; yet it remains one of the largest managed care ecosystems.

Unlike original fee-for-service Medicare, Medicare Advantage is managed care offered by private insurance plans (Medicare Advantage Organizations, or MAOs), which administer Medicare benefits to enrollees through a contractual arrangement with CMS. In this respect, MAOs tend to reflect certain aspects of private insurance. For example, Medicare beneficiaries can enroll in an MAO offering a Preferred Provider Organization (PPO) or a Health Maintenance Organization (HMO) plan. Alternatively, beneficiaries can enroll in an MAO offering a Private Fee-for-Service (PFFS) plan. Some types of plans are also required to offer Part D coverage.

To become an MAO the plan must submit to Medicare “bids” with estimated costs. To successfully bid and receive payment after the bid is accepted, plans must meet certain requirements.⁸⁸ Based on the MAO’s bids, Medicare advances monthly payments to the MAOs and pays rebates when the MAO’s costs are less than the bid.⁸⁹ Successful MAOs offering Medicare Advantage are required to pay for all items and services paid for by original Medicare and are subject to additional requirements, such as fraud and abuse monitoring.

But additional requirements also come with freedom to offer additional services and treatments that original Medicare does not cover. For example, MAOs can offer benefits for acupuncture, counseling, meals, in-home safety assessments, or fitness memberships—items and services not covered by original Medicare. This flexibility may mean that in-home digital diagnostics may have the greatest chance of reimbursement in this growing segment of the Medicare market. Provided the product is reasonable and necessary and not otherwise excluded from coverage, MAOs may have flexibility to reimburse in-home digital diagnostics, even if Medicare itself does not cover those products. As such, MAOs can have a leadership or pioneering impact on this product category.

⁸⁷ Meredith Freed, Jeannie Fuglesten Biniek, Anthony Damico, & Tricia Neuman 2021, *Medicare Advantage in 2021: Enrollment Update and Key Trends*, KFF (2021), <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends> (last visited Aug 25, 2022).

⁸⁸ Something similar occurs for prescription drug plans (PDPs) under Medicare Part D. David A. Simon, *The Other FDA* (working paper 2022).

⁸⁹ 42 C.F.R. § 422.304.

Takeaways:

- Medicare Advantage, or Medicare Part C, is a voluntary program that Medicare beneficiaries can opt into in lieu of traditional Medicare Parts A and B that has nearly 26 million enrollees.
- Digital in-home diagnostics may be easier to reimburse within Medicare Advantage because of the flexibility MAOs have in providing benefits not available under original Medicare.

Table 9: Further Information on Medicare Advantage Reimbursement

Law/Topic	Citations	Other Sources	Summary
Medicare Part C	42 U.S.C. §§ 1395w-21 to 1395w-29 42 C.F.R § 422 et seq.	CMS Webpage on Medicare Advantage Medicare Manual for Part C Plans	Medicare Part C: <ul style="list-style-type: none">• is also known as Medicare Advantage;• is available to Medicare beneficiaries and replaces original Medicare Parts A and B;• is administered by private insurance plans that contract with CMS;• imposes restrictions on what private plans can offer and do; and• may offer a wider range of services than original Medicare.

iii. Medicaid

Individuals who are not elderly or disabled may still receive healthcare ultimately paid for by HHS through Medicaid: the federal government program that provides insurance to low-income individuals⁹⁰ and children.⁹¹ If an individual eligible for Medicaid also receives benefits for Medicare, Medicaid may cover Medicare premiums, co-payments, and co-insurance. A new device like the contact lens mentioned above, then, may be available to these populations through Medicaid. Whether such a device is actually covered, however, is highly dependent on the state in which they reside.

Although a federal program, Medicaid is administered by individual states that elect to participate in it, though states receive significant financial contributions to cover the costs of the program.⁹² Federal law mandates minimum eligibility, coverage, and administration requirements, but states have significant discretion in implementing these requirements, which often determines the benefits individuals receive and how the state pays for them.⁹³ Some states (such as Ohio) offer “managed Medicaid,” a program in which Medicaid (through a state agency), rather than reimbursing for claims directly, offers fixed payments per member per month (“capitation payments”) to managed care organizations that pay claims.⁹⁴

Consider a simple device like a hearing implant. Coverage variability across states means that, although safe and effective, many Medicaid beneficiaries may not be able to access the implant merely because of geography.⁹⁵ Indeed, some states are relatively generous when it comes to coverage of services while other states, in part due to their political and public health cultures, reimburse for a much narrower range.⁹⁶ For in-home digital diagnostic devices like the hypothetical contact lens mentioned above, such variability makes it difficult to make general statements about coverage and reimbursement.

⁹⁰ Native Americans who qualify for Medicaid may enroll in addition to their participation or eligibility in the Indian Health Service (HIS), which provides healthcare to Native Americans.

⁹¹ The disabled who are Medicare beneficiaries may also qualify as Medicaid beneficiaries, which then acts as supplemental insurance. In 1997, Congress set up the related Children’s Health Insurance Program (CHIP), which covers children whose families earn too much money to qualify for Medicaid but earn less than an amount set by the state. Balanced Budget Act of 1997 §§ 4901, 4911-13, 4921-23, Pub. L. 105-33, 111 Stat. 251 (Aug. 5, 1997).

⁹² Alison Mitchell & Evelyne P. Baumrucker, *Medicaid: An Overview*, CONGRESSIONAL RESEARCH SERVICE, <https://crsreports.congress.gov/product/pdf/R/R43357/9> (2015).

⁹³ *Id.*; 42 U.S.C. § 1396a.

⁹⁴ Managed Care, MEDICAID, <https://medicaid.ohio.gov/families-and-individuals/mcare/managed+care> (last visited Aug 17, 2022).

⁹⁵ Michelle L. Arnold, Kathryn Hyer, & Theresa Chisolm, *Medicaid Hearing Aid Coverage For Older Adult Beneficiaries: A State-By-State Comparison*, 36 HEALTH AFFAIRS 1476 (2017).

⁹⁶ Marianne P. Bitler & Madeline Zavodny, *Medicaid*, in THE LAW AND ECONOMICS OF FEDERALISM 183, 183-4 (2017).

Even when it does reimburse for an item, Medicaid tends to reimburse at much lower rates than Medicare.⁹⁷ Lower reimbursement rates can impact development incentives for the large firms and providers that use them. Suppose that the disease which the above-mentioned contact lens diagnoses or treats is most prevalent among the poorest Americans. Medicaid thus may be the main payor that reimburses for the item. If Medicaid compensates healthcare providers who use this device at lower rates than Medicare or private insurance, then firms may not develop the technology. Moreover, reimbursement by Medicare may drive providers to avoid Medicaid patients to obtain higher reimbursement from Medicare and private payors (assuming they reimburse the product), exacerbating existing disparities in access and care.

Takeaways:

- Digital diagnostics may be covered by the states administering Medicaid, but coverage is likely to be variable, raising equity and access issues.
- Coverage by Medicaid can play an important role in creating incentives for in-home digital diagnostic manufacturers to develop devices that address issues faced by low-income individuals and children.
- Even if Medicaid covers an in-home digital diagnostic, it may not provide as much incentive to develop the diagnostic focused on that market because Medicaid reimburses at lower rates than Medicare.

Table 10: Further Information on Medicaid Reimbursement

Law/Topic	Citations	Other Sources	Summary
Health Insurance for Low-Income Individuals (Including Eligible Native Americans) and Children [Medicaid]	42 U.S.C. § 1396 et seq. 42 C.F.R. § 438 et seq.	CMS Webpage on Medicaid CMS Webpage on Outreach to Native Americans /Alaska Natives	Medicaid is a federal law that <ul style="list-style-type: none"> • covers low-income individuals, including children and eligible Native Americans; • states implement by setting eligibility criteria within federally specified limits; • is funded jointly by the state and federal governments; and • reimburses at lower rates than Medicare.

⁹⁷ E.g., Stephen Zuckerman, Laura Skopec, & Joshua Aarons, *Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare In 2019*, 40 HEALTH AFFAIRS 343 (2021).

iv. Penalties and Liabilities Stemming from Fraud and Abuse

While obtaining reimbursement is important, in-home digital diagnostic manufacturers are subject to penalties if they violate the laws governing the process of generating business and submitting claims for reimbursement. These penalties can themselves shape how manufacturers design, market, and seek reimbursement for their in-home digital diagnostics.

There are three principal federal statutes that penalize certain referral arrangements and fraud relating to healthcare.⁹⁸

- The Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7b) imposes criminal and civil penalties on persons who knowingly and willfully solicit or receive “remuneration” for referring or recommending others, or (recommending) purchasing, leasing, or ordering of items or services reimbursable by a federal healthcare program.⁹⁹ Some states have similar companion laws.¹⁰⁰
- The Stark Law (42 U.S.C. § 1395nn) imposes penalties on physicians who refer patients to entities with which they or an immediate family member have financial relationships or who request payment from Medicare for certain services¹⁰¹ for any such referral. Some states have similar companion laws.¹⁰²
- The False Claims Act (FCA) (31 U.S.C. §§ 3729-3733) penalizes persons who know or should know the claims they submit to the federal government are fraudulent,¹⁰³ which includes both the claim itself and any statements or records used to support the claim. Claims that violate the AKS or the Stark Law may also

⁹⁸ There are other statutes governing this area. E.g., 42 U.S.C. § 1320a-7 (requiring the exclusion of certain persons from federal healthcare programs and imposing civil penalties for a variety of behaviors).

⁹⁹ Certain exceptions exist. 42 C.F.R. § 1001.952 (defining exceptions to “remuneration”).

¹⁰⁰ E.g., Tex. Occ. Code § 102.001(a), 102.003 (providing safe harbors coextensive with the Anti-Kickback Statutes).

¹⁰¹ This is limited to so-called “designated health services”: “(A) Clinical laboratory services. (B) Physical therapy services. (C) Occupational therapy services. (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services. (E) Radiation therapy services and supplies. (F) Durable medical equipment and supplies. (G) Parenteral and enteral nutrients, equipment, and supplies. (H) Prosthetics, orthotics, and prosthetic devices and supplies. (I) Home health services. (J) Outpatient prescription drugs. (K) Inpatient and outpatient hospital services. (L) Outpatient speech-language pathology services.” 42 U.S.C. § 1395nn(h)(6).

¹⁰² E.g., Ca. Bus. & Prof. Code § 650.01(a) (“Notwithstanding Section 650, or any other provision of law, it is unlawful for a licensee to refer a person for laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or in the entity that receives the referral.”).

¹⁰³ The legal definition does not require specific intent to defraud and includes “actual knowledge,” “deliberate ignorance of the truth or falsity of the information,” and “reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b).

be fraudulent under the FDCA. Notably, the FCA contains a mechanism for private citizens to bring lawsuits for certain violations (qui tam actions) and share in part of any recovery by the government. Many states have similar laws, some of which apply not only to state healthcare programs but also to commercial payors.

Consider a medical device that diagnoses heart disease and for which the federal government reimburses. The AKS prohibits the device manufacturer from entering into certain referral arrangements with anyone who provides remuneration for such referrals, subject to limited safe harbors that afford protection under the AKS, such as those for employees,¹⁰⁴ drug discounting,¹⁰⁵ rebates paid to group purchasing organizations,¹⁰⁶ and, in some cases, waivers for Part B Medicare deductibles.¹⁰⁷

For example, a violation of the AKS law could occur if a physician receives payments from an in-home digital diagnostic manufacturer for each patient to whom the physician prescribes the device where the payments are not tied to the physician's work on behalf of either the manufacturer or the patient. So too could a manufacturer's overpayment to a Medicare Advantage Organization (a private insurance company operating under Medicare Part C) in exchange for its device's inclusion on the insurance company's formulary. Likewise, contracts to refer and provide in-home digital diagnostics in exchange for a share of revenue generated by the product would likely implicate the AKS.¹⁰⁸

By contrast, a court found no criminal violation of the AKS where a healthcare provider paid a third party to market its products or services, offering \$300 per new patient delivered by such marketing.¹⁰⁹ Because the healthcare provider paid an advertising intermediary that had no control over the decision of the potential physician-customer to use the healthcare provider, the court found the intermediary was incapable of making "referrals"—and hence of violating the AKS. It did, however, leave open the possibility that the provider may be guilty of violating the provision that prohibits persons from receiving remuneration from others to whom they "recommend purchasing" reimbursable items or services.¹¹⁰ At bottom, AKS violations are most likely

¹⁰⁴ 42 U.S.C. § 1320a-7b(b)(3)(B).

¹⁰⁵ 42 U.S.C. § 1320a-7b(b)(3)(A).

¹⁰⁶ 42 U.S.C. § 1320a-7b(b)(3)(C).

¹⁰⁷ 42 U.S.C. § 1320a-7b(b)(3)(D).

¹⁰⁸ OIG Advisory Opinion No. 11-17, Office of the Inspector General, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (Nov. 16, 2011), <https://oig.hhs.gov/documents/advisory-opinions/633/AO-11-17.pdf> (last accessed June 27, 2022).

¹⁰⁹ *United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004) (federal criminal prosecutions under 42 U.S.C. §§ 1320a-7b(b)(1)(B), (b)(2)(B)).

¹¹⁰ Andrew S. Feldman, *That Other Provision of the Anti-Kickback Statute*, 28 HEALTH LAW 1 (2015).

to be prosecuted where the conduct at issue is designed to influence clinical decisions of either providers or patients.

Additionally, the Stark Law prohibits the physician from referring patients to the firm with which the physician has a financial relationship provided Medicare pays for the product, and absent a relevant Stark exception applying to the physician relationship. A physician who has a financial interest in a firm that manufactures an in-home digital diagnostic as part of a clinical laboratory could also violate the Stark Law if the physician refers a patient to that laboratory via the digital diagnostic and Medicare pays for the use of the product or testing.¹¹¹ It is possible, then, for the law to cover an in-home digital diagnostic that enables users to process their in vitro tests at home using computer software if Medicare pays for the product.

Despite the fact that in-home digital diagnostics are used outside the clinic, they can still raise False Claims Act issues since they may be billed as part of physician or hospital services, such as in a hospital-at-home program.¹¹² Overbilling or submitting fraudulent claims in such cases can violate the False Claims Act. For instance, a physician could be liable for using a billing code for (or one that includes use of) an in-home digital diagnostic when the product was not, in fact, part of the service or not medically necessary. A physician or firm could also be liable for fraudulently coding for (and hence obtaining) an in-home digital diagnostic by falsifying information about the need for that diagnostic (i.e., making up a diagnosis or facts related to patient evaluation that would justify use of the in-home digital diagnostic).

¹¹¹ This example assumes the statutory exceptions, such as for owning interest in a publicly traded company, do not apply. 42 U.S.C. § 1395nn(b)-(e).

¹¹² David A. Simon et al., *The hospital-at-home presents novel liabilities for physicians, hospitals, caregivers, and patients*, NAT MED 1 (2022).

Takeaways:

- Federal law prohibits in-home digital diagnostic manufacturers from paying “remuneration,” such as fees or commissions, to others in exchange for referrals that result in the purchase of their products, provided the products are reimbursable by federal healthcare programs. Several exemptions to this law exist, including for employees of the manufacturer and group purchasing organizations.
- Federal law prohibits physicians from referring patients to in-home digital diagnostic or certain other health businesses, such as clinical laboratories, in which the physician has an interest (unless an exception applies) and for which Medicare pays.
- Federal law prohibits submitting fraudulent claims to the federal government, including submitting claims that code for in-home digital diagnostics that are not obtained or that are obtained but are not used because the information supporting their use is fraudulent.
- Companion state laws that mirror federal law but apply only to products paid for by state health programs can also be a risk for in-home digital diagnostic manufacturers.
- In-home digital diagnostic manufacturers and physicians who use them should carefully consider the impact of federal laws on their business models, billing methods, and referral practices.

Table 11: Further Information on Fraud and Abuse Regulations

Topic	Citations	Other Sources	Summary
Federal Law and Regulations Governing Penalties for Illegal Reimbursement Activities	<p>42 U.S.C. §§ 1320a-7b [Anti-Kickback Statute], 1395nn [Stark Law], 1320a-7 [Exclusion Statute], 1320a-7a [Civil Monetary Penalties Law]</p> <p>31 U.S.C. §§ 3279, 3729-3733 [Civil False Claims Act]</p> <p>18 U.S.C. §§ 286, 287 [Criminal False Claims Act]</p> <p>31 U.S.C. § 3279 et seq.</p> <p>42 C.F.R. Subpart C</p>	<p>Health and Human Services-Office of the Inspector General Fraud & Abuse Laws Webpage</p> <p>Department of Justice Webpage on the False Claims Act</p>	<p>The so-called Anti-Kickback Statute (AKS)</p> <ul style="list-style-type: none"> • is a criminal statute; • that prohibits certain kinds of referral arrangements; • where referrals are to goods or services reimbursable by federal healthcare laws. <p>The so-called Stark Law (SL)</p> <ul style="list-style-type: none"> • prohibits physicians from referring patients to services payable by <ul style="list-style-type: none"> ○ Medicare or Medicaid; or ○ a business in which the physician has a financial interest. <p>The so-called False Claims Act (FCA)</p> <ul style="list-style-type: none"> • is governed by both civil and criminal statutes; • makes one criminally liable for knowingly submitting false claims to the government; • makes one civilly liable for knowingly submitting false claims, which includes deliberate ignorance and reckless disregard for the truth or falsity of information; and • allows private citizens to sue civilly via qui tam actions.

			<p>The Civil Monetary Penalties Law (CMPL)</p> <ul style="list-style-type: none"> • imposes fines for a wider range of behaviors than AKS, SL, or FCA; and • fines can range from \$10,000 to \$50,000 per violation.
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C. Legal Intellectual Property Protection of Digital Diagnostics

Although federal law often involves affirmative regulation by governmental bodies, such as FDA and CMS, it also can include laws that regulate behavior among private parties at both the state and federal level. Intellectual property law protects intangibles like patents, copyrights, trademarks, and trade secrets by providing owners with a right to exclude others from it (though in different ways for different types of intellectual property) for a limited period of time. Patent law protects nonobvious, novel inventions, which include both inventions that are novel because of their utility (utility patents) or their design (design patents). Copyright protects original works of authorship. Trademark law protects anything that represents to consumers the source of a product, such as a logo or phrase. Finally, trade secret law protects information that is kept secret, is not generally known, and has economic value because of its secrecy. Patent and copyright law are exclusively federal, while trademark and trade secret are governed by state and federal law.

Each of these tools may enable the diagnostic device manufacturer to protect or even increase the value of their product, an important part of their incentive to invest in development. The benefits of intellectual property thus may enable firms to innovate without having their products or aspects of their brand copied or prices reduced. At the same time, however, intellectual property also increases costs to consumers by limiting access. By providing limited rights of exclusion to the owner, intellectual property also decreases competition. The law tries to balance these interests by placing limits on what can be owned, for how long, and how it can be used to exclude others.

Diagnostic devices may be covered by each type of intellectual property. Patents, for example, may cover the invention of a portable sleep study device. The same device may run on software code that is itself the subject of patent or copyright protection. And the firm that markets the device may choose a name, color scheme, or logo that can serve as its trademark. Finally, the firm may have trade secrets: information—such as customer lists, manufacturing processes, or an underlying algorithm—that the firm keeps secret and that has great economic value because it is known by no one else. By excluding others from using their patents, copyrights, trademarks, or trade secrets, the law provides a means for manufacturers to recoup investment costs and, in theory, make future investments with this in mind.

While intellectual property protections can add value for diagnostic devices, they can also raise costs. Some protections can overlap or run up against intellectual property owned by other individuals or entities. In such cases, diagnostic device manufacturers may have to enter into agreements to use others' intellectual property. In other cases, a manufacturer may decide the risk of using another firm's intellectual property is sufficiently small or cost-effective, and so may choose to litigate issues of ownership and rights violations. The law somewhat discourages this kind of intentional (or "willful") infringement of others' intellectual property by penalizing it more heavily by

awarding increased damages, for example. Despite the law attempting to protect legitimate interests of intellectual property owners, sometimes it may overprotect intellectual property—or enable overprotection by owners of intellectual property. Thus, despite being designed to encourage innovation, protection of intellectual property may also discourage it by decreasing competition.

Takeaways:

- Intellectual property laws can provide incentives to invest in in-home digital diagnostics by enabling the owners of intellectual property to prevent others from appropriating the aspects of the in-home digital diagnostic that intellectual property protects, but they can also raise the cost of such products for consumers.
- Federal law may provide legal protection of different aspects of in-home digital diagnostics, including its technology (utility patents and copyright), design (design patents, trademarks, and unfair competition), and name, logo, or product packaging (trademark law).
- State law may provide legal protection over the design, name, or look of the in-home digital diagnostics, or when there is an unauthorized disclosure of confidential information that has economic value.

Table 12: Further Information on Intellectual Property Protection

Topic/Law	Citations	Other Sources	Summary
Federal Law Governing Inventions	35 U.S.C. § 101 et seq. [Patent Act]	Manual of Patent Examining Procedure (MPEP)	Patent law <ul style="list-style-type: none"> protects useful, novel, and non-obvious inventions; gives inventors a 20-year exclusive right to their invention; and requires inventors to file a patent application with the U.S. Patent and Trademark Office (PTO) to obtain legal protection.
Federal Law Governing Use of Names, Symbols, and Logos	15 U.S.C. § 1051 et seq. [Lanham Act of 1947]	Trademark Manual of Examining Procedure (TMEP)	Trademark law <ul style="list-style-type: none"> protects words, symbols, logos, sounds, shapes, and a variety of other “devices” used to signify that a product or service emanates from a singular source for so long as the device is used in this way; is used by firms to distinguish their products from one another and to signify the uniformity and quality of their products or services; and enables federal registration of trademarks (by application to the PTO), which, though not required to obtain or enforce trademark rights, offers several advantages.
Federal Law Governing the Protection and Use of Creative Works	17 U.S.C. § 101 et seq. [Copyright Act of 1976]	Circulars Explaining Various Aspects of the Copyright Act	Copyright law <ul style="list-style-type: none"> protects original works of authorship, such as books and movies, but also computer software, logos, and designs; and protects works “automatically,” but filing a registration with the Copyright Office is required to successfully sue another party

			for infringing a copyrighted work.
Federal and State Laws Covering the Protection and Use of Valuable Information – Trade Secret Laws	<p>Codified in various state statutes and court decisions</p> <p>18 U.S.C. §§1831 et seq. [Economic Espionage Act]</p> <p>18 U.S.C. § 1836(b) [Defend Trade Secrets Act of 2016]</p> <p>18 U.S.C. § 1905 et seq. [Trade Secrets Act]</p> <p>18 U.S.C. §§ 1341, 1343, 1346 [Frauds and Swindles]</p>	Uniform Trade Secret Act	<p>Trade secret law</p> <ul style="list-style-type: none"> • is a creature of both state and federal law; • generally protects independently economically valuable information, that is not generally known or readily ascertainable by proper means, and that is subject to measures that are reasonable under the circumstances to maintain secrecy; and • can result in criminal punishments under a variety of federal laws.

D. Privacy

Digital diagnostics often also raise privacy concerns.¹¹³ A device that constantly monitors patients for cough, heartrate, or respiratory patterns, contains sensitive data. The same is true of devices that actually diagnose individuals with diseases or conditions. For example, a device that uses a computer program to process human tissue samples to diagnose infectious diseases likely would send information over the internet, raising questions about how the firm safeguards patient data when it processes, communicates, and stores the data.

These products also raise questions about with whom such information can be shared. Suppose an in-home digital diagnostic manufacturer collects user information, and an insurance company, hospital, or employer wants to buy it. Or perhaps the manufacturer wants to sell user information to advertisers, which in turn will sell products to users. When are such actions allowed and under what conditions?

These questions can be answered, in part, by understanding federal laws that regulate privacy, including the Health Insurance Portability and Accountability Act (HIPAA)¹¹⁴ and the Federal Trade Commission Act (FTCA).

Although several laws and a variety of federal agencies regulate information privacy,¹¹⁵ not all of these laws or agencies are of the same importance for in-home digital diagnostics. For example, although FTC regulates data privacy and security, its Safeguards Rule, which requires companies to develop and implement a written information security plan, applies only to financial institutions.¹¹⁶ Likewise, several states have enacted state laws that govern privacy, including laws that govern information collection, storage, and security.¹¹⁷ Additionally, several federal rules

¹¹³ While this report is focused only on U.S. law, it is important to make note of the General Data Protection Regulation (GDPR). Council Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and repealing Directive 95/46/EC (General Data Protection Regulation), 2016 O.J. (L 119) 1. Beyond its importance outside the U.S., the GDPR has set a floor that many multinational companies have applied to all their products, even those operating solely in the U.S. and that would arguably fall outside of the GDPR's scope. For more discussion of GDPR and its relevant application here, see Sara Gerke et al., *Regulatory, safety, and privacy concerns of home monitoring technologies during COVID-19*, 26 NATURE MEDICINE 1176 (2020).

¹¹⁴ Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-91, 110 Stat. 1936 (Aug. 21, 1996).

¹¹⁵ Privacy Regulators, PRIVACY PLAN, https://drive.google.com/file/d/1taa-4xvEXgZYlYv8lAn4wSTtgA7QS3J/view?usp=embed_facebook (last visited Jun 28, 2022).

¹¹⁶ 15 U.S.C. § 6805; FTC Safeguards Rule: What Your Business Needs to Know, FEDERAL TRADE COMMISSION (2022), <http://www.ftc.gov/business-guidance/resources/ftc-safeguards-rule-what-your-business-needs-know> (last visited Jun 28, 2022). Additionally, various state laws, such as unfair and deceptive practice laws and privacy laws, may supplement or impose additional obligations on those handling information. But this report does not discuss them.

¹¹⁷ E.g., California Consumer Privacy Act, codified at Cal. Civ. Code § 1798.100 et seq. For additional information about state privacy laws, see U.S. State Privacy Legislation Tracker,

regarding specific types of information regulate privacy, such as GINA (which covers certain kinds of genetic information) and the Confidentiality of Substance Use Disorder Patient Records regulations (which cover patient records for the treatment of substance abuse disorder).¹¹⁸ These and other similar laws and regulations are not discussed below.

<https://iapp.org/resources/article/us-state-privacy-legislation-tracker/> (last visited Sep 15, 2022). Some state laws also cover security breaches. E.g., Security Breach Notification Chart, PERKINS COIE, <https://www.perkinscoie.com/en/news-insights/security-breach-notification-chart.html> (last visited Sep 15, 2022). For biometric privacy, see A Fresh “Face” of Privacy: 2022 Biometric Laws, TROUTMAN PEPPER (2022), <https://www.troutman.com/insights/a-fresh-face-of-privacy-2022-biometric-laws.html> (last visited Sep 15, 2022).

¹¹⁸ 85 Fed. Reg. 42986, July 15, 2020, codified at 42 C.F.R. pt. 2.

i. Health Insurance Portability and Accountability Act (HIPAA)

One law that does directly implicate in-home digital diagnostics is HIPAA, which applies to “protected health information” (PHI) that is collected or generated by “covered entities,” such as physicians and hospitals, and their “business associates,” typically contractors who work with information provided by covered entities (or subcontractors of those contractors).¹¹⁹ This coverage will affect many in-home digital diagnostics, which may be “business associates” of “covered entities.”

HHS implemented HIPAA primarily via two rules: the Privacy Rule and the Security Rule. The Privacy Rule

- applies to a subset of PHI called “individually identifiable health information”; and
- governs when this PHI can be disclosed or used.

Consider a hospital that contracts with an in-home digital diagnostic manufacturer to ambienly monitor patients and collect their PHI. Because the manufacturer is a “business associate” of the hospital, which is a covered entity, the data collected by the manufacturer would fall under HIPAA.

Despite this seemingly expansive reach, HIPAA does not apply to deidentified PHI, even if it can later be reidentified,¹²⁰ and is subject to a variety of exceptions that allow disclosure in a variety of circumstances, including disclosure:

- to the individual or the individual’s representative;
- for use in treatment, payment, or healthcare operations with the individual’s consent;
- with valid authorization of the individual; and
- in a variety of other situations without written authorization by the individual provided the individual is given the opportunity to object.

Additionally, in some cases the Privacy Rule may not apply to the raw data collected by the device manufacturer that is a covered entity when that information is not transmitted to a healthcare provider.¹²¹ This is because most agreements between business associates and covered entities are limited to data transferred to clinicians or hospitals, and this usually does not include raw device data.¹²² HIPAA also does not

¹¹⁹ 45 CFR § 164.500.

¹²⁰ W. Nicholson Price & I. Glenn Cohen, *Privacy in the age of medical big data*, 25 NAT MED 37 (2019).

¹²¹ I. Glenn Cohen, Sara Gerke, & Daniel B. Kramer, *Ethical and Legal Implications of Remote Monitoring of Medical Devices*, 98 THE MILBANK QUARTERLY 1257 (2020).

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apply to most GWP, which often operate outside traditional healthcare settings and without provider involvement.

While the Privacy Rule focuses on the informational disclosure and use obligations of covered entities and business associates to maintain privacy of PHI, the Security Rule focuses on the protection of information from unauthorized access.¹²³ It requires covered entities and business associates to implement specific electronic security requirements.¹²⁴ When “security incidents” that indicate a potential breach of information occur, the covered entity or business associate is required to follow response and reporting procedures.¹²⁵ The Office for Civil Rights has also recently taken the position that a ransomware attack may result in a breach of the HIPAA Privacy Rule.¹²⁶ For example, if a hacker stole information from an in-home digital diagnostic manufacturer covered by HIPAA, the manufacturer could be liable for breaches of both the Privacy Rule (if PHI is disclosed) and the Security Rule (if it did not have proper safeguards in place).

Takeaways:

- In-home digital diagnostic manufacturers may be subject to HIPAA’s Privacy Rule and Security Rule, which limit how information can be disclosed and how it must be safeguarded.
- HIPAA, however, may not cover a wide range of in-home digital diagnostics if they operate “outside” the traditional healthcare setting, though acting as business associates of covered entities will bring the manufacturer within HIPAA’s purview.
- Digital diagnostic manufacturers may be able to deidentify information and disclose it without violating HIPAA.

¹²³ The Security Rule, Office for Civil Rights (OCR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (2009), <https://www.hhs.gov/hipaa/for-professionals/security/index.html> (last visited Jun 28, 2022).

¹²⁴ I. Glenn Cohen, Sharona Hoffman, & Eli Y. Adashi, *Your Money or Your Patient’s Life? Ransomware and Electronic Health Records*, 167 ANN INTERN MED 587 (2017).

¹²⁵ 45 C.F.R. § 164.304; 45 C.F.R. 164.308(a)(6).

¹²⁶ Fact Sheet: Ransomware and HIPAA, Office for Civil Rights (OCR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (2021), <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/ransomware-fact-sheet/index.html> (last visited Jun 28, 2022).

Table 13: Further Information on HIPAA

Topic/Law	Citations	Other Sources	Summary
Federal Laws and Regulations Governing Privacy	<p>42 U.S.C. § 1320d et seq. [Health Insurance Portability and Accountability Act (HIPAA)]</p> <p>45 C.F.R. § 160.103, [Privacy Rule:] 164.500 et seq., [Security Rule:] 164.102-106, 164.302-318, 164.400-414</p> <p>[Enforcement Rule:] § 160 (various subparts)</p>	<p>HIPAA Guidance Materials</p> <p>HHS Summary of Privacy Rule</p> <p>Security Rule Guidance Material</p> <p>HHS Webpage on the Enforcement Rule</p>	<p>The Health Insurance Portability and Accountability Act (HIPAA)</p> <ul style="list-style-type: none"> • sets privacy protections for certain personal information used by “covered entities” and “business associates”; and • is implemented by HHS. HHS has implemented HIPAA through various rules, including <ul style="list-style-type: none"> • The Privacy Rule, which <ul style="list-style-type: none"> ○ sets the framework for the rights and obligations of covered entities; and ○ balances a variety of interests by limiting the scope of the Rule through various exceptions, such as disclosures required for public health activities and for research. • The Security Rule, which <ul style="list-style-type: none"> ○ is designed to ensure the Privacy Rule works properly—to prevent access to those who are not entitled under the Privacy Rule; ○ requires covered entities and business associates to implement administrative, physical, and technical safeguards; and ○ is flexible, tailoring the level, type, and

			<p>implementation of security measures to various factors, such as the covered entity's size, complexity, and capabilities, along with the technical capabilities, costs, and nature and probability of the risks to the information protected.</p> <p>The Enforcement Rule</p> <ul style="list-style-type: none"> ○ outlines how the Office of Civil Rights (OCR) will investigate violations of and enforce HIPAA; and ○ enables resolution of violations through voluntary compliance, corrective actions, resolution agreements, and referral of severe violations to the DOJ for criminal prosecution.
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ii. The Federal Trade Commission Act

FTC, in addition to regulating the truthfulness of device advertising, also regulates information privacy. The FTCA created the FTC to enforce unfair and deceptive practices in the private market. This includes regulating information privacy by requiring companies to accurately disclose how, when, and for what purpose they use data collected by their product. All companies, even those not covered by HIPAA, must act in a manner that is not unfair or deceptive. FTC has used this mandate to regulate data privacy and security by applying it to the privacy policies and user agreements to which companies require their users to consent.¹²⁷ FTC also uses this authority to require reasonable privacy safeguards, including technical and administrative protections.¹²⁸

Recently, FTC has used its authority to promulgate the Health Breach Notification Rule, which imposes on health app vendors requirements to notify users and FTC when an unauthorized disclosure of certain health-related information is discovered. Additionally, Congress has specifically mandated certain disclosure and notification requirements when the data at issue derives from children using the relevant product. Finally, FTC has indicated interest in policing algorithmic discrimination.¹²⁹

Thus, in-home digital diagnostic manufacturers can be liable for misleading consumers in their terms of service or privacy practice disclosures. This could occur if an in-home digital diagnostic manufacturer, for example,

- states that it will not disclose information for a particular purpose but later does so without notifying the user beforehand;
- fails to state that it will use information for a particular purpose; or
- fails to implement reasonable privacy safeguards, such as measures to control access to information, to securely dispose of data, or to implement cheap and industry-standard security practices.

FTC sued a device company, for example, for misleading consumers about its participation in a privacy-enhancing framework for patient data.¹³⁰

¹²⁷ Woodrow Hartzog & Daniel J. Solove, *The Scope and Potential of FTC Data Protection*, 83 GEO. WASH. L. REV. 2230 (2014).

¹²⁸ Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583 (2014).

¹²⁹ Aiming for truth, fairness, and equity in your company's use of AI, FEDERAL TRADE COMMISSION (2021), <https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai> (last visited Apr 20, 2021).

¹³⁰ Medical Diagnostic Device Maker Settles Allegations that it Misled Consumers about its Participation in the EU-U.S. Privacy Shield, FEDERAL TRADE COMMISSION (2020), <http://www.ftc.gov/news-events/news/press-releases/2020/03/medical-diagnostic-device-maker-settles-allegations-it-misled-consumers-about-its-participation-eu> (last visited Jun 28, 2022).

The in-home digital diagnostic manufacturer may also be liable, particularly if it is also a GWP manufacturer, if it

- fails to obtain consent before sharing user medical information with an advertising network;
- fails to implement reasonable privacy safeguards; or
- suffers a data breach of certain personally identifiable health information and fails to notify its users and FTC within a certain period of time after the breach.

Thus, FTC has the power to regulate deceptive practices generally, which can extend to how firms communicate privacy practices to consumers, as well as substantively protecting privacy through reasonable requirements. FTC has also recently taken steps—for example, by promulgating the Health Breach Notification Rule—to try to increase costs of some in-home digital diagnostic manufacturers failing to safeguard patient information.

Takeaways:

- Digital diagnostic manufacturers must
 - disclose to users how they intend to use information they collect and update users when these uses change;
 - be truthful in advertising and disclosing how they plan to use consumer information; and
 - implement reasonable security and administrative measures to protect consumer information.
- To avoid liability, some in-home digital diagnostic manufacturers must also obtain consent for certain uses and notify users and FTC if they suffer a security breach.

Table 14: Further Information on FTC Regulation

Topic/Law	Citations	Other Sources	Summary
Federal Laws and Regulations Concerning Information Collection and Security of Information	15 U.S.C. § 45 [Federal Trade Commission Act (FTCA)] 16 C.F.R. § 318 [Health Breach Notification Rule]	Remarks by Chair Lina M. Khan Statement of the Commission on Breaches by Health Apps and Other Connected Devices Memorandum of Understanding between FDA and FTC on Regulation	Under the FTCA, FTC's authority to regulate "unfair and deceptive" practices <ul style="list-style-type: none"> • covers privacy practices; • can be used to penalize firms that mislead consumers about how they collect and keep consumer information private; and • has been used to promulgate the Health Breach Notification Rule, which requires "vendors of health records" and "personal health record related entities"—including, according to FTC's interpretation, health app developers—to notify users and FTC if an "unauthorized acquisition" of "personal health record identifiable information" occurs.
	15 U.S.C. § 6501-6508 [Children's Online Privacy Protection Act (COPPA)] 16 C.F.R. § 312 et seq. [COPPA Rule]	Complying With COPPA: FAQs	Children's Online Privacy Protection Act (COPPA) <ul style="list-style-type: none"> • specifically targets companies that collected information about children; and • mandated that FTC issue and enforce regulations concerning children's privacy online. <p>FTC promulgated the COPPA Rule, which</p> <ul style="list-style-type: none"> • mandated that online services and websites disclose what information will be collected from and about children and how it will be used; and

			<ul style="list-style-type: none">mandated that websites use reasonable efforts to provide disclosures to parents and, in some limited circumstances, to obtain verifiable parental consent prior to collecting or using information
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