



Regulatory Roadmap for Digital Diagnostics

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The COVID-19 pandemic helped usher health care delivery out of the clinic and into the home. With outbreaks in hospitals and other medical facilities driving a significant number of pandemic deaths, the virus prompted increasing interest in allowing seniors to age at home utilizing telehealth, wearable sensors, and ambient surveillance, and using technologies such as smart pills for diagnostics, patient monitoring, and adherence.

This Regulatory Roadmap is a deep dive into the legal, regulatory, and policy issues linked to home delivery of care. While the move toward digital home health and digital diagnostics predates COVID-19, the pandemic provided new use cases and challenges.

As with most technological innovations, digital technologies have increased in sophistication and decreased in cost over time.

For example:

- Historically, magnetic resonance imaging (MRI) has required a large machine and a dedicated facility, which cost millions of dollars to purchase, install, and operate. Technological advances have reduced the cost and size of MRI machines, making at-home diagnosis <u>using portable</u> MRIs possible.
- Traditionally, to detect irregular heartbeats, patients had to undergo an electrocardiogram (EKG), something possible only at a physician's office or a hospital. But the Apple Watch can now <u>detect irregular heartbeat</u> on demand with the simple press of a button.
- Ordinarily, diagnosing children with autism is performed by a physician administering tests in a clinical setting. But in 2021, the Food and Drug Administration (FDA) granted do novo authorization for Canvas Dx, software that can help physicians diagnose autism in children between 1.5 and 6 years old using a mobile app and videos.

Other sensor technology, wearables, and smartphones have facilitated and supported a burgeoning set of potential products that can be used to diagnose conditions using digital technologies, eliminating or reducing both the analog component and the need for the clinic. They range from medical grade products like <u>glucose monitors</u> to consumer technologies that monitor our <u>every movement</u>, breath, and utterance, holding the promise of diagnosing anything from <u>respiratory illness</u> to Parkinson's disease.

While promising, these new "in-home digital diagnostic" technologies ("digital diagnostics") raise difficult questions for patients and regulators alike. In a multi-year project, our team at the Petrie-Flom Center's <u>Diagnosing in the Home Project</u> focused on four questions:

- What kinds of safeguards are in place to ensure digital diagnostics are safe and effective?
- Who will pay for these digital diagnostics?
- How will intellectual property and competition law affect the development and accessibility of digital diagnostics?
- How will patient privacy be protected?

With an eye toward policymakers interested in supporting the benefits of moving health care to the home and preventing possible harms, in this Regulatory Roadmap we report the primary findings of this research, which included a Delphi panel (Box 1), and recommend several areas for future action.

Box 1. What is a Delphi Panel?

Areas Identified by Research

Safety and Effectiveness

Safety and effectiveness of digital diagnostics are crucial, but some may be outside the current jurisdiction of FDA-regulated medical "devices," which means they can be marketed without FDA review. To prevent the harm that might occur from misdiagnosis or poor quality information produced by digital diagnostics, policy makers should ensure that:

- risk-based analysis is used determine the rigorousness of FDA review;
- digital diagnostics demonstrate that they work by using data that reflect all potential user demographics; and
- federal agencies like FDA and the Federal Trade Commission (FTC) monitor the marketplace to identify firms and practices that misleadingly market consumergrade products as medical-grade ones.

Who Pays?

Accessing digital diagnostics may depend on an individual's insurance coverage. Some types of insurance plans may pay for only certain digital diagnostics, perhaps limiting access for those on public insurance programs like <u>Medicaid</u>. And those 40 million individuals without insurance may not be able to access digital diagnostics at all. To ensure fair and equitable access to digital diagnostics, policymakers should examine:

- how public insurance could cover and reimburse digital diagnostics equitably, especially those products that receive marketing authorization from FDA;
- the effect of public coverage of digital diagnostics on private insurance companies, which often look to the federal government for guidance; and
- the implications of insurance reimbursement on equitable access to digital diagnostics.

Intellectual Property and Competition

Laws protecting intangible goods—intellectual property (IP) laws, including patent law (which protects technological innovations), and copyright law (which protects original written expression, including computer software)—may cover technology underlying digital diagnostics (either hardware or software). These laws may enable firms to use improvements of varying quality to block competitors from entering the market, thus

raising prices, and perhaps limiting access for all but the wealthiest consumers. Policymakers should evaluate:

- how firms are currently using IP law to innovate or unfairly block competition; and
- whether IP protections or similar IP-like protections, like regulatory exclusivities, are needed for certain types of digital diagnostic development.

Privacy

Digital diagnostics collect vast amounts of information about the user and sometimes their environment. Companies that sell digital diagnostics therefore have access to a trove of data that is highly valuable and highly personal. While a wide array of federal and state laws protect privacy, the main federal law—the Health Insurance Portability and Accountability Act of 1996—applies only in limited circumstances and generally does not apply to many standard consumer products. Policymakers should evaluate:

- integrating digital diagnostics into existing proposals to strengthen consumer privacy, and analyzing whether any special protections are needed;
- providing incentives for digital diagnostic companies to protect privacy, including by designing products with built-in protections; and
- educating physicians and consumers on the privacy practices of digital diagnostics.

Emerging Issues to Watch and Recommendations for Policymakers

Identifying future and emerging issues will help ensure that individuals have access to safe and effective digital diagnostics. To do this, policymakers should apply a consistent framework over time, selecting a few key topics of interest to track as digital diagnostics proliferate. This will ensure that critical issues are identified and resolved, and that the process is replicable going forward. Although the number of emerging issues facing digital diagnostics is vast, five deserve increased attention in the future: reimbursement, children, connecting individuals to care, new pathways to market, and discrimination.

Reimbursement

Current reimbursement of devices is complicated and may be a poor fit for innovative technologies that have marginal benefits or are not currently reimbursed at high enough rates to generate investment.

Policymakers should:

- update coverage reimbursement frameworks to better account for novel technologies and medical devices;
- align reimbursement mechanisms to incentives to innovate, which may stimulate more investment in new *quality* digital diagnostics, including those for underserved populations;
- create incentives or mandates for insurance firms to provide to insured individuals information about the coverage and cost of a digital diagnostic under their plan; and
- build access and equity concerns into reimbursement, including evaluating the potential for reimbursing novel technologies for low-income individuals, including those on Medicaid.

Children

Children are constantly interacting with new technologies. They are also frequently early adopters of them. These factors, combined with developments in software and hardware, have enabled the diagnosis of disease in children using games and phone apps. <u>Cognoa</u>, for example, is a digital platform that tracks children using smart technology. As part of its platform, Cognoa includes an <u>FDA-authorized</u> phone-based application that can help to diagnose autism in children between the ages of 18 and 72 months.

Two other examples, though not diagnostics, are <u>Mindful Powers</u>, which helps children learn meditation techniques, and <u>MindDoc: Your Companion</u>, which lets users log their mental health. While the latter is aimed at children over 12, younger children can use the application. Both offer in-app purchases. They may also share information to and about their users.

To confront the issues concerning digital diagnostics aimed at children, policymakers should:

- regulate the marketing of digital diagnostics aimed at children, particularly consumer-grade products, to avoid confusion about safety and effectiveness;
- regulate how firms buy, sell, and use data from digital diagnostics directed at children;
- require information and training be provided to the consumer prior to using or being able to use the digital diagnostic; and
- in some cases, require verified parental supervision of the use of digital diagnostics where children cannot understand the implications of diagnosis or cannot advocate for themselves.

Connecting Code with Care

One selling point of digital diagnostics is that early diagnosis will result in early treatment, reducing both suffering and the cost of care. Diagnosis, however, is only one important element in a treatment journey. Patients need to both understand their diagnosis and be connected to appropriate providers who can confirm the diagnosis or treat the condition.

To develop a "digital care continuum"—where digital diagnostics are integrated and part of the entire care experience from diagnosis to treatment—policymakers should:

- regulate when certain types of diagnostic tests require consultation with a health care provider;
- mandate that digital diagnostics provide details of where to find more information about results and follow-up care;
- create care infrastructure, such as networks of providers, to address patients using digital diagnostics;

- develop the technological infrastructure to ensure those who access digital diagnostics can also access follow-on technology or care;
- provide legal guardrails for businesses designed to integrate digital diagnostics with at-home care to protect consumers from predatory or nefarious business relationships; and
- work with stakeholders to develop resources for patients who wish to use or do use digital diagnostics.

New Pathways to Market

FDA has taken steps to experiment with new pathways to market in the digital space. A recent foray involved an <u>FDA pilot program</u> designed to assess manufacturers of software devices, rather than the devices themselves.

To remain adaptive and responsive to new technologies, policymakers should:

- provide FDA with additional authority to test and implement alternative pathways to market;
- increase post-market surveillance of digital diagnostics, utilizing their data collection mechanisms for public-health purposes;
- experiment with new pathways to market that focus on small- and mediumsized entities;
- continue to develop new guidance documents and frameworks for evaluating emerging technology, such as AI; and
- develop dynamic evaluation programs that can adapt as technology changes.

Discrimination and Data

Digital diagnostics will collect large amounts of information about their users, sometimes unwittingly. Various third parties may get access to this data—from governments seeking information about menstrual cycles and fertility to enforce abortion laws to insurance companies hoping to discover information about their insured—raising legal and ethical concerns.

To ensure privacy and limit misuse of data, policymakers should:

- develop legal models that can protect patient data privacy and freedom from discrimination even when existing federal laws cannot;
- coordinate with state leaders to develop uniform legislation to protect the privacy of patients; and

• pass legislation that expansively protects consumers from discrimination based on information obtained through digital diagnostics.

Conclusion

Digital technologies will continue to advance and increasingly will become diagnostic tools. As technology pushes digital diagnostics to the forefront of patient care, policymakers should:

- modify existing reimbursement rules or create new ones to ensure equitable and fair access to digital diagnostics while also generating quality innovation;
- identify and regulate to protect against special risks posed to children;
- holistically approach health care regulation to ensure that certain digital diagnostics include adequate access to follow-on information, testing, and treatment; and
- provide more authority to FDA to experiment with new programs for digital diagnostics, including different types of review, post-market surveillance, and data sharing requirements.

Policymakers should remain mindful of the emerging and complex issues outlined in this document to ensure equitable access to innovative digital diagnostics that are safe and effective.