M-Health: The Union of Technology and Healthcare Regulations

Mark J. Silberman* and Lisa Clark†

As healthcare continues to become technology-based, so too does the potential for increased governmental regulation of mobile health (m-health). “M-health” is a broad term that applies to hardware or software that is mobile and delivers healthcare wirelessly. M-health includes consumer- and provider-oriented medical applications (apps), such as weight monitoring apps, and medical devices, such as glucose meters, that send health information back to the provider. It is important for anyone entering the field of mobile healthcare, whether developing apps, providing remote medical care, or simply investing in the future of healthcare technology, to understand the impact governmental oversight can have on this industry. Understanding the different roles to be played by the federal and state governments can be the difference between success and frustration.

KEY WORDS: M-health; mobile health; mobile health device; medical device; remote medical device; healthcare app; healthcare and technology; healthcare regulation; telemedicine; HIPAA.

The courtship between technology and healthcare will need to continue to progress, and to progress rapidly, in order to achieve meaningful healthcare reform. Healthcare reform promotes increased access to high-quality healthcare at a lower cost and with minimized inconvenience to the patient. (Let us ignore that these are the very same goals that inspired Certificate of Need programs, HMOs, and virtually every other “advance” in healthcare administration.) What better way to achieve these goals than via mobile health (m-health), the inevitable offspring of the tryst between technology and healthcare.

Admittedly, the definition of m-health is in development. In its most basic sense, m-health is healthcare delivered wirelessly. M-health has three fundamental characteristics:
1. There must be a device or software that is;
2. Health oriented; and
3. Has mobile use.

The federal Department of Health and Human Services (HHS) defines a mobile health device as: “[A] handheld transmitting device with multi-functional capabilities used to store, transmit and receive health information and has user control over the access to the health information. Mobile devices combine elements of computing, telephone/fax, Internet and networking functions. This generally includes laptop computers, personal digital assistants (PDA), smartphones, and tablet computers. Mobile transmitting devices generally do not include storage devices such as USB drives.”

M-health can apply to mobile patient monitoring or diagnostic and treatment devices as well as applications (apps) that can be added to already existing mobile devices (such as a cell phone or tablet). Examples of m-health products used by the consumer alone include apps to record weight gain and loss. M-health products that support the consumer-provider relationship include wearable blood pressure monitoring devices that transmit health information back to the physician.

HHS Secretary Kathleen Sebelius addressed the role of m-health in “fixing” our healthcare system. At the 2011 mHealth Summit in Washington, DC, Sebelius said, “When we talk about mobile health, we are talking about taking the biggest technology breakthrough of our time and using it to take on one of the greatest national challenges of our time....”1

*Partner, Duane Morris LLP, 190 South LaSalle Street, Suite 3700, Chicago, IL 60603-3433; phone: 312-499-6713; e-mail: mjsilberman@duanemorris.com.†Partner, Duane Morris LLP, 30 South 17th Street, Philadelphia, PA 19103-4196; phone: 215-979-1833.

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In a world where real-time access to information and events is the baseline, it appears inevitable that healthcare consumers will soon demand real-time access to diagnostic and treatment information and related medical guidance.

M-health developers and investors are taking full advantage of this burgeoning market. Countless hours are being expended to develop “the app” that consumers, providers, and payers (including the government) truly “can’t live without,” and investors are lining up with the hopes of cornering the market. But despite ample cause for optimism, it is worth understanding that developing government regulation of m-health will likely cause speed bumps as the m-health industry grows.

THE TORTOISE VERSUS THE HARE

The pace at which technology supports advances in healthcare is astounding, especially when fueled by private investors. By comparison, the speed at which the government is equipped to regulate healthcare is more akin to the unrelenting plodding of a glacier. However, you should never underestimate the destructive power of a glacier. Just as a glacier has the capacity to scour clean all of mankind’s improvements from the face of the earth, so too do the “as-of-yet developed” or “as-of-yet applied” government regulations have the capacity to lay waste to current efforts to develop a sustainable framework for m-health.

Healthcare is among the most highly regulated of industries. Consider the multitude of agencies that have an interest in the wireless delivery of healthcare through a mobile device. Anyone venturing into the m-health arena would be well served to familiarize himself or herself (or retain counsel already familiar) with specific agency regulations and guidance, along with the trends in enforcement actions, to understand and assess the risks.

MEET THE POTENTIAL REFEREES IN THE M-HEALTH GAME

M-health has already garnered the attention of the following agencies.

The FDA regulates “medical devices” through a rigorous clearance and approval process. Accordingly, any implement that qualifies as a medical device, such as a glucose meter, is subject to the FDA review process. In addition, certain apps may be subject to FDA oversight as well, creating legal landmines for developers. In July 2011, the FDA expanded its definition of “device” to include certain mobile apps.3

Apps that will be regulated include ones that transform a mobile platform (e.g., an iPhone or iPad) into a regulated medical device, such as an electronic stethoscope, as well as apps that obtain and/or display information from other regulated devices, such as a remote cardiac monitoring device. However, after significant industry pushback, the FDA recently indicated that final guidance on mobile medical apps will be significantly streamlined. Whether or not a mobile device or app is subject to FDA regulation is an important determination that requires legal assistance.

HHS has a major role to play in the enforcement of m-health. HHS is one of the agencies responsible for overseeing HIPAA privacy and security issues. Consider the potential issues associated with the electronic collection, utilization, and transmittal of personal health information via m-health to allow a physician to see real-time test results broadcast to anywhere in the world. Among others, such access to information includes the accompanying risk of breaches. In accordance with HIPAA, and in addition to state privacy laws, providers and payers are responsible for ensuring the privacy of data from m-health devices and/or apps when the data are shared for treatment purposes. If data are sent to a healthcare facility’s electronic health record, to the patient by e-mail, or to a business associate/subcontractor (e.g., a billing company), then other HIPAA standards apply. HHS recently established an m-health initiative and is expected to be issuing updated guidance in the future.

The Federal Communications Commission (FCC) is responsible for the oversight of any and all medical devices that utilize radio technology to communicate. A Memorandum of Understanding was entered into in 2010 between the FDA and the FCC that committed “to promote collaboration and ultimately to improve the efficiency of the regulatory process applicable to broadband and wireless enabled medical devices.” The FCC recently announced a proposal to allocate wireless spectrum for medical body area network (MBAN) devices in hospitals, clinics, and doctors’ offices. The addition of new spectrum for MBAN devices will significantly expand the available bandwidth for m-health uses.

Reimbursement is a primary motivator of healthcare.

The Federal Trade Commission (FTC) broadly interprets its mandate to regulate unfair or deceptive acts and practices, including false or misleading claims about products or services. More importantly, the FTC historically signals its dissatisfaction via enforcement actions. There is ample evidence that the FTC is acutely aware of the m-health
movement, having already initiated actions against device manufacturers for making unsupportable claims regarding their apps. M-health developers and investors would be wise to consider the FTC’s authority in marketing their products.

**PUT YOUR MONEY WHERE YOUR M-HEALTH IS**

Reimbursement is a primary motivator of healthcare. The smart money is that this will remain true for generations to come. Therefore, whether an m-health device or app is or will be reimbursed by the Centers for Medicare & Medicaid Services (CMS) will likely dictate who succeeds and who fails in the race to m-health. Once these decisions are made, the design of m-health will be restructured and redesigned to fit within the reimbursable regulatory structure. History has proven that every time the government changes how it regulates or reimburses healthcare, the marketplace responds by adjusting itself to ensure continued profitability along with, of course, continued benefit to the consumers of healthcare.

**Who gets paid when the government concludes that it is the device that is practicing medicine?**

As soon as a new technology or reimbursement structure is introduced into healthcare, you have to begin to assess the potential for fraud and abuse. Government attorneys and state and federal prosecutors certainly will. The government highly regulates what items and services it pays for. For example, how will reimbursement requirements related to presence or supervision affect the government’s willingness to reimburse? What will the impact upon reimbursement be when the physician is in a different state (or, for that matter, another country) than the patient? Who, if anyone, gets paid when the government concludes that it is the device that is practicing medicine? How will Stark laws and anti-kickback regulations be applied to m-health devices?

Lest we forget, each individual state has its own glacier that can wreak havoc upon the m-health marketplace.

Individual state regulatory agencies and state attorneys general are starting to get into the mix, and each has the capacity to do so. State laws regarding privacy, false advertising, and unfair business practices, in addition to the multitude of regulatory enforcement tools available, all impact the development of m-health. Perhaps one of the most interesting issues to be determined is assessing at what point m-health products tilt the windmill to constitute the practice of medicine, thereby triggering an additional array of regulatory and practical issues. Additionally, given the budgetary crisis facing so many states, politicians will soon recognize the revenue generating-capacity of regulating m-health.

**ALL’S WELL THAT ENDS WELL**

At the end of the day, the impact of forthcoming regulations will not stand in the way of m-health’s advancement. There is one equalizing factor for those consumers, providers, payers, developers, and entrepreneurs seeking to advance improvements in healthcare delivery via m-health: the political process. When there are people to be helped and money to be made, it is certain that political agendas will creep into shaping the m-health revolution.

M-health has the ability to reshape the delivery of healthcare. As part of m-health’s development, government oversight will be central. As we move forward, a lingering question remains: How long will it be until Medicare will cover the expense of my iPhone?

**REFERENCES**