August 28, 2013

Office of the National Coordinator for Health Information Technology
Department of the Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Comments by Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology [Docket No.   HHS-OS-2013-0003]

Dear Madam, Sir,

On May 30, 2013, the Office of the National Coordinator (ONC) published a *Federal Register* notice seeking comments on the elements ONC, the U.S. Food and Drug Administration (FDA), and the Federal Communication Commission (FCC) should consider as they develop a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

The attached white paper outlines some factors related to innovation that the agencies, and in particular FDA, should consider as they put together the government's strategy. More specifically, it identifies outdated aspects of the existing FDA regulatory framework and suggests significant changes to address the unique aspects of health IT. It also advocates for a holistic approach among FDA, FCC and ONC to avoid confusion, duplication and regulatory conflict.

Epstein Becker & Green, P.C. is a national law firm that focuses on healthcare. With one of the largest healthcare law practices in the United States, we regularly work with medical device manufacturers, software developers, payers, providers, investors and employers with regard to health regulatory policy. In this white paper, we approach the issues raised in the *Federal Register* notice from the perspective of a focus on e-health technologies.

If you would like any further information on any of these topics, we would be pleased to help in any way we can.

Respectfully submitted,

Epstein Becker & Green, P.C.

Enhancing Innovation in e-health through a Systems Approach to Regulation

A Blue Print for FDA Modernization

Epstein Becker & Green, P.C.

August 2013

Introduction

This white paper offers a conceptual blueprint for how the U.S. Food & Drug Administration (FDA) can best foster innovation in the e-health ecosystem while continuing to ensure patient safety. Doing so will require that FDA modernize its regulatory approach to embrace the fact that we are witnessing a transformation of the medical technology landscape from one shaped by individual, discrete products to a new era of complex, connected diagnostic and therapeutic systems that deliver holistic care. This technical convergence will have a profound impact on FDA regulation.

While this paper encourages the use of the existing regulatory authorities to accomplish these changes, it does not advocate the status quo. Instead, we urge FDA to adopt significant, fundamental changes to its approach to keep pace with medicine and technology, and indeed encourage innovation that can do much to enhance the quality of patient care.

e-health

We use the term e-health to refer broadly to the growing practice of stitching together through electronic networks all aspects of healthcare delivery. Used that way, the term encompasses such areas as:

1. Healthcare provider IT networks that create interconnections among medical devices, both diagnostic and therapeutic, often adding linkages to electronic health records;
2. mHealth systems that use cell phones and other mobile platforms to gather, store and often transmit data from medical devices or to function in place of traditional medical devices; and
3. Electronic products used in providing telemedicine services.

All of these areas are marked by a common theme of convergence, where previously disparate activities are now being connected through electronic networks. Software and hardware are being combined to create an endless array of systems for use in nearly every aspect of healthcare from diagnosis to treatment.

Consider, for example, the "smart pill," a drug equipped with a digestible sensor that is activated by the patient's gastric juices. The pill's sensor sends a signal to a patch on the patient's skin. That signal is then relayed, via cell phone, over the Internet to a physician. With this smart pill and the accountability it brings, drug adherence increases significantly, patients stay healthier and our healthcare system is markedly more cost-efficient.

Further, while historically medical devices often have not been interconnected for a variety of technical and business reasons, we believe that the future belongs to those medical devices that operate as part of systems. Groups like the Medical Device "Plug-and-Play" Interoperability Program are working on "accelerating the adoption of medical device interoperability to enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical

apps for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care."

We believe that future innovations toward interoperability will dramatically improve patient outcomes and reduce the cost of providing healthcare. Opportunities for improvement abound. The lack of medical device interoperability has been flagged as a significant risk to patient care. Earlier this year, the ECRI Institute listed medical device and Electronic Health Record (EHR) interoperability as fifth in its list of top health technology hazards for 2013.

On the more positive side of e-health, mobile health offers incredible potential to bring care to where people live, integrating care systems into daily life. This integration means that care will not only be more effective, but likely less expensive.

In a nutshell, e-health offers the opportunity to make healthcare safer and more effective.

The Nature of Innovation in e-health

As already explained, our goal is to identify the key features of research and development that support innovation in e-health and need to be protected from over-regulation. This is necessary to ensure that patients ultimately get the benefit of the promise e-health offers. So we studied the innovation process in e-health, viewing it through the prism of regulation and its potential effects on that innovation. Below are the salient aspects of innovation that regulation potentially touches. We divide the universe of factors important to innovation into two broad categories, specifically (1) the act and process of innovating and (2) the business model for supporting innovation.

The Act and Process of Innovating

We have tried to collect best practices from leading companies in e-health in order to discern how they succeed in innovation. We are sure this is only a partial list, but it represents a good start in identifying what needs to be protected and allowed to flourish.

- *Collaboration among IT technical experts, clinicians, medical device developers and scientists of many sorts*. Collaboration is the wellspring of innovation. Perhaps in some areas of technology, innovation can occur from a lone, brilliant scientist tinkering late at night in his own lab. But in the area of e- health, true innovation uniformly comes from collaboration among very disparate sets of expertise. After all, given the definition above, e-health is about connecting medical devices and other technologies into networks to create powerful systems to deliver healthcare.
- *Finding talent wherever it might be.* In a sense, this is a continuation of the collaboration need, but in this bullet point we focus on the fact that the needed experts might be dispersed around the world. In other areas of technology development, it's more traditional to bring everyone together under one roof to facilitate the

development process. In IT, it's quite common not to bring everyone together physically but to let them interact virtually throughout the United States and the world.

- *Tinkering and experimentation, with feedback loops*. Any form of engineering requires the development of prototypes, but software development in particular involves the development of beta versions that can be tested in real world situations in order to obtain feedback and strengthen the technology. Consequently, to make real progress in e-health, we need to ensure that that tinkering and experimentation can continue in some appropriate way.

- *Major breakthroughs followed by many, many incremental improvements.* The pace of innovation is uneven. Certainly there are inspirations in which new technologies are created, or new uses for existing technology are identified. But those breakthroughs typically are followed by a significant number of incremental enhancements over sometimes a prolonged period.

- *Nonlinear process.* Creative minds tend to zig and zag. If you add to that collaboration where many people are working together, innovation tends to happen here and there, not necessarily according to some linear process. Regulatory restrictions in the name of a quality system that attempt to make development a purely linear process are doomed to cause confusion and unnecessary burden.

- *Short product lifecycles.* Indeed, this is simply the other side of the coin from the rapid progress in e-health technology. But it's important also to understand and appreciate the cultural impact that the short lifecycles have on the developers themselves. These developers thrive in an environment in which change is constant, and progress is something that can be made virtually every day. Fundamentally changing that culture and environment by imposing regulatory obligations that would dramatically lengthen the product lifecycles would have a tremendous stifling impact on the exciting cultures that exist in these technology developers' organizations.

- *Sensible technology standards driven by industry.* The promise of e-health depends tremendously on the interoperability of medical devices and IT systems. Thus, for e-health to flourish, the developers of these technologies need to agree upon common standards to be used. While this in a sense constrains innovation, industry organizations are in a position to develop the standards in a way that balances the need for innovation with the need for standardization.

- *Modularization of software.* It never makes sense to reinvent the wheel. Software development is no exception. Over the last few decades hundreds of thousands of software developers have created literally millions of software programs that accomplish a mind-boggling range of tasks. It simply doesn't make sense to ignore those existing software modules when developing new programs. So instead, developers stitch together existing programs and then add a new innovative program to do whatever is new or different that the developer wants to accomplish. Sometimes this is done by drawing those modules together into a single program, and sometimes it is

effectively accomplished by a software program being designed to interact with other software on a given platform, such as a mobile phone. A simple example is a software application on a mobile phone making use of the existing program that tracks date and time. Any regulation needs to appreciate this fundamental design dynamic.

The Business Model for Supporting Innovation

e-Health innovators must live in the real world, and that real world has economic issues as well. The following are at least a few of the economic factors that need to be considered as we look to preserving and enhancing innovation in e-health.

- *Small companies*. Fortunately for everyone, health IT in particular is not a capital-intensive business, so small companies can engage in innovation and product development. This is good news, because it means that we can open up to a broader group the opportunity to develop innovative products. The bad news is that these companies tend to have less capital, and also tend to need more assistance from government regulators in understanding and navigating complex regulatory systems.

- *Venture capital and angel investment*. These small companies, because they often lack sufficient capital from the founders, need to seek out and obtain venture capital and angel investments. To do so, they need to be able to put together business plans that identify clearly the regulatory demands and the timetables associated with bringing their products to market. Thus, clarity in the regulatory pathway becomes extremely important.

- *Access to markets in a reasonable time.* There's no getting around that e-health is a business. While we all certainly have a focus on the patient and protecting the patient, healthcare doesn't work in this country if those engaged in it can't make a living. Thus, when determining the appropriate level of regulation, we need to keep in mind that the healthcare system cannot succeed in caring for patients if those working in it cannot operate a viable business and cannot bring their products to the market in a reasonable time.

- *Joint ventures and other deals between parts of the e-health ecosystem.* Because we are focused on technology networks, we need to appreciate at the outset that this will mean many different forms of business agreements among vendors supplying various components of those systems and their customers. These deals will impact the intended use of the various components of these systems. Regulators such as FDA focus on a product's intended use, so the regulatory framework will need to be flexible to accommodate these innovative joint ventures that will undoubtedly impact the intended use.

- *Reasonable and clear regulatory risk.* Above we talk about the need for a relatively clear regulatory pathway to market, but here we are focused on regulatory liabilities

associated with marketed products. For innovative businesses to attract capital, the regulatory risks need to be reasonable and clear. These regulatory risks include such post-market obligations as adverse event reporting and conducting recalls. In a networked environment, presently these obligations are anything but clear.

Ambiguity and the Entrepreneur

We have just explained above how clarity is often desirable in regulatory requirements. But it is important to be precise in where clarity is desirable. In fact, depending on the particular regulatory requirement, ambiguity can be either good or bad in its impact on innovation.

- Ambiguity can be good when it creates the opportunity for flexibility in compliance. It is okay, therefore, for many regulatory standards to be written in a general way. The quality system regulations are written at a high level, which in a sense makes them ambiguous with regard to what they require. But that form of ambiguity is good in that it allows flexibility and innovation on the part of the manufacturer in determining <u>how</u> it will come into compliance.
- Ambiguity tends to be bad when it relates to the scope of a regulatory requirement. Industry needs to know <u>whether</u> a particular requirement applies or not. Knowing whether a given piece of software is subject to FDA regulation can make a big difference in the cost and timeline associated with bringing that software to market, so the developer of that software needs a fairly clear and certain understanding of the scope of FDA regulation. Likewise, knowing the classification of a medical device is critical to determining what types of regulatory requirements apply. Ambiguity there is not helpful.

In the next section, we will identify specific areas of harmful ambiguity that need to be resolved so that entrepreneurs can make the business decisions they need to make.

Regulatory Requirements In Need Of a New Approach

In light of those identified best practices associated with bringing innovative products to the e-health market, we would like to connect the dots to highlight FDA regulatory areas in need of modernization. The following table is designed to connect those dots.

Innovation Factor	Regulatory Need
The need of investors to identify the cost and timelines associated with developing products in e-health	FDA needs to provide clarity and predictability with regard to the types of health IT the agency regulates, and for any software that is regulated, the classification.

This needs to extend to both FDA guidance, and FDA enforcement action. FDA needs to act in a way that is clear and predictable. Written FDA rules that the agency ignores destroy that predictability. The agency's words and deeds must match. |
| The accessibility of regulatory requirements to small business | FDA needs to engage in more outreach, both in the creation of useful guidance, but also in proactively educating developers, perhaps through more user-friendly web-based information but also face-to-face educational programs. |
| The development and design of hardware and software components to be used as parts of systems. | A systems approach to regulation that recognizes that each of these hardware and software components is to be used as part of a much bigger and interconnected but unknown network. More specifically, this means that regulators such as FDA, ONC and FCC need to apply a consistent and unified regulatory approach. |
| Component type intended uses, where the full design and intended use of the system is unknown. | FDA has always understood that a company might develop a scalpel with a simple intended use of cutting tissue, without knowing in what surgical procedures doctors might use the scalpel. FDA needs to adopt the same approach of clearing tool type claims when it comes to hardware and software that might be used by healthcare providers as a part of a system.

Further, generic hardware and software that might be marketed for use with medical devices need to be separately classified, to avoid being swept into a higher classification based on the FDA's accessory rule. |

Collaboration among all quarters in the development of e-health technologies, including relationships between vendors and their customers.	FDA needs to modernize its rules on off-label promotion to allow for closer collaboration among vendors, clinicians and other scientists. FDA needs to encourage collaboration as a business model, as opposed to limiting speech. Presently we are working on a proposal for a very different approach to the oversight of collaboration in the healthcare industry. Before presenting it to the federal government, we are distributing copies among many stakeholders in order to improve the proposal.
Practical ways to test low risk components in real world settings, for example through the release of beta software programs	Clarification around the investigational device exemption rules and how they apply to common forms of regulated health IT. We keep hearing people in the health IT ecosystem asking about how they can quickly and efficiently beta-test their products to identify weaknesses. While we believe the basic regulatory system already exists through which this can be done, the agency should clarify the requirements applicable to common testing practices within health IT and examine whether a further refined risk based approach is appropriate.
Frequent adoption of incremental improvements to software and hardware	Any premarket requirements need to be clearly defined with regard to any incremental improvements that trigger premarket requirements, and imposed with a risk-based approach. Only improvements that truly engender material risk should be subject to premarket requirements.
The key role of standalone software	FDA requirements for standalone software including application of the quality system regulation needs to be clarified, and more closely associated with risk-based tiers.
The decentralized and virtual relationship of developers	FDA needs to modernize its registration and listing requirements to reflect the fact that much software is developed virtually.
Software modularization	FDA needs to specify how the medical device classification rules are applied in the context of modularization. This issue boils down to the definition of a product to be classified. For classification purposes, under what circumstances may a particular module be viewed in isolation, when that module connects in some fashion to other software modules? When are the boundaries of the module sufficient to limit the extent of the classification.

The Need for a Holistic Approach to Regulation

Having multiple agencies overseeing a particular industry creates a substantial risk of throwing sand in the gears of innovation through duplicative and disjointed regulation. It can be very hard to serve two masters, let alone three.

In the case of e-health, the government didn't set out to have multiple agencies regulating product development, but through the convergence of the technology, FDA, ONC and FCC can all now find themselves regulating the same products.

To understand the present risk, we need to review a bit of history.

- Starting in 1934, Congress gave the FCC responsibility over telecommunications. So radio transmitters, and eventually television stations, telephones and a wide variety of communication tools were the bread-and-butter of the FCC, and not many of them would have had any direct health-related implications in the early going.
- In 1976, Congress charged FDA with regulating medical devices. In those days, medical devices were typically things that came in contact with the patient, or at least specimens taken from the patient, to aid in diagnosis or treatment of disease. At that time, not very many medical devices would have involved communications capabilities.
- In 2004, the President and later Congress created the ONC to coordinate nationwide efforts to implement and use health information technology and the electronic exchange of health information. Since the government wanted to invest in the adoption of health information technology, they also needed an agency to assure that the money was well spent. Thus, ONC took responsibility for defining what the government would pay for under the meaningful use provisions of the Health Information Technology for Economic and Clinical Health Act of 2009. In their early development, electronic health records (EHRs) and the like would not have directly connected with very many medical devices. Early EHRs tended simply to replace paper ones for storage of information.

All of that was well and good, but technology, as technology often does, evolved substantially since those laws were written.

Describing the change in technology as an evolution may be a bit misleading. The change has been more abrupt and radical than that. This change has been in the direction of connecting various technologies so that they can be more effective as a system than they are individually. Consider:

- Medical device hospital beds becoming electronic hubs into which all of the various patient monitors and therapeutic devices such as insulin pumps are connected and coordinated, and through which data are collected for deposit into the EHR.

- Medical devices being electronically networked together to directly coordinate the delivery of care, for example an oxygen monitoring device might tell an intravenous device to stop delivering narcotics if hypoxemia is detected.

- Enhancements coming from the EHR side, including middleware to directly connect the EHR to medical devices so the data might be transferred automatically.

- With the growth of EHRs and the collection of all that data, naturally attention is turning to clinical decision support software to analyze the data, so the software can help guide the clinician in decision-making. Indeed, clinical decision support software is the focus of the next round of meaningful use adoption.

- In the later part of the 20th century, professional care basically stopped when the patient went home. Now we are seeing a whole slew of technologies that allow for connected health. These include cell phone apps that might extract data from a pacemaker or defibrillator and send it back to a cardiologist, as well as home-based hubs to which all sorts of medical devices might be connected, and the data ultimately relayed to a doctor and into an EHR.

- Now laboratory testing is getting into the act. There is a cell phone app that basically uses the camera to measure color changes in a test strip for urinalysis. Further, laboratory testing itself is now connected through middleware directly to caregivers and EHRs.

- Medical imaging is not to be left out, with ultrasound and other clinical images being transmitted to tablets and cell phones that the doctor can use at the bedside, or even at the doctor's home. It seems reasonable to expect that these mobile monitors will get more sophisticated, and begin to apply computer aided diagnostic software to the images.

- Orthopedic implants can now have sensors attached that allow doctors to remotely monitor the wear and tear on the implant. All of this data then gets stored and trended in an EHR.

- Sensors can even be used preventatively, for example monitoring the environment for allergens and alerting a patient with asthma or his caregiver to potential danger. This data can all get stored and analyzed in the EHR.

All of this is exciting, but it points to the fact that technology of all sorts -- drugs, medical devices and health IT -- is being combined into powerful systems that improve the quality of care delivered.

And this change in technology has a profound impact on regulation. The three agencies – FDA, FCC and ONC – when created each had a clearly separate and distinct zone of responsibility. But now, as technology rushes together, the potential for regulatory overlap becomes real.

And so coordination among the three agencies is essential. This coordination needs to embrace the fact that the market is moving toward integrated systems of drugs, medical devices and health IT, and that

proper regulatory oversight needs to reflect that reality. Disjointed policymaking among the three agencies will not facilitate innovation, and will also not do an effective job at ensuring the safety and effectiveness of these health technology systems. We need a new approach.

One idea that has been floated is essentially treating health IT as a separate and distinct category of health technology and regulating it in its own silo. That would be a profoundly bad idea. As technology and the marketplace move toward convergence, this would be a terrible time for regulation to move toward divergence. If you look at the list of technologies above, deciding to somehow separate out the health IT portion of those systems for its own separate regulatory treatment apart from the drugs and devices that also comprise the systems, would likely lead to confusion, duplication and regulatory conflict.

We do not have a specific model to suggest at this juncture. Instead, we simply urge that the agencies start planning for the future when healthcare is dominated by systems of technology—drugs, devices, health IT—all working together to deliver care.

Conclusion

Innovation and patient well-being are complementary, not competing, policy objectives. Innovation offers great hope to enhance patient care through improving safety and effectiveness, improving quality and indeed even reducing cost. We believe there is actually very good alignment among regulators, patients and industry when it comes to our ultimate objectives. Products that don't work, or even worse hurt people, are not in anyone's best interest. But innovative products that solve a real public health need are in everyone's interest.

We believe that updating the current FDA regulatory system to addresses the unique characteristics of e-health is necessary. Such modernization will encourage the innovation needed to advance healthcare and ensure that patients will receive the benefits of some incredible breakthroughs in a timely way.