Invitation to Join
The mHealth Regulatory Coalition

Purpose of the Coalition

To develop a consensus among industry participants regarding the scope of what the Food & Drug Administration's (FDA) should and should not regulate in the area of mHealth technologies, and propose that approach to FDA for adoption.

Kickoff

We will hold a kick-off and informational meeting on Wednesday, July 8, 2010 beginning at 1:00 pm Eastern, in the offices of Epstein Becker & Green, P.C., Suite 700, 1227 25th Street, N.W., Washington, D.C. For those who cannot attend in person, we will provide a call in number.

Background

The $2.5T healthcare industry is poised to fully embrace the benefits and efficiencies of mobile cellular communications, products, and services. Much of today's care could be delivered with better quality and efficiency and less cost through the use of mobile technologies, all while improving the lives of patients through treatment in the comfort of their own homes and during their daily routines.

Unfortunately, the current uncertainty around the scope and impact of FDA regulatory requirements is impeding progress and adoption of these new technologies. The mHealth Regulatory Coalition is forming to focus on that challenge, and that challenge alone.

The Problem to be Addressed

The FDA is the primary regulatory agency responsible for protecting public health and safety through oversight of medical devices. The agency's regulatory authority extends into information technology integrated with medical device products, and generally wherever technology is used to diagnose or treat disease. In 1976 when the medical device laws were enacted, those laws were given a very broad scope, since no one could foresee all the advances that were to come. So FDA is left to interpret these very general laws as each new technology and intended use comes along.

Those laws create the present uncertainty. And that uncertainty has intensified in recent months as the overall regulation of health information technology, or HIT, has been debated on Capitol Hill and widely discussed in the media. Congressional leaders such as Senator Charles Grassley have formally requested information from both the FDA and HIT industry participants on how they intend to ensure the quality and safety of their products, as the healthcare system becomes increasingly reliant on digital technology and electronic health records. Further, FDA Center for Device and Radiological Health (CDRH) Director Dr. Jeffrey Shuren has testified the agency has the authority to regulate health information technologies. These developments have led companies interested in entering the mHealth market to pause as they consider the scope and nature of these potential hurdles.

In particular, mHealth technology innovators struggle with questions such as:

- ✓ What constitutes a medical claim FDA would regulate vs. general wellness and fitness claims the agency doesn't?
- ✓ What are medical device accessories FDA regulates vs. general purpose communication equipment the agency doesn't?
- ✓ What distinguishes mHealth-related software FDA regulates vs. unregulated software and equipment?
- ✓ Is software delivered as a service via the Internet regulated?
- ✓ Will wireless Quality of Service (QoS) in cellular networks for non-critical medical devices be regulated?

Anyone interested in reading more about these challenges can obtain a copy of Brad Thompson's upcoming book *FDA Regulation of mHealth***,** to be published by MobilHealthNews.com. That newsletter has been publishing Brad's articles on this topic throughout the last year, and this summer plans to release a free, downloadable book comprised of those articles.

The goal of the coalition will be to work with FDA to write a guidance document that addresses what gets regulated and what does not.

What is a Guidance Document?

FDA communicates its views on how advances in healthcare products are regulated primarily through the use of so-called "guidance documents". An important objective of guidance documents is "The Least Burdensome Approach", which means FDA must look for the least intrusive way to assure safety and effectiveness. An example of a guidance document is the 2002 Draft Guidance for Industry and FDA Staff- Radio-Frequency Wireless Technology in Medical Devices.

Unfortunately, though, there is no guidance document that addresses under what circumstances mHealth technology might be regulated, and the ambiguity surrounding mHealth regulation has kept many promising technologies on the sidelines.

To give mHealth companies and their investors the needed clarity around the technologies and uses FDA regulates, the Coalition will develop a guidance document answering the questions listed above. Once drafted, the coalition will formally propose that document to FDA for adoption. Just last month, Dr. Shuren invited the industry to propose guidance documents on important topics, indicating openness by the agency to such proposals.

The mHealth Regulatory Coalition: A Single Purpose with Many Members

The healthcare industry has an ample number of existing associations and advocacy groups that focus on industry segments and participants. While most if not all of these organizations contain an element of regulatory policy as part of their structure, the mHealth Regulatory Coalition is uniquely designed to

focus on mobile health technologies as its singular charter. The Coalition is intended to be a temporary organization-- lasting perhaps one year-- comprised of participants from existing trade associations and sponsor companies that have an interest in obtaining clear guidance from FDA on the scope of FDA regulation of mHealth technologies. Once FDA publishes a proposed guidance, the Coalition plans to dissolve.

Specific Objectives

- The coalition wishes to represent the entire spectrum of mHealth participants, including devices, network operations, handsets, and software. We want to include every participant to obtain maximum clarity from the guidance document. Unlike other organizations, this will not be a Zero Sum outcome with winners and losers.
- The guidance will be developed as a systemic model, so that each participant in the overall "system of systems" will clearly understand their roles and responsibilities.

Why is this important for the IT Industry?

The most current FDA Glossary of Computerized System and Software Development Terminology, released in 1995, lacks entries for words such as Internet, WiFi, mobile, cellular, and Bluetooth, but contains entries for BASIC, Assembler, baud, and batch processing. Advanced network technologies have not been formally recognized as part of the FDA lexicon, and they need to be for the industry to reach its potential to impact healthcare.

How does this benefit your company?

Members will have the ability to influence the development and ultimate outcome of the proposed guidance. As importantly, they will have the opportunity to work with other industry members and with FDA, which in itself provides insight into the dividing lines between regulated and unregulated products. The outcome is the goal, but participating in the process itself will give active participants a much clearer understanding and a time to market advantage.

Organizational Structure and Governance of the Coalition

A. Nature of the Coalition

This coalition will be temporary, existing just long enough to accomplish the purpose of drafting the proposed guidance document. Estimated time for completing the process is one year.

B. Association Membership

The coalition will be open to all associations with an interest in mHealth. We are inviting organizations such as the Continua Health Alliance, the American Telemedicine Association, the mHealth Initiative, HIMSS, the West Wireless Health Institute, the Wireless-Life Sciences Alliance, CTIA and others to join the Coalition. One representative of each member association may attend meetings.

C. Company Membership

The coalition will be open to individual companies involved in mHealth. This includes companies operating in the cell phone manufacturing, telecommunications, semiconductor, component, and medical device industries. Others, such as pharmaceutical manufacturers that are contemplating remote monitoring technologies for patient adherence, may also wish to join. Each company member may send one representative to the meetings.

D. Dues

Association membership will be free to qualifying nonprofit organizations. To cover the coalition's costs, each member company will be charged a monthly fee, based on the size of the company:

- Companies over one billion dollars in sales--$2,000 per month.
- Companies between $50 million and one billion dollars in sales—$1,000 per month.
- Companies under $50 million in sales--$300 per month.

Companies can leave at any time and discontinue their membership and dues. We will start the guidance development process and accruing dues when we reach a critical mass of member companies producing a combined funding of at least $12,000 per month.

E. Association Affairs and Governance

In most cases, we will operate by consensus on policy positions and activities to be undertaken by the Coalition. In any instance in which a vote is required, decision-making will be by 80% rule of all member institutions -- both association and company.

F. Operations

Dane Stout, a 26 year information technology industry executive, will serve as executive director of the coalition, managing its daily affairs. Brad Thompson will serve as general counsel, and his firm, EpsteinBeckerGreen, will assist with the development of the guidance document. Mr. Thompson is a respected Food & Drug attorney with experience in development of policy and interacting with the FDA.

Questions?
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