Dear Member at Large:

Should Health Care Information Technology Be Regulated?

Healthcare Information Technology (Healthcare IT) and associated regulation has sparked much controversy since the publication of the Institute of Medicine (IOM) report *Health IT and Patient Safety: Building Safer Systems for Better Care*. This report recognizes that Healthcare IT is part of a larger more complex sociotechnical system that may pose a risk to patient safety. The IOM report specifically notes that poor usability, workflow integration and complex data interfaces are threats to patient safety. Because of these potential patient safety risks, the report suggested that there is a need for regulatory oversight.

It is important to note that the Food and Drug Administration (FDA) has been regulating software medical devices for decades and medical device software on mobile phones for more than ten years. Three federal agencies – FDA, the Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communication Commission (FCC) – each have unique and complementary responsibilities in the Healthcare IT arena.

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve healthcare delivery. Mobile applications run on smart phones, tablets, and other mobile communication devices and are helping consumers lead healthier lives.

Sunquest believes it is important to adopt a balanced approach to Healthcare IT, one that supports continued innovation, assuring appropriate patient protections. Sunquest wants to partner with other vendors and the federal agencies to help author clear, predictable and reasonable regulations with Patient Safety representing the top requirement. The related impact to Product Development practices must also be explicitly dictated.

Sunquest recognizes the importance of implementing a balanced, transparent approach to regulation that supports and fosters the development and innovation of Healthcare IT solutions and innovative products while assuring appropriate patient protections. Federal Agencies’ regulatory oversight will seek to strike the right balance by providing a risk-based, focused approach to Healthcare IT most especially where its use presents a potential risk to patients if it does not work as intended.

Sunquest has worked with the FDA for several years and has had collaboration and transparency of process with Patient Safety improvement as the outcome. We are confident that as Healthcare IT matures, the regulatory agencies will continue to serve the medical device manufacturers and strive for continued transparency, interaction and collaboration, ensuring predictable and consistent recommendations, which are least burdensome to the manufacturer while protecting the patient.

We have partnered with other like-minded industry participants to form “The HIT Group,” which is committed to spreading related Patient-safety-centric development and supports the delivery of best practices at all times.

We are excited to highlight this coalition and make Patient Safety a certain outcome.

Thanks,
The HIT Group

Sunquest Informations Systems
(additional company names as requested)

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