Clinical Decision Support Coalition

November 18, 2013

VIA EMAIL

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Joe Pitts
Chairman
Subcommittee on Health
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Subcommittee on Health
United States House of Representatives
Washington, DC 20515

Re: CDS Coalition Comments on the SOFTWARE Act

Dear Chairman Upton, Ranking Member Waxman, Chairman Pitts and Ranking Member Pallone:

We appreciate the work this Committee is doing to clarify the regulatory requirements for Clinical Decision Support (CDS) Software.

CDS is a critical aspect of healthcare today and is increasingly important as medical data and individual patient information become more readily available electronically. Volumes of patient data are being generated from medical devices, health information systems and other sources every day. At the same

time, the digital body of medical knowledge is growing exponentially. CDS is the key to enabling effective use of all of this information for the benefit of the patient.

Clinical Decision Support Coalition

The CDS Coalition was formed to ensure that regulation of CDS software is narrowly tailored to promote innovation and avoid overregulation of low risk CDS. The CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare payers, hospitals and other providers, medical device manufacturers, trade groups, and members of the clinical community who represent patients and professional clinical societies.

Over the past year and a half, the Coalition has been developing a framework that appropriately balances patient safety with the need for innovation. Throughout this process, we have solicited feedback from various stakeholders and thought-leaders in the CDS community to ensure the Coalition's proposal reflects the interests of those who use and ultimately benefit from CDS -- patients and providers.

FDA's Approach to CDS

In September 2011, FDA organized a workshop to get input on how the agency should treat CDS. FDA provided a preliminary definition of CDS as any software that converts patient specific information into actionable results through the use of formulae, database look ups, or other forms of analysis. More recently, the Final Guidance on Mobile Medical Apps has provided additional insight into the types of CDS FDA regulates. FDA regulates high risk CDS such as Computer Aided Diagnosis (CADx) but does not regulate a Body Mass Index (BMI) calculator. The Agency announced back in 2011 that it had begun working on a new guidance document that would explain the regulation, or non-regulation, of CDS.

As this committee well knows, in the July 2012 Food Drug Administration Safety and Innovation Act (FDASIA), Congress directed FDA to work with the Office of National Coordinator for Health IT (ONC) and Federal Communications Commission (FCC) to develop a comprehensive approach to regulating health information technology. We understand that the three agencies have indeed been working on that comprehensive strategy, and plan to make their report to Congress early next year.

Because CDS fits squarely within health information technology, we understand that the agencies made the decision that the topic of CDS should be folded into the HIT strategy requested by Congress of the agencies. Consequently, FDA publicly stated that they plan to address their view of the optimal treatment of CDS in that report to Congress, as well as in a request for additional public comment that would be issued about the same time.

To inform the agencies' report to Congress, FDA, ONC and FCC organized and worked collaboratively with a rather substantial advisory committee during the summer of 2013. This advisory committee brought people from many different industries and personal expertise to carefully consider CDS and the optimal approach to regulatory treatment. That advisory committee produced a substantial report in September 2013, which laid out the foundation for the analysis now being done by the agencies. Among other things, the advisory committee noted that FDA should regulate high risk CDS. More broadly, the advisory committee provided a comprehensive taxonomy to explain how policymakers should determine which types are HIT should be considered for possible inclusion in the risk based regulatory framework. The committee also noted the growing importance of software used in systems, and the impact that has on the regulatory paradigm.

We recite all of this because it seems inconsistent for Congress to move forward with legislation to address the regulation of CDS in the fall of 2013 when Congress previously directed the agencies to develop a regulatory strategy for this area and make their report to Congress in early 2014. We understand that the FDA has been waiting to publish its thoughts on CDS so that it can, along with the other agencies, complete the analysis that Congress directed. We do not understand why Congress, after directing this work to be done, would proceed with the SOFTWARE bill now, before the FDASIA process is complete. Further, the draft legislation does not seem to embrace the recommendations of the FDASIA advisory committee, for example in the taxonomy of the HIT, in regulating high risk CDS or in addressing HIT systems.

We think it is important to first hear what the federal experts on health information technology recommend before proceeding to develop legislation. Indeed, we are not aware of any immediate impetus for this legislation, as FDA and the other federal regulators have been mostly hands-off when it comes to overseeing most forms of CDS. Absent some immediate crisis, we think it is more important to take the time necessary to get this right.

Comments on the SOFTWARE Act of 2013

We welcome the opportunity to meet with the committee staff and offer specific, constructive suggestions regarding how to strengthen the design and language of the bill. At this juncture, we would like to offer three high level observations regarding the present bill.

First, we agree with the FDASIA advisory committee that the future of health information technology is systems. The clear trend is toward using software to integrate health technology into coordinated and more effective care systems. The vast majority of electronic medical devices will be in some way

tethered to each other, and ultimately to the electronic health record. Much CDS will be woven directly into that data stream to achieve its maximum effectiveness.

The result of this drive toward connectedness and interoperability will mean that it will be difficult to separate out the components of those systems into the three discrete categories presented in the present bill. We believe that the bill both needs to recognize the interconnectedness of software into systems, but also needs to take a more nuanced approach to categorizing the individual components of those systems into risk-based buckets. Unfortunately, even three sizes will not fit all.

Second, the clinical software category needs to be substantially tightened up, and also needs to recognize variation in risk even within a single category of software. The FDASIA advisory committee in its discussion on taxonomy and safety noted the complex factors that go into defining the categories of software that merit oversight. In our opinion, the present draft of the bill removes from FDA regulation of several categories of software that do in fact require FDA regulation. Those include:

1. High risk CDS. To be clear, most CDS should be unregulated. But as noted by the FDASIA advisory committee, there are high risk software applications such as computer aided diagnosis that could create substantial risk and merit some FDA regulation. This is an example of technology where risk varies greatly within a general functionality, dependent on additional variables such as:
    a. The specific clinical application (there is a big difference between calculating a body mass index and calculating the appropriate dosage of chemotherapy), and
    b. The dependence the user experiences based, for example, on whether the software is designed to be transparent, revealing its underlying data and analysis, and the knowledge and ability of the user to double check the output of the software.

2. Most in vitro diagnostic analyzers and software that perform analysis of human specimens in order to diagnose or manage disease or other conditions, including infectious disease and cancer. Some of these tests are highly regulated by FDA.
3. Most of the elements of radiological imaging equipment that capture, store and display x-ray, ultrasound, CAT scan and MRI images.
4. Medical device data systems that take data from all types of medical devices, including class III medical devices, and store and display that data. These MDDS products are presently regulated by FDA in Class I. On the one hand, they are technologically simple, but on the other hand, if they fail, the effectiveness of the medical device to which they are attached is compromised.

When we formed our coalition to focus on CDS, we all agreed that a bedrock principle and shared value is to put the patient first. Indeed, that's why we have ended up as a coalition that includes industry, providers and patient representatives. We all share a common focus on the well-being of the patient. As much as we like to innovate freely and as much as we like to avoid FDA regulation, some regulation of high risk products is in fact necessary to provide assurance of patient safety. The proposed legislation's category of "clinical software" casts its net too widely, and therefore removes from FDA regulation some software and hardware that really should not be removed.

Third, the legislation is incomplete. As we have studied the wording of the legislation, it is apparent that by design the "clinical software" category is intentionally higher risk software than the "health software" category. We deduce this because the same fundamental language defining those categories as including software for the capture of health information can be found in each of the definitions. In other words, they start from the same core definition, but then the clinical software definition imposes additional limitations. For example, the clinical software definition includes the limitation that the

software cannot directly change the structure or function of the human body of man. It is also limited to software used by healthcare providers in a healthcare setting. Both of those limitations mean that software contained in the clinical software category will be of higher risk than the software contained in the health software category.

Logically, this must mean that the policy behind this legislation contemplates that the clinical software will be regulated to a greater degree than the health software. Why else would the two different categories exist? But the present draft contains no such distinction. We are concerned that the present draft proposes to leave both categories unregulated by FDA, but also adds a new section, section 524C, that expresses the sense of the Congress that the President and the Congress should work together to develop and enact legislation that establishes a risk-based category for software in these new definitions. Thus, this draft legislation includes the basic definitions, but not the regulatory oversight of products in those categories that the legislation itself suggests are needed.

The legislation as it is currently constructed creates new categories of health information technology, but then does not answer the question of how those categories should be regulated. We do not see the benefit of enacting the definitions without the new regulatory approach. We need to do more than just identify the categories – we need to come up with the appropriate regulatory oversight needed to protect the safety of Americans and at the same time assure continued innovation.

Conclusion

We applaud this Committee for working hard to ensure a future for health information technology that is both safe and innovative. We believe health information technology holds tremendous promise to improve the quality of care and reduce the cost. These are quite difficult and complex issues, and

achieving appropriate balance and design is no easy task. We stand ready to work collaboratively with the Committee to develop risk-based regulatory models that assure innovation and protect safety, while at the same time fitting the complexity of the underlying technology.

If you have any questions or would like to discuss any issues further, please do not hesitate to contact me.

Very truly yours,

Bradley Merrill Thompson
General Counsel of the Clinical Decision Support Coalition