CDS Coalition Position on the Software Act of 2013

The CDS Coalition deeply appreciates the interest among members of Congress in the appropriate regulatory treatment of software used in the diagnosis and treatment of patients. Such software, including clinical decision support software or CDS, offers a nearly unprecedented opportunity to improve the quality of care Americans receive.

Achieving the optimal level of regulation requires a critical balancing to ensure that on the one hand innovation is allowed to flourish, while on the other hand patients are protected. In the 2013 draft of the Software Act, the coalition believes that the act goes too far in deregulating CDS that may in fact require regulation to ensure the health and safety of patients.

Position

Our position is that FDA should regulate certain high risk CDS where the intended user is expected to be substantially dependent on the software. Thus we believe, in order to avoid putting patients at risk, the act should be modified to provide for FDA regulation of certain CDS as follows:

Definition: Clinical decision support software is software that recommends a specific diagnosis or treatment of a specific patient and is intended to run on general purpose computers, and is not intended to serve as an accessory to a medical device.

Scope of FDA Regulation of CDS: FDA should only regulate CDS if all of the following are true:

1. The intended use of the software provides a diagnosis of a serious or life threatening disease or other such condition, or directs a specific cure, mitigation, treatment, or prevention of such disease;
2. The intended user of the software is expected to be substantially dependent on the software for the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease. Substantial dependence means:
    a. the intended user is not trained or otherwise qualified to make the decision without the use of the software;
    b. the software does not disclose to the intended user, in sufficient detail for the intended user to make an informed, independent decision, the patient-specific information, the clinical content on which the analysis is based, the output, and the underlying clinical rationale for the output; or
    c. the intended use environment does not allow the user sufficient time to evaluate and consider the output before acting on that output; and
3. The software meets such other criteria as the Secretary shall specify by regulation to promote innovation while protecting patient safety.

Rationale

In proposing this language, we did not try to fit the language specifically in the existing draft of the Software Act because we understand the language of the act is likely to change significantly. At the November 19, 2013 hearing of the Health Subcommittee of the House Energy and Commerce Committee, on the basis of FDA testimony, there seemed to be agreement that there were unintended deregulatory consequences to the current draft. Indeed, on the basis of our own analysis of the language, it appears that the current draft would remove from FDA regulation a large number of software products traditionally regulated by FDA such as many forms of software used in diagnostic laboratory testing or with radiological images such as MRI and x-ray.

Given the mission and composition of the CDS Coalition, we are focused on the act's treatment of CDS. As an initial matter, we note that apparently all three categories of software under the act-- medical, clinical and health-- are intended to include certain types of CDS. More specifically,

1. In the definition of medical software, (ss)(1)(B), covers consumer use CDS that recommends clinical actions that involve over-the-counter remedies that might change the structure or function of the human body.
2. The definition of clinical software, (tt)(1), is expressly directed at CDS intended to aid a healthcare professional in a healthcare setting.
3. The definition of health software, (tt)(2), is in some ways the most significant because it is set up to capture essentially all other CDS that is not specifically encompassed in the other two definitions, which would include quite a lot of CDS.

As the act is currently designed, only medical software would be regulated by FDA. Clinical software and health software would not. Thus, very little CDS would be regulated by FDA because very little would meet the consumer CDS definition, and especially the criterion that the CDS must change the structure or function of the human body. The medical device definition, in contrast, is much broader than just articles that change the structure or function of the human body, and includes articles used in the diagnosis or treatment of disease or other conditions.

The 2013 draft of Software Act separates FDA-regulated from unregulated CDS based on distinctions that do not reflect the real risk factors. Instead, we would urge the sponsors of legislation to look carefully at the work done by the federal advisory committee established under section 618 of FDASIA. That advisory committee, which at the direction of Congress included 30 experts in a very wide range of fields implicated by health information technology, examined this issue in the summer of 2013 and came up with evidence-based, specific risk factors associated with CDS that differ from the ones the Software Act currently employs.

In the legislative language we propose, we have sought to identify some of the most critical factors that determine whether CDS ought to be regulated. Fundamentally, the need for regulation is directly proportionate to the dependence of the end-user on the software to make appropriate decisions. Further, the severity of the diseases and conditions that are the target of the software directly impact the risk of the software. But there are other factors as well that FDA should consider, which is why we further recommend that the issue be addressed by FDA in regulations that seek to balance the need for protecting patient safety with the concurrent need to encourage innovation.