AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

July 2, 2014

Leslie Kux, Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Assistant Commissioner Kux:

The American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, appreciates the opportunity to comment on the "Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report" request for comments published in the April 7, 2014 *Federal Register*.

As required by Section 618 of the *Food and Drug Administration Safety and Innovation Act* (FDASIA), in this regulation the FDA, in consultation with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communication Commission (FCC), developed the FDASIA Health IT Report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology , including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The AAFP is pleased to provide the following comments on this draft report.

The AAFP reviewed the report which at its core creates three categories of health IT:

1. Administrative health IT functions;
2. Health management health IT functions;
3. Medical device health IT functions which the FDA needs to regulate further.

One key issue is the determination of what will be categorized as medical device health IT functions. Clinical decision support (CDS) is a type of health IT function that potentially straddles between medical device and the health management health IT functions. In the preliminary FDASIA Report, the three agencies asks what types of CDS functionality should be subject to the health management health IT framework and which types should be the focus of FDA oversight. The AAFP believes any given piece of CDS software should involve a three-part test in order to be regulated by the FDA. We believe the FDA should determine whether the CDS is a medical device, whether it's risky enough to merit regulation (i.e. the risk of morbidity and mortality of clinical domain being supported or the role CDS plays in diagnosis or treatment) and, if the potential risk is substantial. To be regulated, the software must meet all three requirements and not fall under the auspicious of the practice of medicine, since the FDA does not have regulatory oversight over the practice of medicine.

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In the determination if CDS has substantial potential risk, the FDA should evaluate the transparency to the user, the competency of the intended user, and the sufficiency of time to evaluate the support by the user. A lack of transparency in regards to how the CDS arrived at the recommendation provided to the user increases its potential risk. The lower the competency of the intended user (e.g. consumer as compared to a physician) the higher the potential risk. If the user does not have sufficient time to evaluate the recommendation from the CDS and act, then it has a higher potential risk.

To help make the point, here are two of examples of CDS that would be toward the opposite ends of the spectrum:

- Our first example is CDS to assist with the application of intravenous tPA for acute stroke patients. In this example, the inherent risk of morbidity and mortality for the patient is high. The intended user of the CDS is a physician, so the competency of the user is high, which lowers the risk. The administration of tPA for appropriate stroke patients should be within minutes, which means the time to react to the CDS recommendation is constrained, which increases the potential risk. Finally, depending on how the CDS is implemented, the heuristic to determine applicability of tPA administration and the formula to calculate the dose could be hidden from the physician (intended user). In this case, oversight by FDA is needed. That oversight could be simply requiring a process of extensive testing. It might be the need to provide the intended user with transparency into the heuristics to easily and quickly determine how the recommendation was formulated.
- Our second example is CDS to assist with the determination of needed preventive screening. In this example, the inherent risk is very low. The intended user could be any health care professional and the risk would be low. With preventive screening there is ample time to contemplate the recommendation from the CDS. Finally, should the implementation of CDS show how the recommendation(s) were made and links to the supporting evidence, the transparency of the CDS would be high. This second example would not require any FDA oversight.

The AAFP urges the final FDASIA Health IT report to distinguish these risks that come from medical devices from those that come from the practice of medicine. The AAFP urges that the FDA and FDASIA working group provide ample guidance to the industry to limit the confusion as to what CDS requires oversight and which do not. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Steven E. Waldren, MD MS, Director, Alliance for eHealth Innovation at 1-800-274-2237, extension 4100 or swaldren@aafp.org.

Sincerely,

Jeffrey J. Cain, M.D., FAAFP
Board Chair