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Health IT is foundational to improving the quality, safety and affordability of healthcare.

Healthcare in our country is undergoing fundamental change to make it safer, better, and more efficient. Health IT is critical to these efforts. It provides access to current, accurate patient information, such as medication history, laboratory and x-ray results, and it supports the clinician in preventing errors, identifying gaps in care, and suggesting appropriate diagnostic and treatment paths.

Health IT does not replace physician judgment, but, rather, provides guidance and support. The ultimate responsibility for treatment decisions and clinical care will always rest with the treating clinician.

To ensure continued innovation and leverage the power of health IT, we need a new regulatory framework that is risk based and specific to health IT.

Today, the FDA has authority to regulate medical devices under amendments to the Food, Drug and Cosmetic Act adopted in 1976. The definition of medical device in the Act is broad and can be interpreted to include all health IT, including medical software.

The current regulatory approach for medical devices, however, is not well-suited for health IT.

Medical software is fundamentally different from medical devices in two important ways.

First, the safety of a medical device is almost entirely dependent upon how it is manufactured. The safety of health IT, on the other hand, hinges upon how it is designed and, perhaps more importantly, on how it is deployed. Thus, health IT safety cannot be ensured simply through good manufacturing practices.

Second, medical devices, *unlike health IT*, are directly involved in the treatment of a patient, with little if any opportunity for a clinician to intervene. The majority of medical software does not directly or independently act upon a patient, but rather provides data and guidance. The ability of a “learned intermediary” to utilize professional judgment distinguishes this technology from traditional medical devices.

We risk using a law enacted nearly half a century ago to regulate a rapidly changing and dynamic era of technology.

The Bipartisan Policy Center (BPC) last month released a report in response to The FDA Safety and Innovation Act that recommends dividing health IT into three categories:

The first and highest risk category includes technology linked to -- or used to operate -- a medical device. This technology would continue to be regulated by the FDA as a “medical device”.

The second category includes medical software that merely guides the physician, such as clinical decision support or Electronic Health Records (EHRs). This group would be subject to rigorous accreditation by an independent third-party, or perhaps the ONC.

Finally, the third category, non-clinical technology such as billing and scheduling software, would not be subject to regulatory oversight.

The BPC approach is flexible, protects patient safety, promotes innovation, and leverages existing quality and safety standards.

Health IT improves quality and patient safety, enables payment and delivery reform and promotes efficiency and lower cost. That is why it is so important that we regulate health IT thoughtfully to advance care and support innovation. That is why we need a new risk-based framework, such as that proposed by the BPC.