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AMERICAN MEDICAL
ASSOCIATION

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Bakul Patel
Senior Policy Advisor
United States Food and Drug Administration
Center for Devices and Radiological Health
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed
        Risk-Based Regulatory Framework [Docket No. FDA-2014-N-0339]

Dear Mr. Patel:

On behalf of our physician and medical student members, the American Medical Association (AMA)
appreciates the opportunity to provide comments on the Food and Drug Administration Safety and
Innovation Act (FDASIA) Health IT Report: Proposed Risk-Based Regulatory Framework (Proposed
Framework). The AMA applauds the collaboration of the Food and Drug Administration (FDA), the
Federal Communications Commission (FCC), and the Department of Health & Human Services' Office
of the National Coordinator for Health Information Technology (ONC) on developing the broad
parameters of the Proposed Framework. We strongly support the proposal to establish a risk-based
framework for oversight and regulation of health information technology (health IT) and the proposed
clarification of the FDA's existing risk-based approach to direct regulation of the smaller universe of
health IT products that the FDA determines are medical devices. The AMA also supports current efforts
to establish a health IT Safety Center to monitor safety problems with electronic health records (EHRs)
and other health IT.

While the AMA appreciates the various provisions outlined in the Proposed Framework, we believe that
the development and implementation of a patient safety infrastructure is urgently needed. The current
authorities of the FDA, FCC, and ONC do not provide a comprehensive and integrated approach to
existing safety concerns or those that will continue to evolve and emerge as technological innovations
rapidly progress. The AMA is committed to seeing widespread deployment of well-developed and safe
technology in health care. While health IT has the potential to help improve patient safety, it can also
cause unintended harm, as noted by the Institute of Medicine (IOM) and other stakeholders. We therefore
support quick but informed action to ensure the safe use of these products. The following comprises the
AMA's initial set of comments and recommendations on the Proposed Framework.

PROPOSED RISK-BASED FRAMEWORK

The AMA strongly agrees that the Proposed Framework should focus on health IT functionality and should not be organized based on platform or product name/description. Given the rapid rate of technological change and innovation in this space, the alternative approach would be very challenging to organize and update. In addition, the AMA supports the recommendation to retain the FDA's current statutory scope of authority to only directly regulate products that the agency determines meet the statutory definition of a medical device, with the caveat that it will not directly regulate health management information technology even if it meets the statutory definition of a device. We support this approach because devices within the purview of FDA regulation should have a higher level of associated risk, and believe that FDA resources should not be diverted or diluted to products that do not pose real safety concerns. In addition, FDA oversight and regulation could slow innovation in this space.

With respect to the proposed three categories of health IT functionality, i.e., 1) administrative health IT functions; 2) health management health IT functions; and 3) medical device health IT functions, the AMA agrees that these categories generally outline important distinctions in risk that warrant different levels of oversight. However, we caution that identifying the appropriate category for a specific functionality is challenging and will require input from various stakeholders as well as revisions over time. More clarification is needed with respect to how to clearly divide the three levels and what factors should be considered relevant when assigning different health IT functionalities. Initially, we recommend that these categories be flexible and adoptable so that the framework can accommodate new technologies and other innovations in health care. As new tools emerge, stakeholders should be consulted on what level of risk is or is not appropriate.

PROPOSED FOUR PRIORITY AREAS

The overarching proposal limits the FDA's enforcement discretion, with the exception of medical devices, and utilizes a framework that focuses on four priority areas: 1) promote the use of quality management principles; 2) identify, develop, and adopt standards and best practices; 3) leverage conformity assessment tools; and 4) create an environment of learning and continual improvement. We generally agree that the first three areas are supported by minimal regulation to promote innovation while enhancing overall patient protections. The AMA strongly recommends, however, greater specificity concerning the fourth priority area—a recommendation to establish an infrastructure of engaged stakeholders to support learning and continual improvement. **While considerable flexibility should be given to innovate, a well-defined and fully funded set of mechanisms and policies must be in place to: 1) actively monitor for adverse events; 2) receive information concerning adverse events; and 3) to avert or mitigate adverse events.**

The AMA recommends the Agencies consider the experience of patients, consumers, and health care providers in reporting adverse events and harm. Yet, the current proposed priority areas and steps do not provide a "one-stop shopping" approach to the identification of adverse events from these key participants. In addition, the Proposed Framework lacks recommendations for active sentinel capabilities broadly in the area of health IT. The Proposed Framework primarily hinges on the establishment of the health IT Safety Center as a convener. The Safety Center does not, however, elucidate how it will build upon and improve the evidence-based foundation for health IT safety by analyzing the best available data and evidence.

The AMA appreciates consideration of existing safety models, such as the National Transportation Safety Board and the Aviation Safety Information Analysis and Sharing (ASIAS) organization, in identifying, averting, or mitigating adverse events, as well as models within health care, such as the Agency for Healthcare Research and Quality's (AHRQ) patient safety organizations (PSOs) and the Veteran Health Administration's HIT Safety Center. We feel a collaborative government and industry initiative on data sharing and analysis to discover safety concerns before incidents occur is a strong framework to build upon. We therefore believe the ASIAS model warrants further study and additional outreach to trusted stakeholders with experience in this area may be necessary.

We also appreciate reliance on existing FDA infrastructure for safety issues for FDA regulated products. However, the FDA's Manufacturer and User Facility Device Experience (MAUDE) are very limited in scope—FDA regulated devices—and is passive. The issue and challenges comes with identifying more active monitoring through sentinel type strategies of all health IT, not just those that are FDA regulated devices. Accordingly, the AMA strongly recommends the ongoing use of PSOs and a centralized entity to receive adverse event reporting.

HEALTH IT SAFETY CENTER

Structure

The AMA strongly recommends that there be one entity for consumer and provider reporting for patient safety issues stemming from health IT, including medical devices regulated by the FDA. Typically, consumers will not be able to differentiate if a safety issue stems from a device or health management functionality. A single entity would therefore streamline the process for reporting safety concerns. We recommend continued use of the MAUDE/adverse reporting if individuals are aware of these reporting options, but, in general, individuals should be directed to a single entity to avoid confusion. This reporting entity (possibly a PSO or the Safety Center) would be a gatekeeper that determines what issues implicate devices and then should be directed to the FDA. The reporting entity would also determine what complaints are related to non-device products and do not go to the FDA for consideration. Importantly, both of these types of safety concerns still need to be assessed and require active review and monitoring. As currently drafted, the report appears to take a bifurcated approach—the Safety Center talks broadly about building upon health IT safety evidence, while the FDA surveillance process only refers to devices. We would encourage that many of the same device surveillance tools be used for non-devices. In addition, the entity reviewing these non-device products needs to have expertise both in technology and patient safety.

The AMA also strongly supports the use of PSOs, which are the mechanism under federal law to ensure that information about errors are legally protected and confidential, including the identity of the reporter, to encourage and promote the reporting of errors that could negatively impact patient safety. Yet, we recognize that PSOs are typically focused on clinical events, not technology events. Therefore, this reporting source may have limitations if used in the health IT environment without other expertise. We also support ONC's recommendation to work towards incorporating the AHRQ common format into certified EHRs to make it easier for physicians and other health care providers to report patient safety events to PSOs. We note that careful attention needs to be paid to ensure that the reporting of patient safety events to PSOs via certified EHRs occurs in a manner that maintains the confidentiality and legal protections of the information reported.

Governance

With respect to governance, the AMA agrees that the health IT Safety Center should be multi-stakeholder and include several practicing physicians who use and understand EHRs and other health IT. The Safety Center should focus on high-value issues promoting innovation and build upon an increasingly evidence-based foundation. There are a number of benefits and challenges associated with a Patient Safety Center that is a governmental body. We have outlined these concerns below and encourage further discussion on each of the benefits and drawbacks.

The benefits include:

- More formal oversight of the industry—the Safety Center will generally be regulating safety events post-market where real harm can now occur to patients, customers, and physicians. In addition, more formal oversight at this stage is less likely to stifle innovation or new products compared to pre-market regulation;

    - Greater stakeholder involvement by engaging with relevant agency officials;
    - Greater authority as seen by the public and other stakeholders; and
    - Similarity to other markets (transportation, airlines, etc.) that typically employ some form of government oversight.

The drawbacks of a government run Safety Center include:

    - Lack of flexibility, which is needed for an area that is rapidly evolving;
    - Lengthy implementation to comply with notice and comment rulemaking despite the pressing need for a Safety Center; and
    - Concerns with funding sources.

Engagement with the private sector

The Safety Center must also implement a mechanism to consistently engage with the private sector to facilitate the listing of health IT products and product information. We support the proposal that vendors be required to identify products which pose "at least some risk," though it is unclear who would define risk levels or how to appropriately present such information. The AMA would discourage a process that relied solely on the vendor's for this determination. Such product information should be communicated broadly, possibly through a federal website.

Our understanding is that the private sector has not fully engaged on these activities itself in part due to the constraints of the EHR Meaningful Use (MU) and certification program. The AMA agrees that these requirements are overly rigid, complex, and time-consuming. Vendors are focused on meeting certification and are unable to divert resources elsewhere. Scaling back certification and the MU requirements, on both vendors and providers, could encourage greater private sector activity in the Safety Center and other safety initiatives.

Education

A key and growing policy priority is to educate physicians on how to identify and report health IT patient safety events. This will build physician understanding of reporting adverse events to advance the development of health IT systems and ensure safer performance. Knowing that they are contributing to health IT safety solutions might also serve as a catalyst for physicians to participate in PSOs and voluntary reporting. Entities that receive the reported data can work to identify common safety concerns and best practices to minimize risk. In addition, physician involvement in the Safety Center will further ensure that education and best practices are disseminated and incorporated into care practices.

To disseminate key information, the Safety Center should broadly provide comparative user experiences, which should look at both traditional and non-traditional methods of disseminating this information. Traditional methods include PSOs that are already tasked with identifying trends in safety issues and engaging with the provider community to educate and disseminate best practices. Non-traditional sources include deploying technology to identify user experiences and potential safety concerns. Such innovative sources could include "crowd sourcing" tools being used for big data and applications used to pick up on industry trends from the users themselves. There are specific examples of this approach such as Flu Tracker where patterns emerge that trigger use of traditional investigational and survey methods to ascertain whether systematic failures and adverse events are, in fact, occurring.

Overall, we are very concerned that there is a consistent lack of focus on the ambulatory setting. While research has been done on health IT systems and patient safety in inpatient settings, there has been limited research on the impact of EHRs and other technology on patient safety in the ambulatory setting. AMA's report titled, *Research in Ambulatory Patient Safety 2000–2010: A 10-year review* made the following recommendation:

> Further research should be supported on the role of information technology to improve ambulatory patient safety, including computerized physician order entry and electronic medical records. These technologies should be evaluated within the larger contexts where they would be implemented and used:
>
> - The processes within which the technology will be embedded (e.g., the medication process).
> - The systems within which the technology will be used (e.g., the physician office practice).

We therefore encourage greater research and education on the impact of health IT systems in ambulatory and other care settings.
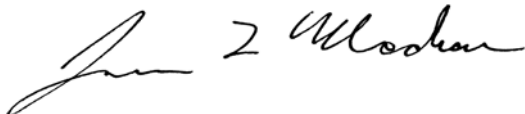
ADDITIONAL RECOMMENDATIONS

The AMA has the following additional comments concerning the various recommendations and options identified in the Proposed Framework, the FDA-convened meeting, and the ONC Safety Workgroup discussions:

- The AMA agrees that some of the most challenging policy questions concern clinical decision support (CDS) because most systems would not be regulated by FDA. While many agreed during the FDA-convened workshop that the presence of "competent" human intervention excluded these tools from regulatory oversight, we urge that the agencies continue to consider the potential impact of these tools. There remain questions whether the learned intermediary concept extends to the consumer space. While members of the FDAISA workgroup weighed in, further research, monitoring, and analysis on this issue is needed.
- Entities need to identify differences between product design safety issues versus site specific implementation problems, e.g., problems with the actual software/hardware/technology vs. customer-specific implementation decisions/customization/ local compliance decisions/ health IT support staff (or lack thereof).
- EHRs alone are not equal to health IT. EHRs are a part of health IT but a health IT Safety Center and Proposed Framework need to have a broader scope to include health IT more generally.
- There is a tendency to ignore the mobile health app space despite accumulating evidence that many consumer and even physician targeted apps are at best misleading and at worst dangerous. Although there were FDA panels dealing with the need for standards and for conformance testing, no conclusions were reached. We believe there needs to be a robust mechanism in place to start addressing mobile health apps. The agencies should further explore partnerships or collaborations with technology vendors as additional sources of insight into that aspect of the market.

The AMA stands ready to continue to offer advice and suggestions on ways to improve the Proposed Framework and the Safety Center. The course that is charted now will have a significant impact on the future state of health IT. We encourage FDA, FCC, and ONC to consider these comments and work with physicians to improve EHRs and other technologies. If we can be of any further assistance, please contact Margaret Garikes at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD