



May 15, 2013

The Honorable John Thune  
United States Senator  
511 Dirksen Senate Office Building  
Washington, DC 20515

The Honorable Richard Burr  
United States Senator  
217 Russell Senate Office Building  
Washington, DC 20510

The Honorable Lamar Alexander  
United States Senator  
455 Dirksen Senate Office Building  
Washington, DC 20515

The Honorable Tom Coburn  
United States Senator  
172 Russell Senate Office Building  
Washington, DC 20510

The Honorable Pat Roberts  
United States Senator  
109 Hart Senate Office Building  
Washington, DC 20510

The Honorable Mike Enzi  
United States Senator  
379A Russell Senate Office Building  
Washington, DC 20510

Dear Senators:

Thank you for the excellent, thoughtful, and thorough work that went into the recent Reboot Report on strategies needed to successfully adopt Health IT. The purpose of this brief comment is to raise awareness about some specific needs of the healthcare community that should be addressed as part of the Reboot strategy.

On behalf of the AAMI membership, I am writing solely to bring to your attention an additional resource that we hope you will use as you refine and move forward with your recommendations. That resource is a significant report that synthesizes the views of 275 multi-disciplinary leaders across healthcare who participated in an October 2012 summit on interoperability co-convened by AAMI and the FDA. The subject of the summit was *interoperability in and around medical devices*, with an emphasis on patient safety. Some of the issues you raise in the Reboot Report were discussed by the multi-disciplinary attendees at that event. For this reason, we wanted to be sure that your team has access to the post-summit report, which includes information we believe will help inform your work: [http://www.aami.org/interoperability/Interoperability\\_Summit\\_publication.pdf](http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf)

This report synthesizes two days of moderated discussion and the priorities that the 275 attendees together set for a safer path forward with medical device interoperability. The priorities are divided into seven themes, and each theme is organized by challenges, priority issues, and

suggested organizations and agencies to take ownership of resolving the issues. The seven themes are:

- 1) Standardize to achieve success.
- 2) Align incentives, expectations, roles and responsibilities.
- 3) Drive patient safety with a systems approach to design and implementation.
- 4) Focus on human behavior first.
- 5) Improve regulatory clarity.
- 6) Streamline critical workflow to improve return on investment.
- 7) Remove barriers with shared, continuous learning.

Here are two of many examples that relate specifically to content in the Reboot Report. These two examples fall under Theme 2 (align incentives, expectations, roles and responsibilities):

Challenge	Priority Action	Accountability
Misaligned incentives across the board for improving interoperability.	Align interoperability requirements with Stage 3 of the incentive requirements. Require that interoperable systems that provide safety assurances are eligible for reimbursement by the Centers for Medicare & Medicaid Services (CMS).	ONC, CMS, and others
Confusion increases risk: who “owns” the system, who is the systems integrator, and who is responsible for interoperability testing, safety, maintenance, and liability. Unless an obvious systems integrator emerges, healthcare delivery organizations are systems integrators by default—whether or not they know it.	Clarify who is responsible for interoperable systems throughout their lifecycles.	FDA, ONC, TJC, CMS, State regulators, and many others

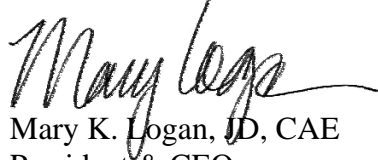
The report is available for unlimited use for non-profit purposes. We hope you will do so.

AAMI is a diverse non-profit community of 7,000 professionals from many domains in healthcare, all experts on healthcare technology, especially medical devices. AAMI is an ANSI-accredited standards development organization, and its community of industry, regulators (e.g., FDA, CMS), clinicians, researchers and independent experts together develop standards, technical information reports, and related information about medical devices. Its emphasis is on the safety and performance of medical devices. AAMI is *not* an advocacy organization. It is a neutral organization that highly values its neutrality and “honest broker” reputation. For this reason, we are not writing to comment specifically on the Reboot Report itself or to respond to the specific questions posed to the healthcare community.

May 15, 2013

Thank you again for focusing on a goal that is critical to us: improving patient safety. We believe patient safety is at risk unless the important issues raised in the summit report are addressed with intentionality.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Logan", with a long horizontal flourish extending to the right.

Mary K. Logan, MD, CAE  
President & CEO  
AAMI

CC: Honorable Kathleen Sebelius, Secretary Department of Health and Human Services

CC: Ms. Marilyn Tavvener, Acting Administrator, Centers for Medicare & Medicaid Services

CC: Dr. Farzad Mostashari, National Coordinator, Office of the National Coordinator for Health IT