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March 10, 2010

The Honorable Charles E. Grassley
219 Dirksen Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Grassley:

The Healthcare Information and Management Systems Society (HIMSS) represents individuals and organizations unified around the cause of improving the quality, cost effectiveness and safety of, and access to, healthcare through the best use of information technology (IT) and management systems. We share your commitment to improving the healthcare experience for all patients.

HIMSS has a goal of improving patient safety and quality of care such that, by the year 2014, 75 percent of all healthcare information systems are using optimized safety and quality improvement tools – a significant step forward from the recent past. HIMSS promotes integrating patient safety tools and practices into all healthcare organizations, clinicians, patients and community members. The benefits of these practices are improved healthcare quality, communication between patients and caregivers, patient education, and patient services. Good patient safety practices and strategies can also help make organizations and processes more accessible, efficient and cost-effective.

To bring attention to best practices in patient safety, HIMSS works in partnership with the [American Society for Quality](#) to showcase real-world examples and personal stories about how organizations have leveraged health IT to improve patient safety. The information gathered in these "[Stories of Success](#)"¹ case studies will help all healthcare stakeholders understand how health IT can be used as a tool to improve patient safety and quality.

In response to your letter of February 24, 2010, we are eager to assist in any way we can. You referenced the 1997 article in the *Journal of the American Medical Informatics Association*, "Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems." As background information, the Center for Healthcare Information Management (CHIM) was dissolved and its corporate members became part of HIMSS in 2001. The article also references the Computer-based Patient Record Institute (CPRI).

CPRI was dissolved in 2002 and its individual and corporate members also became part of HIMSS.

Today, HIMSS is a cause-focused [membership organization](#)² of over 27,000 individual members, more than 400 corporate members, and more than 50 non-profit groups across a wide spectrum of healthcare stakeholders. In the 1990s, at the time of the article's publication, CHIM met the definition of a trade association - safeguarding and promoting members' interests. In 2010, HIMSS does not meet that definition. Approximately 10% of our broad corporate constituency belongs to the [Electronic Health Records \(EHR\) Association](#), an independent unit within HIMSS operating as a trade association since 2004. All stakeholders within HIMSS share an outcomes-oriented vision to improve healthcare through the best use of IT and management systems.

With respect to your specific questions from the HIMSS point of view:

1) *What is HIMSS' position on the issues and recommendations set forth in the JAMIA article?*

ANSWER: While we would hesitate to establish a position on recommendations published 13 years ago, as a cause-focused Society we share the authors' commitment to improving patient safety through the best use of health IT and management systems.

a. One of the recommendations addressed FDA's regulatory role. What is HIMSS' position on FDA's current role in the regulation of HIT products? Would you support providing FDA with more authority in this area? Is there another agency that should be given authority to regulate the safety of HIT products?

ANSWER: Your questions regarding the FDA's role are very relevant and important. On February 25, 2010, Jeffrey Shuren, FDA's Director for Devices and Radiological Health [stated](#), ". . .HIT software is a medical device. . .to date, FDA has largely refrained from enforcing our regulatory requirements with respect to HIT devices."³ While as of this writing, HIMSS does not have an existing position, such new comments by Dr. Shuren present opportunities for HIMSS to consider a position on this topic.

b. Another recommendation called for the adoption of a code of good business practices by health care information system vendors and software producers. According to the JAMIA article, "the health care information system industry, through the Center for Healthcare Information Management (CHIM), is in the process of refining its code of good business practices." It has

been over a dozen years since the publication of the JAMIA article.

- i. What is the status of those codes? Please describe how they were developed and when they were adopted, including any updates and modifications.*
- ii. Are the codes publicly available on HIMSS' website? If so, please provide the web address. If not, please provide the Committee with a copy and explain why the codes are not public.*

ANSWER: CHIM's work on the project referenced above ended before CHIM was dissolved in 2001. In 2004, HIMSS developed a [professional practice standard](#) on business ethics⁴ for professionals in healthcare. In addition, in 2007 the HIMSS Board of Directors approved our [Business Conduct Guidelines](#)⁵.

HIMSS believes that all engaged in a transaction – providers, vendors, and consultants – must be truthful and forthcoming in regards to product/company representations and acknowledge conflicts of interest. Our professional practice standard functions as a reference for healthcare information and management systems professionals for conduct that constitutes the highest levels of ethical business practices. Our business conduct guidelines promote ethical and socially responsible conduct in regards to five areas: demonstrations, site visits, and education; conferences; consulting relationships; sales & promotional meetings; charitable donations; and gifts.

2) The JAMIA article discussed the evaluation of complex, interconnected systems, noting that "A software product may work well in isolation but fail when integrated with other software products or with unsupported network interfaces." The authors also stated that "Because each clinical site combines different software products in different combinations, a universal evaluation of whether or not a given product will function safely when embedded in a clinical environment is impractical," and suggested the establishment of local and regional Software Oversight Committees (SOC).

- a. How many SOCs or comparable oversight entities have been established since the publication of this article?*
- b. Who selects the members?*
- c. Who funds them?*
- d. Has there been an evaluation of the effectiveness of SOCs or comparable oversight entities in reviewing and monitoring complex HIT systems and their subsequent versions?*
- e. Do the SOCs or comparable oversight entities evaluate the health information technologies being developed and*

*implemented to ensure that they are safe and effective for use?
If not, why not and what entity(ies) should be carrying out that
function?*

ANSWER: As “SOC” is not a term with which we are familiar, we assume that the authors’ recommendations pertaining to their specific concept were not implemented. However, the intent of their comments has been, and continues to be, actively addressed by many committed professionals and organizations. Since 1997, much has been accomplished to solve the problems noted by the authors above, such as: *“A software product may work well in isolation but fail when integrated with other software products or with unsupported network interfaces.”*

In 1997, HIMSS and RSNA created “[IHE](#)”⁶ – a global, non-profit, private-sector initiative that publishes frameworks in the public domain for passing vital health information seamlessly and securely – from application to application, system to system, and setting to setting across multiple healthcare enterprises. IHE enables implementation of established standards to enable exchange of clinical information within and across healthcare enterprises to address key clinical use cases (maternal health, wounded warriors, chronic care, public health, etc).

In the ensuing 13 years, private industry and non-profit associations such as HIMSS have invested over \$10 million to make IHE a reality with no funding from the federal government. With a minimal investment of federal funding, the vision of IHE could become a reality much quicker and help meet the safety goals that you and Congress are pursuing.

In 1999, IHE added an independent, monitored, vendor-neutral setting to execute coordination, tools, and opportunities for face-to-face interoperability testing. This process, known as a “[Connectathon](#),” gives vendors of health IT systems implementing IHE integration capabilities the opportunity to test their work to ensure it functions as intended.

In the early 2000s, to support the needs of local and regional initiatives worldwide, the Connectathon process expanded to enable other capabilities to be tested along with IHE profiles. For example, at the [IHE North America Connectathon](#), [HITSP](#) (the Healthcare Information Technology Standards Panel) and [CORE](#) (the Committee on Operating Rules for Information Exchange within CAQH) specifications are also tested.

IHE Connectathon participants test their implementations of IHE profiles and other standards-based specifications with corresponding systems from industry peers, exchanging information and performing all of the transactions required for the roles and functions they have selected. Subsequent to

successful testing of their healthcare IT systems, the participating organizations may publish integration statements to declare to purchasers the proven interoperability capabilities of their products.

In 2010, more than 104 organizations tested over 150 healthcare IT systems at the weeklong testing event in Chicago.

3) What is HIMSS' position on requiring manufacturers of EHRs and other HIT products in clinical use to report safety issues related to the use of those products to a regulatory entity?

4) What is HIMSS' position on requiring manufacturers of EHRs and other HIT products in clinical use to notify other health care clients or potential health care clients of the safety problems that were reported to them?

ANSWER: While HIMSS has no position on these specific questions, we are committed to improving patient safety through the prevention of medical errors, and the mitigation of harm when errors do occur. As such, in 2003 our Board of Directors adopted a position statement on [medical errors reporting](#).⁷

HIMSS has long encouraged the industry to focus on error prevention. One element in learning how to deliver higher quality care can stem from careful analysis of past errors. However, as we strongly believe in the prevention of errors, HIMSS supports the use of best practices which have been proposed by such organizations as the National Quality Forum, the American Hospital Association, the Agency for Healthcare Research & Quality, the Centers for Medicare & Medicaid Services, and the Institute for Healthcare Improvement. Some are currently utilized by [The Joint Commission's Core Measures](#) system to document the adherence to best practices as reinforced by evidence-based analysis of good quality care. Such resources highlight opportunities of where healthcare organizations may become more compliant with broadly-accepted best practices. The clinical community has well-documented that adherence to best practice improves the overall quality of care.

As part of a more complete framework designed to improve the overall effectiveness of the U.S. healthcare system, HIMSS has encouraged the adoption of technologies such as bar-coding of patients, their medications, and their providers combined with rules-based computerized practitioner order entry systems supporting best practice. Such technologies can help reduce the incidence of medication-related errors in the institution.⁸

HIMSS supports and participates in health IT standards development and harmonization activities to enforce patient safety through HITSP and [ISO/TC 215 Health Informatics](#) (International Standards Organization's Technical Committee 215). These standards activities are addressing issues to ensure

the safety and effectiveness of medical devices, privacy/security for EHR systems, quality, public health case reporting, population health and pharmaceutical products.

HIMSS is aware of unintended consequences that can occur from use of IT in healthcare – known as “e-iatrogenesis”. For example, a member of the HIMSS senior staff was a contributing author to the 2008 Joint Commission [Sentinel Event Alert #42](#)⁹. This Alert suggests actions to help prevent patient harm related to the implementation and use of health IT and converging technologies. These recommendations highlight the importance of ensuring the proper installation of systems, and sufficiently training those caregivers using the systems.

Our [“Medical Devices Quick Start Guide”](#)¹⁰ provides points of reference and consideration for the purchase and implementation of a clinical documentation system that integrates with networked medical device systems. Specifically, a table within the Guide provides lessons learned and best practices for mitigating the human factors that can result in e-iatrogenesis.

In addition, HIMSS partnered with NEMA (the National Electrical Manufacturers Association) to develop the Manufacturer Disclosure Statement for Medical Device Security ([MDS²](#)) form¹¹. The intent of the MDS² is to supply healthcare providers with important information that can assist them in assessing the security vulnerabilities and risks associated with electronic Protected Health Information (ePHI) stored or transmitted by medical devices. The MDS² allows device manufacturers to provide information regarding the security-related features of the medical devices they manufacture a standardized manner.

We appreciate this opportunity to answer your questions and hope to be of continued assistance. Additional information that might be of interest to you can be found on the HIMSS website, including our Patient Safety & Quality Improvement [landing page](#)¹². If you have any questions or require additional information, please contact me or Carla Smith, HIMSS Executive Vice President, at csmith@himss.org or 734-477-0860.

Sincerely,



H. Stephen Lieber, CAE
President and CEO

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- ¹ HIMSS/ASQ Stories of Success. January 2010. <http://www.himss.org/storiesofsuccess/>
- ² Information about HIMSS's membership categories can be found at <http://www.himss.org/ASP/membershipHome.asp>
- ³ Testimony by Dr. Jeffrey Shuren to the HIT Policy Committee. February, 2010. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910717_0_0_18/3Shuren_Testimony022510.pdf
- ⁴ HIMSS Professional Practice Standard on Business Ethics. September 2004. www.himss.org/asp/ContentRedirector.asp?ContentId=58787&type=HIMSSNewsItem
- ⁵ HIMSS Business Conduct Guidelines. December 2007. http://www.himss.org/ASP/about_BusinessConduct.asp
- ⁶ IHE information can be found on both the HIMSS (http://www.himss.org/asp/topics_ihe.asp) and the IHE (<http://www.ihe.net/>) websites
- ⁷ HIMSS Position on Medical Errors Reporting. April 2003. <http://www.himss.org/content/files/2003MedErrorsPositionStatement.pdf>
- ⁸ Ibid.
- ⁹ The Joint Commission's Sentinel Alert #42. December 2008. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.htmf
- ¹⁰ HIMSS Medical Device Quick Start Guide. June 2009. <http://www.himss.org/content/files/PSQO/MedDevPtSafetyQuickStartGuide.pdf>
- ¹¹ HIMSS/NEMA Manufacturer Disclosure Statement for Medical Device Security form. September, 2008. http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=99
- ¹² HIMSS Patient Safety and Quality Improvement Landing Page. Updated February 2010. http://www.himss.org/ASP/topics_patientSafety.asp