June 4, 2013

The Honorable John Thune	The Honorable Richard Burr
United States Senator	United States Senator
511 Dirksen Senate Office Building	217 Russell Senate Office Building
Washington, DC 20515	Washington, DC 20510
The Honorable Lamar Alexander	The Honorable Tom Coburn
United States Senator	United States Senator
455 Dirksen Senate Office Building	172 Russell Senate Office Building
Washington, DC 20515	Washington, DC 20510
The Honorable Pat Roberts	The Honorable Mike Enzi
United States Senator	United States Senator
109 Hart Senate Office Building	379A Russell Senate Office Building
Washington, DC 20510	Washington, DC 20510

Dear Senators:

Siemens Healthcare, Health Services (Siemens HS), appreciates the opportunity to respond to the April 16, 2013, report: "REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT."

Background

Siemens AG is a multinational company in electronics and electrical engineering operating in the industry, energy, infrastructure and cities and healthcare sectors. In the United States, Siemens AG employs over 57,000 people and has nine corporate headquarters. Siemens HS is the information technology (IT) business of Siemens Healthcare. We are headquartered in Malvern, Pa., employing about 5,000 individuals worldwide. We have been a leader in healthcare IT (HIT) for more than 40 years. As an HIT vendor, Siemens HS was a pioneer of the HIT industry starting in 1969 and has been developing and implementing electronic health records (EHRs) for decades. Our provider customers have achieved impressive outcomes after implementing our EHR solutions. These include reductions in medical errors, patient falls, hospital acquired conditions, readmission rates, wait times, and many more. As a result, we appreciate the level of effort required to achieve great value when implementing EHRs.

We are fully committed to helping our customers achieve the incentives provided by the EHR Incentive Programs ("the Program") authorized under the HITECH Act of the American Recovery and Reinvestment Act. We have witnessed significant increases in the level of adoption within our customer base. We found that the incentive monies have been instrumental in helping our customers acquire and implement certified EHR technology. But, while increases in adoption rates are evident, we are concerned with the toll on providers as a result of escalating requirements. The current situation poses risks to the goals of the Program. The goal of achieving advanced EHR capabilities will be jeopardized by the rush to collect incentive payments and avoid penalties. We are moving too far, too fast, without gaining an understanding of what the Program has already achieved. As former national coordinator of

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway,
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
www.usa.siemens.com/healthcare

HIT David Brailer, MD, PhD, recently stated: the Program is creating a "race to adopt" mentality, taken from your REBOOT white paper.

Siemens applauds your comprehensive review of the Program and we believe that you raise many important questions that need to be considered. We support the report's call for a "pause" to enable a closer look at the Program's initial rollout. The American Hospital Association (AHA), the Healthcare Information & Management Systems Society (HIMSS) and the College of Healthcare Information Management Executives (CHIME) also support an analysis of the Program in letters responding to the REBOOT white paper. This assessment needs to determine the efficiency and effectiveness of the Program's implementation approach as well as the Program's ability to meet the objectives set forth in the ARRA-HITECH Act (HITECH Act Sect. 3001 (b)). The assessment should also recommend corrections to the approach in order to better achieve these objectives.

A framework for evaluation needs to be established where an initial assessment would, at a minimum, establish a baseline for ongoing Program evaluation and include the following areas:

- Determine the gains in care quality, safety and efficiency by providers that have attested to Meaningful Use Stage 1.

- Assess the progress toward real, cross-provider interoperability and assess the necessary standards development and their level of deployment.

- Review the maturation of proposed quality measures.

- Assess providers' ability to perform associated process re-engineering and care improvement steps needed to optimize their EHR investments.

- Understand the ability (and limited resources) of providers to operationalize HIT systems, while at the same time, comply with ICD-10, and rules associated with hospital acquired conditions, value-based purchasing, bundled payments, etc.

- Assess providers' ability to maintain necessary levels of investment to sustain current stages and meet future stages of Meaningful Use.

Ultimately, the findings of this assessment should provide direction to improve the Program. Additionally, to make use of the added time that would be gained while such an assessment is performed, we suggest that the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for HIT (ONC) concentrate on improving the quality of several of their deliverables, for example:.

- Address hundreds of issues raised about:
    o ambiguous or conflicting rules,
    o incorrect or incomplete quality measure definitions,
    o ambiguous or incorrect interoperability implementation guides, and

- o incorrect testing tools for interoperability and quality measures.
- Conduct better validation of test tools that were deployed without sufficiently being tested, e.g., the Cypress tool.
- Reduce inconsistencies and "errors" across the auditors of the Program. As one example, an auditor required that a provider include deceased patients in their statistics. This was done in order for the provider to meet a requirement for following-up with a certain percentage of patients. CMS must provide more clear guidelines to ensure that the auditing program is improved before moving to Stage 2 where the requirements are much more significant.

With greater demand for performance information and a greater willingness to integrate performance information into public policy, it is critical that the transformation of measurement is given adequate time along with stabilized testing tools for electronic measurement to mature. Variation in performance measure specifications and in certification tools leads to variation in measure reporting. Such variation runs counter to the overall desire for standardized reporting across health care organizations. Many of the issues and errors reported to ONC and CMS have not yet been fully addressed leaving many uncertainties, thus increasing potential variation in quality reporting for Meaningful Use in 2014.

Key concerns

1. Pace of adoption

2. Impact of penalties on hospitals and providers

3. Immature interoperability standards

1. Pace of adoption

As mentioned above, our organization has decades of experience in implementing HIT, including EHRs. We have firsthand experience of the effort required to implement them in an approach that optimizes the technology and capabilities. HIT technology is not a standalone solution but rather supports the clinical work of physicians, nurses and professionals in nearly all hospital departments. Building new workflows, integrating departments and establishing tools to help these individuals provide safer, more effective care is a significant undertaking. "Rushing" an implementation stymies the opportunity to optimize the technology, jeopardizing the ability to achieve the desired Program outcomes and may have an adverse effect on patient safety.

2. Impact of penalties on hospitals and providers

The looming penalties of the Program are causing this rush to adopt. And the officially published EHR adoption figures do not clearly reflect the actual numbers of eligible hospitals or providers that have attested for the Medicare EHR Incentive Program. This makes it difficult to project the percentage of the remaining eligible hospitals and providers that did not achieve Meaningful Use Stage 1. Those hospitals who have not achieved Meaningful Use Stage 1 by October 1, 2014, will face Medicare

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway,
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
www.usa.siemens.com/healthcare

reimbursement cuts. The result is that misrepresenting adoption statistics, by including those who have received both Medicare and Medicaid reimbursement, belies the true nature of the Program's effectiveness and paints an inaccurate picture of nationwide adoption. When the penalties become effective for hospitals and providers, there could be a far more significant impact than the adoption numbers would suggest, e.g., more hospitals will be penalized than anticipated. With penalties taking effect, we could reach an adoption rate "saturation point" where there is a significant number of "have nots" vs. "haves" who achieved Meaningful Use.

3. Immature interoperability standards

Over the last 25 years substantial interoperability has been achieved *within* individual provider organizations, but the solutions and standards that enabled that success are not scalable in their current form to easily support interoperability across providers. Progress toward the goal of cross-provider interoperability has been limited due to a combination of:

- loss of focus: expanding the scope (regulating functional capabilities beyond interoperability) and micromanaging the "how" (establishing process thresholds rather than outcomes thresholds); and

- lack of understanding the magnitude and challenges to connect the thousands of providers that have different levels of technology, different vocabularies, different skills, different goals, and different cultures.

The 2014 Edition on standards and certification criteria to be used in Meaningful Use Stage 2 clearly increased the requirements for cross-provider interoperability. However, a number of standard implementation guides are effectively still in a draft stage per the standards organizations owning them. Yet these still novel standards are being instituted for widespread use. Numerous clarifications and errata continue to be identified while preparations for Meaningful Use Stage 2 have to effectively conclude by October 1, 2013.

ONC defined a reasonable framework to focus and progress the development and roll-out of standard implementation guides that support cross-provider interoperability. While there is room for improving on these processes, we are actually rushing through the steps without adequate time to ensure the resulting standard implementation guides actually work. We do not have time to determine if they are mature enough to be mandated across the industry. Mature standard implementation guides are essential to ensure we can communicate consistently and unambiguously across providers.

We suggest that the Program and approach be re-calibrated to improve its focus on interoperability, building on the experiences to-date, addressing the complexities and realities of transparent health information exchange across providers, patients, and other stakeholders. Only by adding an additional third year to Stage 2 and delaying Stage 3, can providers and vendors provide adequate attention to the necessary standards development, coding, testing, piloting, publishing, and roll-out before we can reasonably mandate standards for wide adoption.

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway,
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
www.usa.siemens.com/healthcare

Patient Safety Oversight of HIT

In addition, there is confusion and potential duplicative patient safety oversight with ONC. While the ONC had an essential role in devising the Program and implementing the HITECH requirements, we believe that their long-term role needs to be clarified.

Specifically, as ONC evaluates patient safety requirements there needs to be more clarity over the direction and nature of their role as generally related to patient safety for health IT in relation to FDA. For example, ONC has proposed a Patient Safety and Surveillance Plan that is expected to be released in June 2013. At the same time, in legislation to reauthorize the Medical Device User Fee and Modernization Act (MDUFMA), Congress specifically requested that the Administration create an outside group to review and recommend a regulatory framework for HIT. That group was established in April 2013 and a final set of recommendations is expected to be released by FDA, ONC and FCC sometime in January 2014. Part of these recommendations will be the definition of HIT that will bring critical clarity so the future oversight framework will be applied consistently by the Administration across all HIT product types. We strongly recommend that the Administration withhold all judgments associated with HIT regulation, that impact all areas of health IT, e.g., clinical decision support and mobile medical applications, until the FDASIA stakeholder work group and the Administration have finished their process of receiving public comments, complete their work and give Congress time to take action based on their input. If ONC or FDA were to issue guidance before completion of this important process, this action would seem to defy Congressional intent and dismiss the contributions of important stakeholders in the HIT marketplace.

The ONC has an important role to play and should focus on developing international and national standards to support interoperability, privacy and security and reporting (e.g., clinical quality measures, disease registries, etc.).

I appreciate this opportunity to provide commentary and our perspective on your REBOOT white paper and on the EHR Incentive Program. I look forward to any discussion to help clarify our comments or offer support.

John P. Glaser
CEO

Health Services
Siemens Healthcare