Office of the National Coordinator
Health IT Policy Committee (HIT-PC)
Hearing
May 27, 2014

Siemens Testimony, Catherine Britton – May 27, 2014

My name is Catherine Britton. Thank you for giving me this opportunity to speak with you today about Siemens Healthcare's experience with the development and customer implementations of the 2014 Edition's modifications to Stage 1 and introduction of Stage 2.

Siemens' comprehensive experience with the 2014 Edition can be leveraged to provide constructive input to the framing of the 2017 Edition including the introduction of Stage 3. Customer feedback Siemens has received to date is highly consistent with and has informed our perspective. Siemens universally recognizes and endorses the intentions of the program to use healthcare IT, meaningfully, to facilitate high quality, efficient care within and across care venues. However, we are significantly challenged to endorse specifics about the implementation of the program and, with our clients, request a focus on those activities that are:

- Prioritized with documented Line of Sight to the MU program's core intent of measurable improvements in health, quality, and cost
- Specified with high quality and without ambiguity
- Provided sufficient time for equally high quality implementation.

To that end, experience with the 2014 Edition translates directly to input to the contemplated 2017 Edition.

Timeliness and Quality. The 2014 Edition was communicated September 2012 to go into effect FY (EH/CAH) and CY (EP) 2014. The 2014 Edition provided 13 months from release to the start of reporting and 24 months to the start of the last reporting period. **Clearly the 13-24 month timeline has proven too short and the proposed 2017 Edition timeline does not yet accommodate that learning.** The final set of standards was incomplete and required considerable updates and clarifications, thus further constraining the timeline.

Providers underestimated the scope of impact which further exacerbated the timeline. Communications emphasized the 2014 Edition as requirements for "stage 2" thus immediate impact focus was for a minority of providers in 2014. In actuality, nearly 80% of the material impact to vendors and providers, such as Clinical Quality Measures (CQMs) and Patient Electronic Access (Core 6), applied to Stage 1 which was applicable to the majority of 2014 reporting providers. Stage 2 represented only a minor uplift from the additional requirements levied on the 2014 Edition's Stage 1 requirements. Therefore, perception was that ~ 30% of providers were substantially impacted in the 13 months allotted when, in actuality 100% of providers bore more than 80% of the impact in the immediate timeline. The Stage 2 emphasis under served the urgency of CQM and Core 6 process analysis and (re)design in 2013 and CEHRT upgrades needed for the market as a whole.

The quality of the finalized MU measures and CEHRT standards, including CQMs, protocol mandates, and industry readiness (e.g., HISP/Direct address support for Patients) remain a considerable challenge even at this date. The 2014 Edition's combined factors of:

- truncated implementation time for solution developers and providers (i.e., less than 13 months overall),
- lack of clarity of scope of those impacted (perceived impact on 30% of customer base for Stage 2 vs. actual impact to 100% of customer base),
- broad process impacts due to extensive breadth scope and prescriptiveness of specifications,
- and substantial change to and remaining quality defects in specification detail

unnecessarily challenged clients' to deploy quality implementations and hampered their enthusiasm for the program. Translating this experience directly to the 2017 Edition and MU reporting periods, our recommendations are:

- Provide the required 18 month timeline and align that timeline among program(s) participants. The full set of requirements for the 2017 Edition need to be published in their final, complete, and high quality form in July 2015 should drive a start of MU reporting periods (any/all stages) no sooner than January 2017. The reporting periods should be aligned among interoperability participants (EP/CAH/EH) to accommodate mutual and consistent prioritization of interoperability efforts. The timeline should be aligned among relevant programs (e.g., IQR and MU) for quality reporting. This time and alignment is needed to accommodate provider process analysis, solution development, training and knowledge-transfer, testing and validation, rollout, process and feature implementations, and consistently prioritized interoperability.
- The quality and completeness of the 2017 Edition Final Rule and associated specifications should be secured upon release so that the time allotted can be fully and effectively utilized. The standards should be released in the form of the "tip sheets" where CMS and Line of Sight ONC requirements are clearly and concisely represented without ambiguity. For vendors, test specifications and test data should be released simultaneously for full clarity in development scope. CQMs should be consistent with each other and with the automated measures. Test tool quality should be governed and not require vendor alpha testing and protracted defect resolution releases.
- The breadth of scope impact to providers of the 2017 Edition, all stages, should be fully considered to ensure the scope is manageable within the timeframes and should be clearly and unambiguously communicated to appropriately focus provider attention.

Prioritized and Validated Scope: Clients recognize that criteria such as CQMs, public health exchange, Patient Electronic Access (Core 6), and Summary of Care (Core 12) are key enablers of the program's intent of measurable improvements to health, quality and cost. However, high quality attention on these key items has been challenged by both the clarity and quality of their definition and by the additional Meaningful Use scope that may appear "superfluous" or even conflicting by comparison. Key messages are repeated throughout the providers:

Prioritize and Validate scope to avoid "Meaningless Use": Focus should be on the "what" and "why" of national health priority outcome management and measurement rather than on the "how" of list making and specification of prescriptive processes especially when those specifications are not validated with clinical practitioners. For example, provider feedback indicates that more robust processes exist for tobacco use, race and ethnicity recording, and patient education and that existing standards are hard to align with the 2014 Edition's prescribed details for these criteria. Further, CQM quality defects continue to risk provider confidence in the program's ability to accurately measure quality or guide payment reform. Specifications for Core 6 and 12 such as scope of results in the C-CDA, SNOMED codification of problems and procedures, and the counting of transitions/referrals are out of alignment of clinical standard practices and have caused unnecessary implementation challenges and a diffusion of attention from important tenets of the program. **It is important to manage the scope of what is required as well as the quality of how it's specified to ensure success.** The following recommendations are based on lessons from the 2014 Edition that can be directly applied to the 2015 Edition's and HIT-PC's 2017 Edition preview:

- Scope the specification to be outcome measured vs. design prescribed: As an example of our recommendation of scope, HIT-PC recommendations include an increase in CDS utilization and broader focus on priority domains. Conversely, HIT-PC suggests prescriptive certification-only criteria of CDS response tracking without clarity in how providers would utilize that feature and what outcome is desired. Further, the 2015 Edition proposes a substantial scope for

prescriptive design and implementation of CDS and eCQMs. No recommendation includes the priority of addressing definitional quality (of current CQMs and proposed extensions to CDS) nor does the timeline allow sufficient time for clinical and technical standards validation for the prescriptive design proposals. Generally the scope (and specifically the CQM/CDS scope), needs to be prioritized to address patient safety, successful outcomes in patient / population health and operational efficiency rather than prescribe premature software design approaches that may inhibit technological and/or clinical innovation.

  - Scope the specification to be outcome measured vs. process measured. The HIT-PC and the 2015 Edition's 2017 Edition preview propose a substantial scope of process measurements and "lists of data" objectives items that should be replaced with the outcome measurement intended or, if that is lacking, de-scoped entirely in favor of complete focus on those remaining items that do have clear outcome definitions. For example, objectives for increased and changed patient information, order tracking, electronic notes, patient education, notifications, secure messaging, and Patient Generated Health Data should be evaluated for replacement with corresponding outcome measurement(s) such as demonstrable reduction in re-admission rates or medication errors, demonstrable benchmarking on healthcare disparities, demonstrable operational efficiency of sharing previously collected data, etc. Note that if the data/processes in these proposals are relevant to a measurable quality indicator, additional process measurement and certification criteria are superfluous and increase cost without clear benefits. If criteria are not Line of Sight to some measurable outcome, it may be counterproductive to collect the data or mandate the process.
  - Key items should be recast and/or aligned with outcomes enabled by interoperability or patient engagement to ensure quality specification and implementation. For example, use cases for UDI and Patient Generated Health Data should be validated for practical and prioritized use within and across venues and replace what, as written is essentially list making. State agencies need to be aligned to expansion of public health initiatives. Protocols selected and mandated for interoperability should be validated as appropriate for and sufficiently mature to achieve the goals. Patient identity / matching and privacy and security policies should be aligned for effective interoperability.

- In order to not cause delays and unnecessary complexity, no certification-only criteria should be proposed. The MU program has required features to be certified by the vendors that providers are not required to use thereby delaying CEHRT availability and diverting resources from innovation and market-driven development. Some of those features have been abandoned entirely causing waste and opportunity costs. Certification requirements should be line of sight to prioritized, outcome-oriented provider requirements. We've also know that development of high quality software requires an understanding of the intended use which tends to be incorporated in the meaningful use rule, rather than in the certification rule.

Aligned scope: For practical and effective implementations and meaningful outcomes, the standards need to be aligned within the industry.

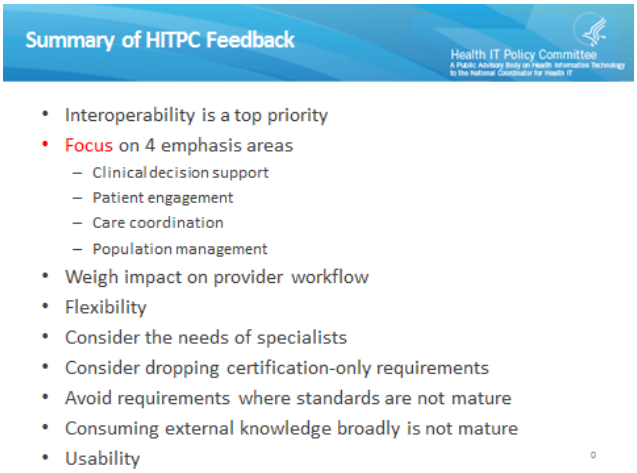
- EP and EH/CAH reporting period offsets challenge interoperability and patient engagement; timelines need to be aligned for effective interoperability.
- The standards not aligned with state infrastructure such as privacy and security, public health readiness, and HIE / Patient portal infrastructure. 2017 Edition proposals in the 2015 Edition need to be scoped to match state readiness.
- CQMs are not aligned with each other nor with core measures.
- Joint Commission requirements are not aligned with the Meaningful Use program specifications. Note that alignment does not mean synonymy, necessarily. An unintended consequence of a lack of

alignment is that vendors and providers both expend time and resources to analyze and implement if and how to align and/or may maintain duplicate processes without clear alignment, thus reducing operational efficiency and leaving fewer resources for innovation.

In summary, our recommendations are as follows and as depicted in the annotated HIT-PC Stage 3 recommendation slide:

- Maximize probability of success and program efficiency by providing no less than 18 months from the final specifications and reporting requirements where final specifications are defined as complete, high quality, consistent, and unambiguous information.
- Maximize collaboration and probability of success by aligning reporting and interoperability priorities among all program(s) participants and stakeholders (i.e., states).
- Maximize program enthusiasm and success by securing both a scope of requirements and a high quality definition of those requirements to a prioritized set that is Line of Sight well defined, measurable improvements in health and cost. It is important to manage the scope of what is required as well as the quality of how it's specified to ensure success.
- Avoid unintended consequences such as provider drop out and stifled innovation by avoiding prescriptive requirements for collecting lists of data, measuring processes, and/or designing software.
- Maximize probability of interoperability success by ensuring appropriateness and maturity of selected standards.

Thank you again for the opportunity to contribute to the 2017 Edition, Stage 3 recommendations.



Siemens

The **Siemens Healthcare Sector** is one of the world's largest suppliers to the healthcare industry and a trendsetter in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Siemens offers its customers products and solutions for the entire range of patient care from a single source – from prevention and early detection to diagnosis, and on to treatment and aftercare. By optimizing clinical workflows for the most common diseases, Siemens also makes healthcare faster, better and more cost-effective. Siemens Healthcare employs some 52,000 employees worldwide and operates around the world. In fiscal year 2013 (to September 30), the Sector posted revenue of 13.6 billion euros and profit of 2.0 billion euros. For further information please visit: www.siemens.com/healthcare.

Catherine Britton

Catherine Britton leads the Siemens Health Services ARRA product solution team. Catherine has 30 years of experience in all facets of software solution development including requirements solicitation and elaboration, development, test, deployment, education, and implementation. For more than 20 years, Catherine has been providing solutions for the worldwide Healthcare IT including RIS / PACs in the first filmless hospitals in the world, oncology information management, cardiology solutions, and acute and ambulatory domains.