References to Synchronized Clocks and NTP in ONC Meaningful Use Stage 2 Final Rule

The contents of this document were quoted from:
http://www.ofr.gov/OFRUpload/OFRData/2012-20982_PI.pdf
Released August 23, 2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary 45 CFR Part 170 RIN 0991-AB82
Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services. ACTION: Final rule.

Page 444:
(g) "Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299)."

Page 54:
"We also proposed that the "patient accessible log" capability would need to record the date and time each action occurs using a system clock that has been synchronized following either Request for Comments (RFC) 1305 Network Time Protocol (NTP) v3 or RFC 5905 Network Time Protocol Version 4: Protocol and Algorithms Specification (NTPv4)."

Pages 80-82
Comments. Commenters expressed support for our proposed "synchronized clocks" standard and our proposal to permit either NTPv3 or NTPv4. They noted that the use of these synchronization technologies is very common and supported in all major operating systems. Along those lines, they stated that it was unclear why this would be a requirement for EHR technology certification because it is unlikely that the EHR technology itself will be directly implementing this type of synchronization and more likely that it will be relying on the lower level systems' clock functionality (e.g., the operating system within which the EHR technology runs). One commenter stated that it is important to avoid a requirement that would make the operating system (that provides the standard clock) part of what is needed for EHR certification as this would impose artificial limits on what operating systems can be used without certifying multiple permutations. This commenter contended that because the ability to use an operating system clock is common, it was unnecessary for this standard to be required for certification. They requested that if we did include it for certification, that we acknowledge that: the operating system keeps the time, the EHR technology gets the system clock, and that a particular operating system is not required to be part of EHR technology for certification.

Response. We thank commenters for supporting this proposal. As we indicated in the Proposed Rule, our responses here also apply to comments received on other certification criteria that also referenced the "synchronized clocks" standard. **We acknowledged in the Proposed Rule and here again our understanding and expectation that EHR technology will likely obtain a system time from a system clock that has been synchronized following the NTPv3 or NTPv4 standard. We expressly worded the standard to acknowledge this likely scenario by stating "[t]he date and time recorded utilize a system clock that has been synchronized...."** (Emphasis added.) **We do not intend for this specific capability to create a binding relationship between EHR technology and a particular operating system. For certification, EHR technology must be able to demonstrate, as the standard states, that it can utilize a system clock that has been synchronized following NTPv3 or NTPv4**. Accordingly, we have retained this proposal and finalized it for the certification criteria to which it pertains."

Page 127

Electronic Medication Administration Record

MU Objective - Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

2014 Edition EHR Certification Criterion - § 170.314(a)(16) (Inpatient setting only – electronic medication administration record)

"We proposed to adopt a new "eMAR" certification criterion with the inclusion of the "synchronized clocks" standard. We made this proposal based on the recommendation of the HITSC for a new 2014 Edition EHR certification criterion to support the MU objective and measure to automatically track medications from order to administration…"

Page 261

Auditable Events and Tamper-Resistance; and Audit Report(s)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criteria

§ 170.314(d)(2) (Auditable events and tamper-resistance)

§ 170.314(d)(3) (Audit report(s))

"We proposed two revised certification criteria at § 170.314(d)(2) and (3) – one focused on the capability to record auditable events and another focused on the capability to create audit reports – in place of the single 2011 Edition EHR certification criterion for audit logs adopted at § 170.302(r). We also proposed to move the specific capability "detection" from the integrity certification criterion (§ 170.302(s)(3)) to the proposed auditable events and tamper-resistance certification criterion. We made these proposals based on HITSC recommendations as well as stakeholder feedback that indicated splitting the 2011 Edition certification criterion

into two separate certification criteria would permit a wider variety of EHR technologies to be certified as EHR Modules. We also expanded upon the scope of the HITSC's recommendation to address input from the HHS Office of Inspector General (May 2011 report25) and to reflect our general belief that a more stringent certification policy for audit logs will ultimately assist EPs, EHs, and CAHs to better detect and investigate breaches. The proposed expansion included the specific capabilities that the audit log must be enabled by default (i.e., turned on), immutable (i.e., unable to be changed, overwritten, or deleted), and able to record not only which action(s) occurred, but more specifically the electronic health information to which the action applies. The proposed certification criterion would also require that the ability to enable and disable the recording of actions be limited to an identified set of users (e.g., system administrator). Further, to accommodate these changes, we proposed a revised standard at § 170.210(e) and proposed to require that: 1) when the audit log is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the action(s) that occurred must be recorded; and 2) as applicable, when encryption for end-user devices managed by EHR technology is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks)), user identification, and the actions that occurred must be recorded. Finally, we acknowledged, as recommended by the HITSC, that an example standard that could be followed in designing EHR technology to meet these certification criteria could include, but is not limited to ASTM E2147-01, Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems."

P266: "…One commenter suggested that we clarify that audit logging requires at a minimum date, time, and user id to determine who accessed certain electronic health information. With limited exceptions, commenters generally supported the adoption and application of the clock synchronization standards we had proposed."

Impression:
ONC's reassertion of the importance of enabling accurate date and time stamps is most welcomed.

For information on our research on medical device clock accuracy and synchronization, please visit http://mdpnp.org/devicesynchronization.html.

Julian M. Goldman, MD
jmgoldman@partners.org
August 24, 2012