

Technical Note: Time Synchronization

Industry Regulations, Standards and Best Practices Relevant to Time Accuracy

Professionals in the healthcare field are well aware of the importance of accuracy. There are strong needs and requirements for accurate time in software, databases, all computing devices, network infrastructure, documentation and medical equipment.

Besides HIPAA there are many other existing and proposed regulations, standards and best practices that require accurate time for a range of applications from computing systems to quality of care metrics. We provide this list as a reference to the industry. If you know of any updates to these or additional standards related to records management, internal controls, timely diagnosis and care, security and authentication and more, for the healthcare industry, please contact us.

ASTM

ASTM Committee E31 on Healthcare Informatics develops standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare. It includes Subcommittee E31.20 works on "Data and System Security for Health Information."

CCHIT

Certification of Ambulatory and Inpatient EHRs, Final Security Criteria, includes a requirement for the accuracy of time as it relates to the Electronic Health Record. The statements are as follows:

The system shall provide authorized administrators with the capability to read all audit information from the audit records in one of the following two ways: 1) The system shall provide the audit records in a manner suitable for the user to interpret the information. The system shall provide the capability to generate reports based on ranges of system date and time that audit records were collected. 2) The system shall be able to export logs into text format and correlate records based on time (e.g., UTC synchronization). See S7, S8.1 and S8.2.

CMS Conditions of Participation for Hospitals §482.24.

Defined standards and requirements for medical records, whether they are in paper or electronic format. These regulations are the foundation for maintaining a legally sound health records.

Time synchronization supports the following regulation statement:

All entries in the medical record must be timed, date, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code. Authentication may include signatures, written initials or computer entry.

FDA 21 CFR Part 11

Section 11.10 describes measures designed to ensure the integrity of system operations and information stored in the system. Such measures include: (1) validation; (2) the ability to generate accurate and complete copies of records; (3) archival protection of records; (4) use of computer-generated, time-stamped audit trails; (5) use of appropriate controls over systems documentation; and (6) a determination that persons who develop, maintain, or use electronic records and signature systems have the education, training, and experience to perform their assigned tasks.

- ASTM
- CCHIT
- CMS
- FDA
- HIPAA
- HL7
- IHE
- JCAHO
- NQA/MS QualityNet
- Society of Chest Pain Centers
- Stroke Center Certification

HIPAA

Security and Electronic Signature Standards (2002) addresses the following policies and practices, and procedures. A few examples:

- Security and confidentiality policies: Requirement for a time source behind the firewall for secure and accurate networking.
- Audit Trails: Requirement for documentation to support Time Stamps, Audit Trails, File Logs, etc...as it relates to Electronic Health Records.

HL7

The HL7 EHR Interoperability Model (EHR/IM) establishes an industry consensus view of "What is EHR Interoperability?" It provides a reference list of characteristics of (and requirements for) interoperable EHR records.

2.7c: An Act occurs at a specific date/time and has an elapsed time - date/time consistent with a Master Clock system

The HL7 EHR Functional Model (EHR-S FM) specifies over 160 functions that may be present in an Electronic Health Record System. These include:

- *IN.1.5 – Non-Rupudiation: time stamp is important for non-repudiation*
- *IN.1.6 – Secure Data Exchange: use standardized time-keeping per the IHE consistent time profile*
- *IN.2.3 – Synchronization: synchronize data*

HL7 works in process involves specifying the requirements of a legal EHR. Under consideration for the HL7 Legal EHR Functional Profile includes:

- *Auditable Records: date and time stamps are important for audit capabilities with standardized time-keeping per the IHE consistent time profile.*
- *Chronology of Events: Shall maintain proper chronology of events.*

IHE

IHE's IT Infrastructure Radiology, Cardiology, and Patient Care Devices (PCD) Technical Frameworks identify the problem of inconsistent time.

Problem	IHE Domain	IHE Integration Profile	Transaction	Actors
Inconsistent Time	Infrastructure Radiology Cardiology Patient Care Devices	Consistent Time (CT)	NTP or SNTP request/send	Time Client Time Server

Consistent Time (CT) Integration Profile provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second.

CT Actors

- Time Client – Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers.
- Time Server – Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g., satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s).

CT Transactions

- Maintain Time - NTP transactions used to maintain time synchronization.

JCAHO

The Joint Commission on Accreditation of Healthcare Organizations requires: Organizations to maintain complete and accurate medical records (RC.01.01.01). It also requires Documentation in the medical record is entered in a timely manner (RC.01.03.01).

Provides guidelines for the appropriate authentication of medical record entries:

- Standard IM 7.1.1 states that only authorized individuals may make entries in the medical record.
- Standard IM 7.8 states that every medical record entry must be dated, its author identified and, when necessary, authenticated.

NQA/CMS - Inpatient Hospital Quality Measures (Quality Net)

The Joint Commission and CMS Reporting of Core Measures for Hospital Quality Measures requires accuracy in documentation related to time sensitive data currently being reported for acute myocardial infarction include:

- ECG within 10 minutes of arrival
- Fibrinolytic therapy received within 30 minutes of hospital arrival
- Primary PCI received within 90 minutes of hospital arrival

Timely care is also defined for surgical care, emergency department care, and stroke care.

Society for Chest Pain Center Accreditation

Synchronized time is an important process improvement tool as required by Chest Pain Center accreditation in two ways: as a functional facility design practice and for accurate performance metrics.

KEY ELEMENT #7: Functional Facility Design

- “Clocks are synchronized within the main ED, Triage area, 12-Lead ECG machines and Cath lab.”

KEY ELEMENT #2: Emergency Assessment of Patients with Symptoms of ACS – Timely Diagnosis and Treatment

Examples of measurements and Procedures:

- “Tracking time of arrival”
- “Time to first” [ECG, biomarker result, fibrinolysis, balloon, primary PCI, etc.]
- “ECGs repeated at five (5) to ten (10) minute intervals”
- “Return calls in ten (10) minutes”

Stroke Center Certification

The Joint Commission's Certificate of Distinction for Primary Stroke Centers requires the following measurements:

- Arrival time
- Diagnostic brain image completed and results reported to or reviewed by the stroke team within 45 minutes
- Time to thrombolytic administration

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