University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

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One Chart Compliance with 21 CFR Part 11

The electronic medical records are maintained within the One Chart Powered by Epic system which is installed and operated by The Nebraska Medical Center (Hospital). This system is run as a closed system as defined by 21 CFR 11.10.

During the installation process, the One Chart core team implemented the Epic core functionality as defined in the Epic document 21 C.F.R. Part 11 Compliance and Epic All Applications dated September 5, 2010. As defined within the document, the One Chart system site responsibilities were implemented.

Site Responsibilities which were implemented include:

1) Documentation of the change management processes for any changes to the system.
2) System is configured to generate a Master Summary report. The Save EMR To File functionality allow the generation of a soft-copy of a patient's health record in Rich Text or PDF format, which can then be copied to CD, DVD, flash drive or a similar device.
3) The Epic provided specific requirements, recommendations, and support for establishing your production backup strategy were followed.
4) The legal retention period for backups is being met.
5) Epic's access control ability is fully implemented and is in compliance with the entities access control policies and procedures.
6) Epic's auditing capabilities is enabled and the audit log is retained per your record retention standards.
7) Job descriptions specify the qualifications necessary for the team members who configure, support, or use Epic.
8) Entity has established and enforces written policies which hold individuals accountable for actions taken under their electronic signature.
9) Entity has established appropriate control over systems documentation.
10) Entity has a process for verifying the identity of an individual prior to issuing access credentials.
11) Documentation which certifies to the FDA that the electronic signatures in their system are legally binding and equivalent to a traditional handwritten signature has been developed.
12) Inactivity timeout is set per policy.
13) Entity has established and enforces written policies which hold individuals safeguarding their user id's and passwords.
14) Entity has established and has trained on the security incident response plan. Incidents would include but not be limited to:
    - Reporting of compromised ID's/passwords
    - Lost or stolen devices
    - Etc.
15) A process for initial and periodic testing of devices such as token or grid cards has been established.

Prepared by:

Brian Fox,
The Nebraska Medical Center
Information Custodian, One Chart

Sharon Welna
HIPAA Information Security Officer

Christopher J. Kratochvil, M.D.
Associate Vice Chancellor for Clinical Research

Dave Fuller, R.N.
Executive Director, One Chart Implementation

987878 Nebraska Medical Center / Omaha, NE 68198-7878 / 402-559-8490 / FAX: 402-559-8445 / http://www.unmc.edu/research_leadership.htm