HealthCare.

Januaray 19, 2021

Title 21 of the federal regulations part 11 (21 CFR Part 11) provides criteria under which the Food and Drug Administration (FDA) will consider electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional handwritten signatures. It applies to any paper records required by statute or agency regulations and supersedes any existing paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures which meet the requirements of the rule will be considered to be equivalent to full handwritten signatures, initials, and other general signings required by agency regulations.

Persons that create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. 21 CFR Part 11 provides a list of requirements for both open and closed systems to include:

- System access be limited to authorized individuals
- Operational system checks be used to enforce permitted sequencing of steps and events as appropriate
- Authority checks be used to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform operations
- Device checks be used to determine the validity of the source of data input or operation instruction
- Written policies be established and adhered to holding individuals accountable and responsible for actions initiated under their signatures, so as to deter record and signature falsification.

21 CFR Part 11 provides additional requirements for open systems including utilization of document encryption and digital signatures.

In August 2003, the FDA clarified the requirements in 21 CFR Part 11 related to manufacturers of electronic systems. Under the narrow interpretation of the scope, specific requirements for validation, audit trail, legacy systems, copies of records, and record retention were outlined.

UK HealthCare, in conjunction with their vendor partners, has performed a review of the compliance of systems in the UK HealthCare environment to the requirements in 21 CFR Part 11. UK HealthCare has determined that the applications listed below are compliant with the requirements specified in 21 CFR Part 11.

- Allscripts Touchworks Version 17.1 CU8
- Allscripts Sunrise Acute Care Version 17.3 CU6

Cecilia Page

Cecilia Page
Chief Information Officer
UK HealthCare

Douglas W. Fee

Douglas Fee
Chief Information Security Officer
UK HealthCare