UK HealthCare

21 CFR Part 11 Statement of Compliance

January 9, 2023

Background

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.

Certified Health Information Technology

In September 2013, the FDA released guidance on the use of computerized systems in clinical investigations. They stated:

> *"Adequate controls should be in place to ensure confidence in the reliability, quality, and integrity of the electronic source data. The determination of whether a computer system used in a clinical investigation is suitable for its intended purpose might not be under the control of the clinical investigator(s) or sponsor (e.g. EHRs). The performance standards for these computer systems may be regulated by other authorities and under the control of, for example, healthcare providers or institutions."*

The FDA recognized that electronic health records (EHRs) would be regulated by other authorities, deferred to 45 CFR part 170, and concluded that it "does not intend to assess the compliance of EHRs with part 11."

In July 2018, the FDA further clarified:

> *"Under the ONC Health IT Certification Program, certified EHR technology would be in compliance with applicable provisions under 45 CFR part 170. EHR technology with certified capabilities*

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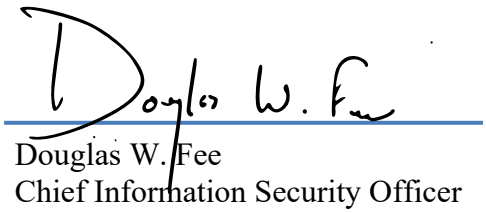
> *generally has clear advantages, because many of the certification requirements are aimed toward ensuring interoperable data sharing and enabling processes to keep electronic data confidential and secure. In particular, all EHR technology certified under the ONC Health IT Certification Program is required to meet certain privacy and security protection requirements for an individual's health information (see 45 CFR 170.314(d)(1) through (8) and 45 CFR 170.315(d)(1) through (11)). FDA encourages the use of such certified EHR systems together with appropriate policies and procedures for their use."*

As a healthcare delivery organization, UK HealthCare utilizes EHR technology certified by the Office of the National Coordinator for Health Information Technology (ONC). The ONC has certified the Epic EHR as follows:

Product	CHPL Product Number
Beacon Cancer Registry Reporting	15.04.04.1447.Beac.22.17.1.220511
Beaker Reportable Labs Reporting	15.04.04.1447.Beak.22.16.1.220511
Electronic Case Reporting	15.04.04.1447.Elec.22.17.1.220511
EpicCare Ambulatory Base	15.04.04.1447.Epic.AM.22.1.220713
EpicCare Inpatient Base	15.04.04.1447.Epic.IN.23.1.220713
Infection Control Antimicrobial Use and Resistance Reporting	15.04.04.1447.Infe. 22.15.1.220511
National Healthcare Survey Reporting	15.04.04.1447.Nati.22.10.1.220511
Syndromic Surveillance Reporting	15.04.04.1447.Synd.22.16.1.220511

Compliance

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that UK HealthCare intends that all electronic signatures in the Epic EHR executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures.



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