



CFR Title 21, Part 11 Attestation

Part 11 of Title 21 of the Code of Federal Regulations establishes the criteria under which the U.S. Food and Drug Administration (FDA) considers electronic records, electronic signatures and handwritten signatures executed to electronic records to be trustworthy, reliable and generally equivalent to paper records and handwritten signatures executed on paper. Froedtert Hospital and the Medical College of Wisconsin provide the following Electronic Health Record and Electronic Signature certifications for the Epic Electronic Health Record (EHR) System.

Electronic Health Record Certification

In January 2011, the Office of the National Coordinator (ONC) for Health Information Technology (HIT), in the US Department of Health and Human Services (DHHS), issued the final rule to establish the Permanent Certification Program for HIT (45 CFR Part 170). Froedtert Hospital and the Medical College of Wisconsin use the Epic EHR as the legal medical record to collect standard clinical data for patients participating in clinical studies. ONC has certified the Epic EHR as follows:

Vendor	Product	Product Version	Certification and Testing ¹	Practice Setting ²	EHR Classification ³	ONC CHPL Product Number ⁴	CMS EHR Certification ID ⁵
EPIC	EHR	2010	CCHIT	Ambulatory	Complete	1112-5473555-2	30000001SVJQEAO
EPIC	EHR	2010	CCHIT	Inpatient	Complete	1112-5743555-1	30000001SVDWEAC

- (1) The Certification Commission for Health Information Technology (CCHIT) is approved by the ONC Accredited Testing Laboratories (ATL) program for EHR testing, and by the ONC Authorized Certification Bodies (ACB) program for EHR certification.
- (2) Certification is for both ambulatory and inpatient settings.
- (3) EPIC EHR is certified as "Complete."
- (4) ONC Certified Health IT Product List (CHPL) product number to each certified system.
- (5) The Centers for Medicare & Medicaid Services (CMS) currently provides reimbursement incentives for eligible professionals and hospitals who are successful in becoming "Meaningful Users" of certified EHR technology under the EHR Incentive Program (42 CFR Part 495). A CMS EHR Certification ID is required to attest "Meaningful Use" to qualify for reimbursement.

Electronic Signature Certification

Pursuant to the Code of Federal Regulations, Title 21, Part 11, Subpart C – Electronic Signatures, this is to certify that Froedtert Memorial Lutheran Hospital, 9200 W. Wisconsin Ave, Milwaukee, WI 53226 and the Medical College of Wisconsin, 8701 Watertown Plank Rd, Milwaukee, WI 53226, intend that all electronic signatures in the Epic EHR executed by employees, agents or representatives of each respective organization, are the legally binding equivalent of handwritten signatures.

Signature

1-15-13

Date

David D. Gutterman, MD
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Signature

1/8/13

Date

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