



## Source Documentation Information

Part 11 (21 CFR part 11) provides criteria under which FDA will consider electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional handwritten signatures. Part 11 applies to any paper records required by statute or FDA 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 FDA regulations.

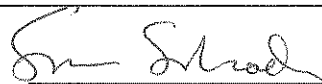
The following information regarding University of Michigan Health System (UMHS) electronic medical records systems is provided to document that these systems meet Part 11 requirements.

Vendor	Product	Product Version	Certifying ATCB*	Practice Setting* (Ambulatory/Inpatient)	EHR classification (Complete/Module)	CHPL Product Number*
Epic	EpicCare – Core EMR	2010	CC-1112-574355-2	Ambulatory	Complete	CHP-007508
Allscripts	Sunrise Acute Care Module Set	5.5 FP1	CC-1112-498885-6	Inpatient	Modular	CHP-006464
Hyland Software	OnBase	11.0	11172011-1385-8	Ambulatory	Modular	CHP-007924
Hyland Software	OnBase	11.0	12012011-1382-6	Inpatient	Modular	CHP-007917

\*In January, 2011, the Office of National Coordinator (ONC) for Health Information Technology (HIT), under the US Department of Health and Human Services (HHS), issued the final rule to establish the Permanent Certification Program for HIT (45 CFR 170). There are 6 ONC-Authorized Testing and Certification Bodies (ATCB) that test and certify Complete and/or Module Electronic Health Records (EHRs), for both ambulatory and inpatient settings, and issue a Certified Health IT Product List (CHPL) product number to each certified system. At present 5 of the 6 ATCB have been authorized by ONC to serve as ONC-Authorized Certification Bodies (ONC-ACBs); See <http://www.healthit.gov/policy-researchers-implementers/testing-laboratories-certification-bodies>.

**CMS EHR Certification ID\*\*:**

\*\* The Centers for Medical & 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 495). A CMS EHR Certification ID is required to attest "Meaningful Use" and qualify to receive reimbursement.

 4/12/13

Sue Schade Date  
Chief Information Officer  
Medical Center Information Technology  
University Of Michigan Hospitals and Health Centers