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. ICSA Labs has certified the Epic EHR as follows:

<table>
<thead>
<tr>
<th>Certifying Body</th>
<th>Practice Type</th>
<th>Product Certification #</th>
<th>Developer</th>
<th>Product Name</th>
<th>Version</th>
<th>Certification Edition</th>
<th>Additional Software Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ICSA Labs</td>
<td>Inpatient</td>
<td>CHP-0271136</td>
<td>Epic Systems Corporation</td>
<td>OptTime Surgical 2014 Certified Module</td>
<td>Epic 2015 Modular EHR</td>
<td>2014</td>
<td>EpicCare Inpatient 2014 Certified EHR Suite</td>
</tr>
<tr>
<td>4 ICSA Labs</td>
<td>Ambulatory</td>
<td>CHP-027706</td>
<td>Epic Systems Corporation</td>
<td>Beacon Oncology 2014 Certified Module</td>
<td>Epic 2015 Modular EHR</td>
<td>2014</td>
<td>EpicCare Ambulatory 2014 Certified EHR Suite</td>
</tr>
</tbody>
</table>

CMS EHR ID: 0014EKB9C00Q93W

1) ICSA Labs is an ONC-Authorized Certification Body (ONC-ACB) that is accredited to test and certify Electronic Health Record (EHR) technology for the Office of the National Coordinator’s Health IT Certification Program. ICSA Labs is authorized to certify Complete and Modular EHR technology in the ambulatory and inpatient domains.
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

Ann B. Nattinger, MD, MPH, MACP
Senior Associate Dean for Research
Lady Riders Professor of Breast Cancer Research
Professor of Medicine
Medical College of Wisconsin
8701 W. Watertown Plank Road
Milwaukee, WI 53226

Signature

Jonathon D. Truwit, MD, MBA
Enterprise Chief Medical Officer
Sr. Administrative Dean
Professor of Medicine
Froedtert & Medical College of Wisconsin
Froedtert Health Executive Office 4th Floor Cancer Center Ste C4000
9200 West Wisconsin Avenue
Milwaukee, WI 53226