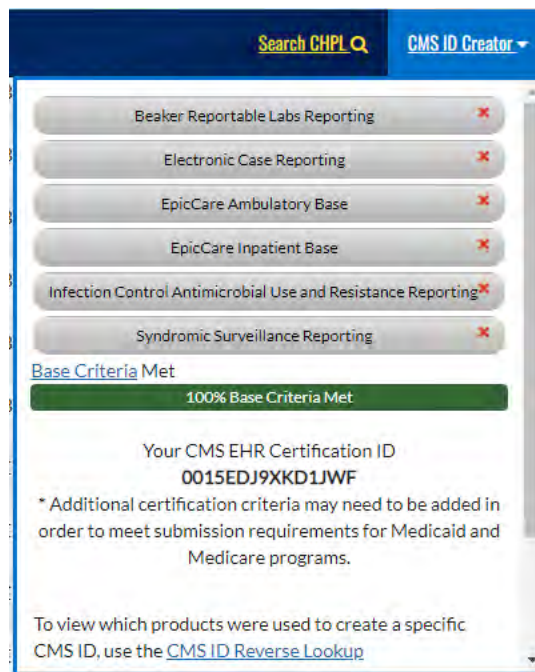


## CFR Title 21, Part 11 Attestation

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 (EHR) System.

### Electronic Health Record Certification

The 2015 Edition Health IT Certification Criteria (2015 Edition) builds on past rulemakings. On October 16, 2015, the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Modifications was published. 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. Drummond Group has certified the Epic EHR as follows:



- 1) Drummond Group is an accredited lab and certification body for Health and Human Services (HHS) under the Office of the National Coordinator (ONC) that provides high-level testing services for software developers in the healthcare space.
- 2) Certification is for both ambulatory and inpatient settings.
- 3) EPIC EHR is certified at 100% Base Criteria.
- 4) ONC Certified Health IT Product List (CHPL) EHR Certification ID.



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.

A handwritten signature in black ink, appearing to read "Ann B. Nattinger".

---

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

A handwritten signature in black ink, appearing to read "Jonathon D. Truwit".

Jonathon D. Truwit, MD, MBA  
Enterprise Chief Medical Officer  
Sr. Administrative Dean  
Professor of Medicine  
Froedtert & Medical College of Wisconsin  
Froedtert Health Executive Office  
4<sup>th</sup> Floor/Cancer Center Suite C4000  
Milwaukee, WI 53226