HL7 Electronic Health Record Work Group (EHR WG) – Reducing Clinician Burden Project
A Perspective on the History and Progression of EHR System Functionality Standards, Certification and Adoption
Updated: 30 July 2020

Let's follow the timeline...

When	Event/Activity
2000	• Health Level Seven (HL7) forms its Electronic Health Record Work Group (EHR WG). • HL7 is an ANSI-accredited Standards Development Organization, formed in 1986, which invites all industry stakeholders to participate in their open, consensus standards development process.
2003	• March: Four organizations approach HL7 to develop a standard focused on EHR System Functionality – US Veterans Administration (VA), US Department of Health and Human Services (DHHS)/Assistant Secretary for Planning and Evaluation (ASPE), Health Information and Management Systems Society (HIMSS) and the Robert Wood Johnson Foundation. • May: EHR WG begins work on the EHR System Functional Model (EHR-S FM). • Many stakeholders contribute substantially to EHR-S FM development: clinicians, provider organizations, payers, government providers (VA, DOD, HIS...), professional societies, patient advocates, public health agencies, accreditation bodies, software developers and implementers, medical device manufacturers, imaging companies, pharma, representatives from the international community and more. • The EHR-S FM includes major sections focused on Direct Care functions, Supportive functions and Information Infrastructure functions. • The EHR-S FM includes, for each function, detailed conformance criteria.
2004	• April: President George W. Bush forms the US Office of National Coordinator for Health Information Technology (ONC) under DHHS. • July: EHR WG completes balloting and publishes the first EHR-S FM, as a Draft Standard for Trial Use (DSTU). • August: The Certification Commission for Health Information Technology (CCHIT) is formed by the American Health Information Management Association (AHIMA), HIMSS and the National Alliance for Health Information Technology (NAHIT, part of the American Hospital Association).
2005	• CCHIT welcomes many industry representatives to focus on different aspects of EHR system functionality, generally across the same stakeholder spectrum represented in the HL7 EHR WG standards development work (as noted above). • CCHIT incorporates and derives many EHR-S FM functions and conformance criteria as the basis for their certification criteria. Other standards are also referenced.
2006	• EHR WG continues work to refine and update the EHR-S FM. • EHR WG begins development of many Functional Profiles (FPs). FPs allow modification and supplement of base EHR-S FM functions and introduction of specialized functions and conformance criteria – based on particular requirements of care settings, services, specialties and other domains. • CCHIT begins certification of ambulatory EHR systems. • CCHIT establishes a Roadmap for certification, outlining progressive steps year to year which raise the bar by adding additional functional requirements. The Roadmap offers forward guidance to industry.
2007	• EHR WG completes balloting and publishes EHR-S FM Release 1, as a normative Standard. • CCHIT begins certification of inpatient EHR systems.
2008	• EHR WG continues work to refine and update the EHR-S FM. • CCHIT continues certification following the progressive steps of the Roadmap.
2009	• EHR WG completes balloting and publishes EHR-S FM Release 1.1, an incremental update. • ISO TC215 (Health Informatics) completes balloting and publishes ISO/HL7 10781 EHR-S FM R1.1 as a full International Standard. • Congress passes the HITECH Act as part of the American Recovery and Reinvestment Act, including provision for the multi-stage Meaningful Use and EHR Incentive Programs.
2010	• ONC publishes its first set of EHR system certification criteria for Meaningful Use, Stage 1 (MU S1). • ONC regulations for MU S1 cast aside ISO/HL7 10781 EHR-S FM R1.1 – including its well-established functions and conformance criteria – along with all CCHIT certification criteria and its progressive Roadmap. All MU S1 criteria are new and promulgated in the form of a top-down mandate. • Although a vital component of the EHR WG and CCHIT process, the ONC regulatory process effectively excludes direct stakeholder engagement and the voice of the clinician is thus silenced.
2011	• CCHIT terminates its separate voluntary EHR system certification program, having certified ~200 systems representing about 75% of the commercial US EHR market. • *At this point, there were no dominant EHR system vendors.* • CCHIT is granted Accredited Certification Body status under the ONC MU S1 program. • ONC begins MU S1 certification of EHR systems.

2014	• CCHIT withdraws its ACB status and ceases operations. • EHR WG completes balloting and publishes EHR-S FM Release 2, a major update, with sections focused on Care Provision (CP), Care Provision Support (CPS), Administrative Support (AS), Population Heath Support (POP), Record Infrastructure (RI) and Trust Infrastructure (TI). • ONC begins MU S2 certification of EHR systems.
2015	• ISO TC215 completes balloting and publishes ISO/HL7 10781 EHR-S FM Release 2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269
2016	• ONC begins MU S3 certification of EHR systems.
2018	• EHR WG forms Reducing Clinician Burden Project, in part to identify EHR system functions and conformance criteria focused on burden reduction as a preparatory lead-in to EHR-S FM Release 3. https://wiki.hl7.org/Reducing_Clinician_Burden
2020	• EHR WG completes balloting and publishes EHR-S FM Release 2.1, an incremental update. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=528
Now in Progress	• ISO TC215 will ballot and publish EHR-S FM R2.1 as ISO/HL7 10781. • EHR WG continues to develop the framework for EHR-S FM R3. One key decision establishes that data requirements will reference FHIR Resources, Implementation Guides and Profiles, as appropriate. • EHR WG completes balloting and is ready to publish an EHR System Usability Functional Profile, based on the EHR-S FM. • EHR WG/RCB Project Team submits comments on DRAFT ISO 27269 – International Patient Summary – focused on burden reduction for clinicians who are recipients of Patient Summaries from external sources. https://wiki.hl7.org/w/images/wiki.hl7.org/9/9d/IPS-Burden_Comments-20200330.pdf
Also...	• A wide array of EHR System Functional Profiles have been developed – each establishing specific functionality for care settings, services, specialties and other domains – all based on ISO/HL7 10781 EHR-S FM. Many of these FPs have been balloted and published by HL7. https://wiki.hl7.org/w/images/wiki.hl7.org/c/cc/EHRS_FM-Functional_Profiles-20200729.pdf • A number of national initiatives are known to have used/referenced ISO/HL7 10781 EHR-S FM in their particular EHR adoption/incentive programs and the EHR-S FM has been partially or fully translated into multiple languages for these engagements. https://wiki.hl7.org/w/images/wiki.hl7.org/6/60/EHRS_FM-National_Initiatives-20200204.pdf

Assessing Clinician Burden – Is it Time to Re-evaluate our Approach to EHR System Realization, considering Open Functionality/Usability Standards and Open Development of Conformance/Certification Criteria?

From its inception, the HL7 EHR WG was organized to develop open, consensus and voluntary standards – for the US and international communities – welcoming all stakeholders materially impacted. Voluntary in this context means: 1) voluntary participation in standards development; and 2) voluntary adoption of resulting standards.

We were pleased with the formation of CCHIT (2004) who used/referenced HL7 Standards in development of certification criteria for their branded process of evaluating and certifying EHR System functionality (continuing until 2011).

We were disappointed when ONC chose to exclude references to ISO 10781 EHR-S FM, its functions and conformance criteria, along with the entire body of CCHIT certification criteria and its Roadmap, when developing Meaningful Use Stage 1 EHR Certification Criteria (2010). We were also disappointed when ONC chose to replace an open, consensus and voluntary process (as employed by HL7 and CCHIT), with a closed process which then promulgated a set of top-down regulatory mandates (continuing to this day).

We believe that a substantial portion of the current overload of clinician burden and the negative effects of burnout might well have been avoided if (US) clinicians and other key stakeholders could have continued their vital contributory role in open EHR system functionality/usability oriented standards development and the system certification process.

Now that HHS-driven EHR Incentive and follow-on Programs have succeeded in achieving wide-scale adoption of EHR systems by US providers, we urge CMS and ONC to consider how to promote open standards-setting to specify EHR system functionality, conformance and certification criteria, engaging all materially impacted stakeholders, especially front-line clinicians and more broadly the EHR system developer and user community. Their voices must be heard and their input engaged to guide the process and ensure suitable, well-ordered and productive EHR system solutions are available to meet their needs and to facilitate safe, efficient and effective clinical practice and patient engagement.