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The Health Level Seven EHR-S Records Management  
and Evidentiary Support Functional Model, Release 1  
(Based on the HL7 EHR-S Functional Model, Release 1)

**HL7 EHR-System  
Records Management and  
Evidentiary Support (RM-ES)  
Functional Profile,  
Release 1**



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## Preface

### ***i. Notes to Readers***

The EHR-S Records Management & Evidentiary Support (RM-ES) functional profile is a universal profile. It sets a foundation for other derived profiles to establish realm-specific language related to the management of health records within the EHR-S for business and evidentiary purposes and related laws/legislation, regulations and standards. The profile is unique because it does not stand on its own. The profile should be coupled with a care setting profile, specifically care settings which are required by regulation or law to maintain health records. A care setting profile will identify the functionality and conformance criteria that support the collection of content for the required health record. The RM-ES profile identifies the system functionality and conformance criteria that provide a mechanism to support the healthcare organization in maintaining a legally-sound record within their EHR system.

To reflect the universal applicability of the profile, a call for volunteers was published requesting workgroup members with a variety of expertise and from a variety of realms. The call resulted in a workgroup with members mainly from the U.S. and one member from Canada. After the public comment period additional volunteers came forward to assist with reviewing input and updating the profile. The group referenced a variety of resources (technical, professional and legal) in developing the profile including ISO, ASTM, Canada Health Infoway, CCHIT, HL7 messaging standards, *HL7 Interoperability Model*, The Sedona Conference® Working Groups (a legal think tank) and the procedures related to discovery of electronically stored information. The review identified core concepts, many of which were already in the EHR-S Functional Model and some that were new. Many of the concepts were consistent across the standards reviewed. The goal of this profile is to express those concepts in the framework of the EHR-S functional model through function statements and conformance criteria.

### ***ii. Acknowledgements***

The EHR Technical Committee is indebted to the following workgroup facilitators, members, and expert guests for their contributions towards the Records Management-Evidentiary Support domain and the materials presented in this profile.

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### ***iii. Changes from Previous Release***

In September 2008, the EHR-S RM-ES Functional Profile passed normative ballot. After the ballot period comments were reviewed and the profile updated as the final document you find here. There were a number of substantive changes reflected in the September 2008 version: 1) Addition of new child function for emergency access control; 2) Deletion of three metadata functions; 3) Elimination of the function on chronology of events; and 4) Elimination of function replication of views.

## Introduction

The EHR-S Evidentiary Support & Records Management (RM-ES) Functional Profile, a project of the HL7 EHR Technical Committee, is aimed at developing a universally applicable *HL7 Normative Functional Profile* for EHR systems, conforming to the HL7 Electronic Health Record System (EHR-S) Functional Model. An EHR-S must be able to create, receive, maintain, use and manage the disposition of records for evidentiary purposes related to business activities and transactions for an organization. One of the secondary uses for EHR data is medico-legal purposes – ISO 20514 defines medico-legal purposes as evidence of care provided, indication of compliance with legislation, and reflection of the competence of clinicians. This profile establishes a framework of system functions and conformance criteria as a mechanism to support an organization in maintaining a legally-sound health record. Since legal validity is at stake for uses of electronic records for evidentiary purposes, including admissibility of medical records, the RM-ES profile is important to health care operations and to interoperability. This profile is also aligned and supportive of the HL7 Interoperability Model which provides greater granularity for a persistent record/unit of record.

### **1 Background (Reference)**

The Legal EHR-S Profile Workgroup was established to inform HL7 and other healthcare standards development organizations (SDOs) of the unique medico-legal requirements related to electronic records management necessary to create and maintain a legally sound electronic health record within an EHR-S. The workgroup sought out members from a variety of realms and with a variety of backgrounds. Subject matter experts in the legal, technical and health information management fields participated with thoughtful insight and input. Membership in HL7 was not a prerequisite for participation.

### **2 Methods, Description and Project Plan (Reference)**

#### **2.1 Description**

An expert workgroup developed the EHR-S Records Management & Evidentiary Support Functional Profile building on the work completed by a previous group that identified EHR-S functionality for maintaining a legally sound electronic health record. The charge of this workgroup was to develop a profile for managing electronic records and maintaining a legally-sound EHR within an EHR-S by completing the following:

- Review and update the work of the previous Legal Workgroup including a review of applicable resources, specifically, ISO, ASTM, HL7 Messaging, Canada Health Infoway, the Sedona Conference® Working Groups (a legal think tank) and procedures related to discovery of electronically stored information.
- Develop a RM-ES functional profile (based on the most current version of the EHR-S functional model) including completion of applicable profile documents (i.e., profile registration), identification of applicable functionality, and development of conformance criteria.
- Determine connection, if any, between the EHR Technical Committee interoperability work/research being completed.
- Conduct a 30 day public comment period and reconcile the responses prior to balloting the profile.

## *2.2 Scope of Project*

The scope of this project was to address universal concepts in alignment with guidelines, standards, and requirements related to managing electronic records and maintaining a legally sound EHR (for any care setting maintaining).

## *2.3 Out-of-scope for Project*

Realm-specific requirements and laws, as well as principles that are not widely accepted, were out-of-scope for this project.

# **3 EHR-S Records Management & Evidentiary Support: Definition, Standards, Implementation and Interoperability (Reference)**

## *3.1 Definition*

An EHR-S must be able to create, receive, maintain, use and manage the disposition of records for evidentiary purposes related to clinical and business activities and transactions for an organization.

## *3.2 Standards and Requirements*

Some criteria and functions are based on widely accepted standards from Standards Development Organizations (SDOs) such as the International Organization for Standardization (ISO), ASTM, Canada Health Infoway and HL7 as well as 2007 EHR product certification requirements from the Certification Commission for Healthcare Information Technology (CCHIT).

## *3.3 Implementation*

It is recommended that the RM-ES profile be coupled with a care setting profile, specifically care settings (e.g. physician offices, long term care facilities) which are required by regulation or law to maintain health records. The care setting profile identifies the functionality that supports the content for the legal health record (also known as the formal health record) while the RM-ES profile identifies foundational functionality that promotes data integrity and trustworthiness. This profile is not intended to stand alone, and the following options illustrate how it could be applied:

- EHR-S Records Management-Evidentiary Support functional profile paired with a care setting profile, with the care setting profile referencing the RM-ES profile (examples of care setting profiles include the Emergency Department, Behavioral Health and Long Term Care – Nursing Home profiles),
- EHR-S Records Management-Evidentiary Support functional profile completely incorporated into the content of a care setting profile, or
- EHR-S Records Management-Evidentiary Support functional profile clarified through a realm-specific derived profile that specifies relevant jurisdictional laws, rules, and regulations (e.g. Canada could create a derived profile tailored to the realm). Care setting profiles developed in the realm could be paired with their realm specific RM-ES profile.

A care setting profile will identify the functionality and conformance criteria which supports the collection of content for the required health record and relevant realm-specific jurisdictional laws, rules and regulations. The RM-ES profile identifies universally the functionality and conformance criteria to support the maintenance of a legally-sound electronic health record within the EHR-S.