HL7 EHR Work Group
Electronic Health Record - System Functional Model, Release 2.0

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Chapter Two: Conformance Clause

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Chapter 2 Introduction (Reference)

The following is the EHR Technical Committee approved, Conformance Clause. As important background on conformance, please note the following:

1. This conformance clause defines what it means to conform to the EHR-S Functional Model.
2. Conformance to the Functional Model is defined for functional domain profiles, and for functional companion profiles. An EHR system does not directly conform to the Functional Model, rather it conforms to one or more functional profiles.
3. Conformance criteria are associated with functions in the EHR-S Functional Model.
4. This conformance clause does not specify testing or validation procedures to determine whether an EHR system conforms to a functional profile or whether a functional profile conforms to the EHR-S Functional Model.

2.1   Scope and Field of Application (Normative)

This *conformance clause* defines the minimum requirements for *functional profiles* claiming conformance to the EHR System Functional Model. It also identifies how EHR systems achieve conformance to the Functional Model, which is via the system's conformance to a particular functional domain profile, multiple functional profiles, or combination of domain and companion profiles. This clause specifies:

*   The purpose, structure, and use of conformance criteria that are to be included in the Functional Model and conforming functional profiles,
*   The rules for defining conforming functional profiles of the Functional Model,
*   The relationship between functional profiles and EHR systems,
*   Sample conformance clauses and use case scenarios,
*   Guidance on the conformance requirements that a functional profile might levy on EHR systems,
*   Guidance on the purpose and use of an EHR system Conformance Statement.

While the conformance requirements for functional profiles can be found in this clause, they necessarily reference the Functional Model and other sources.

This conformance clause does not specify testing or validation procedures to assess a functional profile's conformance to the Functional Model. It also does not specify testing or validation procedures to determine whether an EHR system conforms to a functional profile or matches its Conformance Statement.

2.2   Concepts (Normative)

2.2.1 Functional Profiles

Creating a functional profile is a method for defining subsets of the Functional Model. A functional profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain EHR systems, healthcare delivery settings, or for other purposes (e.g. profile for Records Management and Evidentiary Support EHR).

Functional profiles can be created by healthcare community stakeholders with interest in using and/or providing a functional profile for an EHR system. Functional profiles can represent the functionality required and desired for a care setting or application, or reflect the functionality incorporated in a vendor's EHR system. Once a functional profile is defined it can be implemented by EHR systems or it may trigger the creation of derived functional profiles. A *derived functional profile* is a functional profile that is created from an existing functional profile, inheriting functions from the base (existing) functional profile.

There are two types of functional profiles. The Functional Domain Profile is the common type of profile used to describe an EHR system for use in one or more care setting, or an EHR systems for use in a selected realm to meet the rules, regulations and standards applicable for that realm. The Functional Companion Profiles is a type of profile that must be paired with one or more Domain Profiles. The purpose of a Companion Profile is to add unique features to an EHR System, such as for research or for evidentiary support. For example, many EHR systems in a clinic environment do not need to support clinical research. But for a clinic that was supporting advanced research, they might want an EHR system that was both capable of all of the expected functions for routine clinic patient care activities, but also had unique feature to support the nneds for research reporting and clinical trials.

There are two type of mandatory inheritance in the EHR-S FM. All Functional Domain Profiles will inherit all functions in the Overview section of the Function List Chapter and their related "shall" criteria. All criterion listed in a parent function will be applicable to all the childen of that parent function.

A formal process exists for registering and balloting functional profiles. Functional profiles that are submitted to the HL7 EHR WG with an attestation of conformance to Chapter 2: Conformance Clause of the HL7 EHR-S Standard and successfully complete review by the WG are designated as "*Registered functional profiles*". Registered functional profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR TC ballot at the committee level will be designated as *HL7 Informative functional domain or companion profiles*. HL7 Informative functional profiles are eligible to undergo full membership ballot via the HL7 consensus process. *For additional information on registering and/or balloting functional profiles, see the reference information in the How To Guide for Profiles (under development).*

2.2.2 Conformance Model

Conformance to the Functional Model is defined for functional profiles. A functional domain profile conforms either (1) directly to the Functional Model or (2) to another conforming functional domain profile.   NOTE: All domain profiles must include all the functions and 'SHALL' criteria of the Overarching Chapter. An EHR system does not conform directly to the Functional Model; rather, it conforms to a functional domain profile, or to a domain profile in combination with a selected companion profile . Thus, functional profiles claim conformance to the Functional Model and EHR systems claim conformance to one or more conforming domain functional profiles. An EHR system can also claim conformance to a domain functional profile, in combination with one of more companion profiles. An EHR system cannot claim conformance to only a companion profile.   Figure 1 on the next page illustrates this relationship.
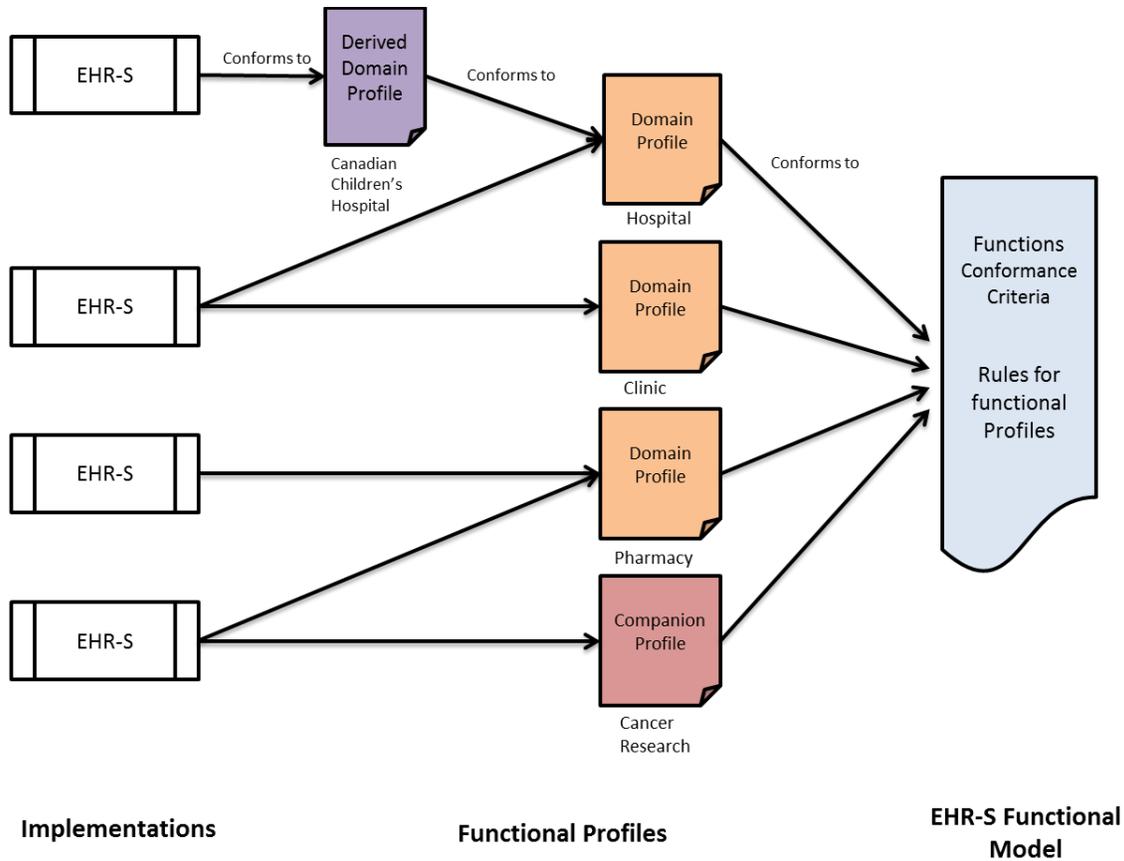
Figure 1 Conformance Relationships

2.2.3 Profile Traceability

Functional profiles allow for added specificity and extensibility to the Functional Model with changes allowed to the base FM functions and criteria. However, section six of this chapter defines rules for these changes. It is also required that any changes and additions be tracked. Two added columns in profiles accomplish this. One column will document the unique source FM row number for each item in the new profile (or source profile for a derived profile). The second column will provide codes for the type of changes from the source FM (or source profile). Together, these two traceability columns will keep track of the origins of the functions or criteria – and whether it is modified or unchanged from that within the FM or the source profile. This may be important when questions arise as to where did it come from, why did you choose or modify it, etc. It can also be helpful to have traceability back to the FM functions and criteria if and when revisions to a profile or for derived profile are needed to reflect care setting, regulatory, technology changes – or a future new release of the FM..

Figure 2 Conformance Relationships

2.3   Normative Language (Normative)

The following keywords (i.e., normative verbs) **SHALL** be used to convey conformance requirements.

- SHALL – to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
- SHALL NOT – to indicate a prohibited action. Synonymous with 'prohibited'.

- SHOULD - to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
- MAY - to indicate an optional, permissible action. Synonymous with 'is permitted'.

The EHR-S Functional Model (i.e., all chapters) contains normative, informative, and reference sections. In this conformance clause chapter, the normative content defines how a functional profile achieves conformance to the Functional Model.

2.4 Conformance Criteria (Normative)

Every function in the Functional Model is associated with a set of conformance criteria. These *conformance criteria* form the basis for determining whether the function has been implemented.

2.4.1 Criteria in the Functional Profile

Functional profiles also have conformance criteria associated with functions in the functional profile. The functional profile's criteria are either (1) adapted from the Functional Model criteria with care-setting and application specific information or (2) if no care-setting or application specific criteria are present, inherited directly from Functional Model. Functional domain and companion profiles **MAY** change Functional Model criteria to match the needs and priorities of the functional profile's constituency, e.g., by making it more specific, or changing it from 'may' or 'should' to 'shall'. The functional domain profile **SHALL NOT** be made less restrictive than the Functional Model by changing 'shall' criteria to 'may' or 'should' criteria (The functional companion profile MAY be less restrictive that the FM by ignoring 'shall' criterion). Functional domain and companion profiles **MAY** also add additional criteria.

2.4.2 'Dependent SHALL' Criteria

Conformance criteria that contain the keyword 'shall' **and** a dependency on situational conditions are called 'dependent shall' criteria. The 'dependent shall' **SHALL** contain the phrase "in accordance with scope of practice, organizational policy, or jurisdictional law" or other appropriate grammatical tie-in words (e.g., 'based on' rather than 'in accordance'). A 'dependent shall' criteria is used to highlight only these (i.e., scope of practice, organizational policy or jurisdictional law) conditions. A 'dependent shall' criterion is a mandatory criterion for functional profiles and situational for EHR systems. Specifically,

- All functional domain profiles SHALL inherit the criterion, if the function appears in the functional profile.
- An EHR system SHALL implement the criterion only if the criterion is applicable per the stated dependency in the functional model

2.4.3 Referencing Other Criteria or Functions

There is often a link between functions and their criteria with other functions and criteria. For example, a given function may depend on another function or on a specific criterion associated with another function.

A criterion in the functional profile that references another function in the functional profile **SHALL** reference that function by indicating its name and ID, as "X.n.n (Name)". If the referenced function is required to be implemented, then all the 'shall' criteria of this referenced function apply. If the referenced function is a parent with children, the reference must be explicit on whether the children are included in the reference, all or selected ones. See the examples below:

- The system SHALL/SHOULD/MAY conform to TI.1.1 (Entity Authorization) …
- The system SHALL/SHOULD/MAY conform to TI.2 (Audit) and all child functions.

- The system SHALL conform to CPS.4 Support Orders , and separate function(s) The systems SHALL conform to CPS.4.3 Non-medication Orders. The systems SHALL conform to CPS.4.6 Support for Referrals and all children functions

A criterion in the functional profile that references a specific criterion in another function **SHALL** reference that function by rewriting the referenced criterion as one of its own and indicating a (ref: F#, CC3) the function and criterion number from where it came.

2.5   Functional Model Structure and Extensibility (Normative)

2.5.1 Hierarchical Structure

Functions **MAY** be contained (i.e., nested) within other functions. A nested function is a 'child' to its 'parent' (i.e., the function that contains it).   A child **SHALL** always have a parent. A function that is not a parent to another function is considered a 'leaf'. Figure 2 illustrates this hierarchical structure.

The Functional Model is represented as a hierarchical list of functions, consisting of functional header parents, functional header children and functional leaf functions. Headers include an ID, Name and "P" in the column labeled "Type". Parent and Child Headers **MAY** contain conformance criteria only if the criteria apply to all its descendent functions (i.e., children, grandchildren,and leafs).   Leaf functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria and have a "L" in the "Type" column. Conformance criteria listed in a parent function **SHALL** be inherited by all its children functions.
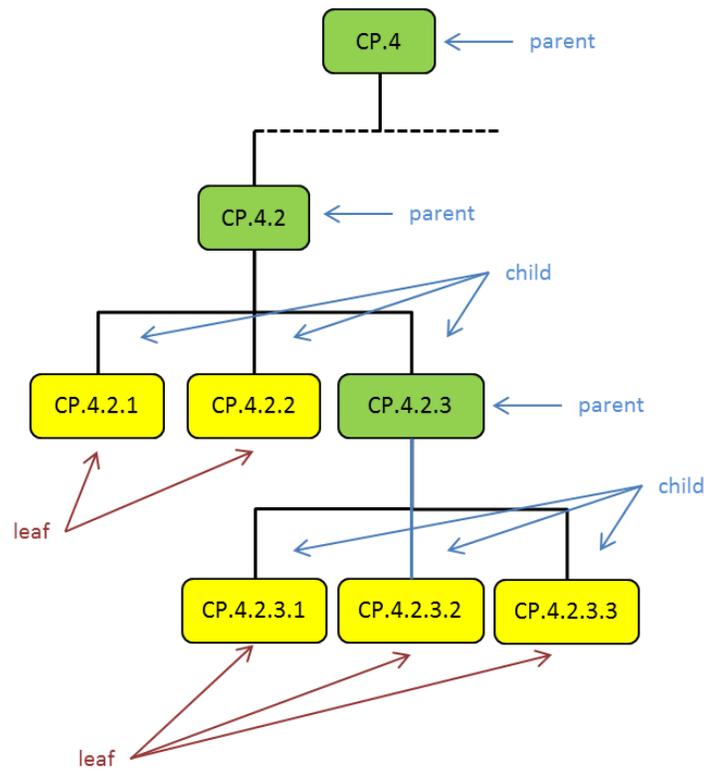

Figure 3 Portion of the Functional Model hierarchical structure

(Note: The numbering schema above reflects functions in the Care Provision chapter. For instance, CP.4.2 is the function 'Manage Medication Orders.)

Functional profiles either:

- Select functions from the Functional Model for inclusion in the functional profile,
- Deem a function in the Functional Model as not applicable, thus do not select it for inclusion in the functional profile,
- Add a new child function when it has been determined that there is no applicable function in the Functional Model to represent a functional need in the functional profile.

2.5.2 Naming Convention

Functional profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the functional profile. It is recommended that the HL7 Affiliate for the respective realm coordinate and the profile maintain a mapping of the Functional Model function name and/or statement and the realm-adjusted name and/or statement.

2.5.3 Priorities

Functional profiles indicate the importance and/or immediacy of a functional profile by associating a priority with a function. Three priorities have been defined, Essential Now, Essential Future, and Optional.

- Essential Now indicates that the implementation of the function is mandatory, as of the profile issuance date.
- Essential Future indicates that the implementation of the function is currently optional but will be mandatory at some future time, which is specified by the functional profile
- Optional indicates that the implementation of the function is optional.

Any or all of these priorities **SHALL** be used in a functional profile. If the Essential Future priority is used, then functional profiles are required to define the timeframe associated with implementing functions. A timeframe **MAY** be a date, time allotment (e.g., year 2008 or 4 months after functional profile publication), or event (e.g., republication of this functional profile). A functional profile **MAY** define multiple timeframes for the Essential Future priority. If multiple timeframes are defined, then the timeframe **SHALL** be used to qualify each occurrence of the Essential Future priority (e.g., EF-2008, EF-2009).

2.5.4 Extensibility

To accommodate changes in technology as well as functional profiles' needs, the Functional Model is designed for extensibility, for functions and their related criteria. Incorporation of additional functions in the functional profile beyond what is defined in the Functional Model is accommodated through a set of rules for adding new functions as defined in Section 2.6.2.

Incorporation of additional criterion, changing the sequence of criterion and providing greater profile-specific detail, beyond what is defined in the Functional Model, is accommodated through a set of rules for adding new criterion or changing existing criterion as defined in Section 2.6.2.

2.6 Functional Profile Conformance (Normative)

A functional profile claiming conformance to the Functional Model **SHALL** meet all requirements specified in the 2.6.1 Rules for Functional Domain Profiles or in the 2.6.5 Rules for Functional Companion Profiles.

2.6.1 Rules for Functional Domain Profiles

Functional domain profiles that adhere to the Rules for Functional profiles **SHALL** claim conformance to the version of the EHR-S Functional Model from which it was derived.

Functional profiles claiming Functional Model conformance SHALL:
1. Identify the Functional Model with version/date, from which the functional profile is derived,
2. Include a description, version and issuance date of the functional profile,
3. Contain a conformance clause which
   a) Defines the requirements that EHR systems must satisfy in order to claim conformance to the functional profile,
   b) Defines the requirements that functional profiles derived from the functional profile (i.e., derived functional profiles) must satisfy in order to claim conformance to the functional profile.
   c) Specifies that functions designated with the priority 'Essential Now' SHALL be implemented by conformant EHR systems.
   d) Specifies that functions designated with the priority 'Essential Now' SHALL be included in any derived functional profiles.
   e) If Essential Future is used, defines the meaning of 'Essential Future', including specifying the timeframe for when these functions are required to be implemented.
   f) Requires that at least one function, regardless of its priority, be implemented in order for an EHR system to claim conformance to the profile.
4. Include all functions in the Overarching section of Chapter Three as Essential Now and identify functions from other section of Chapter Three of the Functional Model that are applicable to the functional domain profile. For each identified function, indicate its priority (i.e., Essential Now, Essential Future or Optional).
5. For each function, derive conformance criteria based on the Functional Model's conformance criteria.
   a) In the functional profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
   b) If there are 'shall' criteria (for the function in the Functional Model), then those criteria **SHALL** also exist for the function (in the functional profile). Additionally, if the function is split (in the functional profile), then the parent's 'shall' criteria **SHALL** appear in at least one child of that function.
   c) If, as yet there is no 'shall' criterion (for the function in the Functional Model), then at least one of the 'should' or 'may' criterion **SHALL** be made mandatory, i.e., a 'shall' criterion.
   d) Adhere to the rules for referencing functions or criteria in Section 4.3.
6. For any function in the functional model where one or more criteria are 'dependent shall' criteria, the functional profile for that function SHALL
   a) Replicate verbatim each 'dependent shall' in the functional profile, regardless of whether the dependent situation applies or not.
   b) When the dependent situation applies, create 'shall' criteria that apply the dependency to the 'dependent shall' criterion, resulting in one or more new, constrained versions of the 'dependent shall' criterion.
   c) State the specific scope of practice, organizational policy, and/or jurisdictional law which applies or state why these dependencies do not apply.
7. Adhere to the rules for creating new functions in functional profiles in Section 6.2.
8. Adhere to the rules for creating and changing conformance criteria in Section 6.1.2
9. Complete the two traceability columns, see Section 2.2.3, for any changes to functions or criteria, and include the following codes for type of change: (1 – sequence, 2 – optionality, 3 – content, 4 – new). Multiple codes are allowed to document the type of

changes. For example criterion #3 that is move to #1, changed from SHOULD to SHALL and with realm specifics on standards required would be "1,2,3".

10. Be structured in accordance with the structural requirements defined for the Functional Model in Section 2.5.1
11. Use the Glossary Action verbs for modifying or creating new conformance criterion.

Functional domain profiles claiming conformance to the Functional Model MAY:

1. Create additional functions according to the rules specified in Section 2.6.2.
2. Contain conformance criteria more specific and limited in scope than those of the Functional Model.
3. Replace the text 'standard(s)-based' found in some criteria with specific standards and/or specifications named at the most discrete level of designation.
4. Change a 'should' criterion to a 'shall' or a 'may' criterion.
5. Change a 'may' criterion to a 'shall' or a 'should' criterion.
6. Ignore a 'should' or 'may' criterion in the functional model (i.e., not include it in the functional profile).
7. Add additional conformance criteria beyond those in the Functional Model.
8. Make the order of the conformance criteria significant (e.g., put all 'shall' criteria first).
9. Enforce common resolution of ambiguous semantics of the Functional Model.
10. Make the functional profile public (e.g., published on a web site) so interested parties can see/use it.
11. Submit the functional profile for registration review by the HL7 EHR Work Group.

Functional domain profiles claiming conformance to the Functional Model SHALL NOT:

1. Specify any requirements that would contradict or cause non-conformance to the Functional Model.
2. Modify the name or statement of any function in the Functional Model, except to allow for alignment with realm specific nomenclature as specified in Section 5.2.
3. Change a mandatory conformance criteria to an optional criteria (i.e., replace the 'shall' within the criteria to 'should' or 'may') of any function in the Functional Model.
4. Modify any requirements of a function not selected for the functional profile (i.e., all unselected functions default to the Functional Model's criteria. If a profiling group wants to change something, they SHALL promote it into their functional profile).

2.6.2 Rules for Creating New Functions in Functional Profiles

If a function is not adequately specified for a functional profile or does not exist, the functional profile **SHALL** only create new children, the new children can be parents or leafs . Figure 3 illustrates the addition of a new child function.
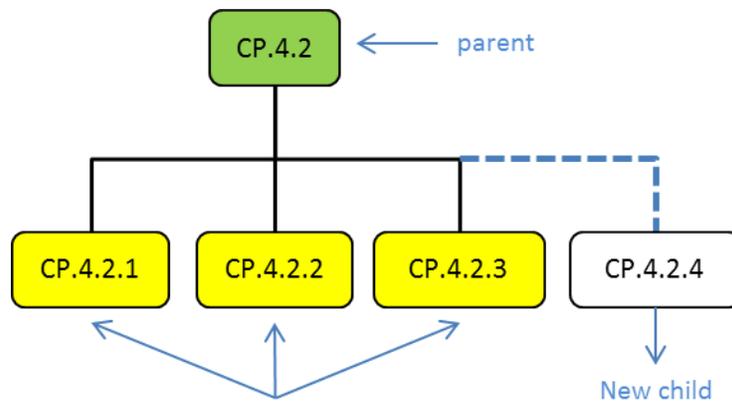
Figure 3 Creating a new function

The following rules specify the method for creating new functions.

1. Whenever possible, conformance criteria SHOULD be used to avoid creating a new function. This may be done, for example, in cases where the original function's conformance criteria are too broad: divide the Functional Model's or base functional profile's inherited conformance criteria into two criteria in the functional profile, one being mandatory and the other optional.

2. When a 'leaf' function exists (a child that is not a parent) but is too broadly specified in the Functional Model or base functional profile for conformance criteria to adequately constrain it, then the function MAY be split as follows:
   a) The original 'leaf' function is retained as the parent of its newly created children functions,
   b) The original 'leaf' function's conformance criteria **SHALL** be distributed among its children functions.

3. When no candidate function exists to express the requirements of a functional profile, a new child function MAY be created (e.g., adding a new kind of summary list under the summary list's parent).

4. 'Parent functions SHALL NOT be split. This preserves the structure of the underlying functional model in the functional profiles.

If new children functions are created by a functional profile that is balloted or registered, these new functions will be captured by the HL7 EHR WG and tracked for review. The EHR TC **WILL** use these new functions and related criterion as input and candidates for changes to the Functional Model (e.g., inclusion, relaxation of conformance criteria). The EHR WG MAY maintain a file of functions and criterion reviewed and rejected for inclusion in a future version of the FM.

2.6.3 Rules for Derived Functional Profiles

Derived functional domain profiles claiming conformance to one or more base functional domain profiles SHALL:

1. Adhere to all the rules for functional profiles as specified in Section 2.6.1
2. Adhere to the rules for creating new functions as specified in Section 2.6.2, if not prohibited by the base functional profile.
3. Identify the base functional profiles from which it is derived.
4. For each function inherited from a base functional profile, retain and not change mandatory conformance criteria to optional conformance criteria.

2.6.4 Conformance Statement

Functional profiles **MAY** want to require that a conformance statement be produced for systems claiming conformance to the profile. A *Conformance Statement* provides information about an

EHR system, by presenting in a uniform manner the functions that have been implemented by the EHR system. A blank (i.e., yet to be completed) Conformance Statement typically takes the form of a questionnaire or checklist, to be completed for each EHR system.

A Conformance Statement provides a concise summary of a functional profile. It follows a standard layout, thus providing EHR system vendors and users a quick overview of the functional profile's functions. Moreover, it can also be used to highlight optional functions and capabilities supported by the EHR systems as well as document any extensions (i.e., additional functionality beyond what is in the functional profile) or specializations that have been made. An EHR system's Conformance Statement provides information that can be used in assessing the EHR system's conformance to a specific functional profile. Additionally, organizations wishing to acquire an EHR system **MAY** produce a Conformance Statement to indicate the functions that are required and/or desired in an EHR system

Functional profiles **MAY** want to include a blank Conformance Statement in order to promote consistency among completed Conformance Statements. Conformance Statements can be useful in determining the chances of interoperability between two EHR systems, by comparing the functions supported by each EHR system. Additionally, for conformance testing purposes, it can be used to facilitate the selection of tests that would be applicable to a particular EHR system being tested. For example, if an EHR system did not implement functions designated as 'Essential Future', this would be evident in the Conformance Statement and the tests for these functions (which are unimplemented) would not be performed.

2.6.5 Rules for Functional Companion Profiles

Functional companion profiles that adhere to the Rules for Functional profiles **SHALL** claim conformance to the version of the EHR-S Functional Model from which it was derived. Functional companion profiles will follow the section 6.1 Rules for Functional Domain Profiles and the section 6.3 Rules for Derived Functional Domain, except for the exceptions and addition described below:

Functional companion profiles claiming Functional Model conformance SHALL:
1. Adhere to section 6.2 for adding new functions,
2. Contain a conformance clause which
   a) Defines at least one functional domain profiles for which the companion profile can be linked that EHR systems must satisfy in order to claim conformance, or state any specific domain profiles that can or cannot be link to the companion profile,
   b) Defines the requirement(s) that companion profiles derived from the base functional companion profile (i.e., derived functional profiles) must satisfy in order to claim conformance to the functional companion profile.
3. Include **only functions being modified** from the Overarching section of Chapter Three as Essential Now and identify functions from other section of Chapter Three of the Functional Model that are applicable to the functional companion profile. For each identified function, indicate its priority (i.e., Essential Now, Essential Future or Optional).
4. For each function, derive conformance criteria based on the Functional Model's conformance criteria.
   a) In the functional profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
   b) If there are 'shall' criteria (for the function in the Functional Model), then those criteria **MAY** also exist for the function (in the functional companion profile) if changes.. Additionally, if the function is split (in the functional profile), then the parent's 'shall' criteria **MAY** appear in at least one child of that function.
5. For any function in the functional model where one or more criteria are 'dependent shall' criteria, the functional companion profile may elect to ignore the criterion, but **if selected** for that function SHALL follow the rules of section 6.1.1.

Functional companion profiles claiming conformance to the Functional Model MAY:
1. Ignore a 'shall', ''should' or 'may' criterion in the functional model (i.e., not include it in the functional profile).

There are no exceptions to section 2.6.3 for Derived Functional Companion Profiles

2.7 Use Cases and Samples (Reference)

2.7.1 Functional Profile Use Cases

Care Setting

It is determined that a new care setting functional domain profile is needed to reflect the care setting specific requirements. To help ensure widespread use and uniformity, the functional profile authors elect to undergo the registration review followed by the HL7 consensus process (i.e., submitting the registered functional profile for an "Informative" committee level ballot). If successful, the result will be designated a HL7 Informative Functional Profile.

After looking at current list of HL7 informative functional profiles, the decision to create a new functional profile is made. Each function in the EHR System Functional Model is examined and those that are relevant to the care setting are chosen. From these functions, a small set of 'core' functions are selected as being essential and mandatory. For each function, conformance criteria is developed either adapting the Functional Model conformance criteria or in a few cases, using the Functional Model criteria as is. To complete the functional profile, a description of the functional profile, including its intended use and audience as well as a conformance clause is written. The functional profile is made public by publishing it on various web sites. Additionally, the functional profile is submitted to HL7's EHR technical committee for registration review, comment and ballot.

Community of Interest derived functional domain and companion profiles

A community of interest (e.g., regional health information exchange network) wants a functional domain profile to reflect their specific needs, and the needs of one of their members to support clinic research.

The Community of Interest doesn't want to create a new functional profile from scratch. After looking at the list of Registered Functional Profiles, they find an existing functional profile that is very close to what they want. Using this functional profile as the base, they accept all the functions designated as 'Essential Now', reject functions designated as 'Future' and add several more functions. For each function, they review the conformance criteria and adapt the criteria to reflect their situational information.

For the one member of the community that needs to support research, a functional companion profile is created. The functional profile is only needed to address the narrow areas of operation that are specific to research. So, the group finds an existing companion profile for clinical research and modifies it to reflect the functions needed for the specific disease state implications for the research activities of their member. Now the Community of Reference can seek a vendor that can meet the needs of both the domain profile for the group and the companion profile for the unique member.

Vendor functional domain profile and overarching conformance

A vendor with an EHR system wants to claim conformance to the EHR System Functional Model.

The vendor identifies and lists all the functions that are in his product. The vendor adds a description and a conformance clause (see samples in section 7.2). This is the vendor's functional domain profile. If the vendor has actually implemented all the functions listed, then this is equivalent to 'Essential Now' and these functions are mandatory. If functions that are currently implemented and those that will be implemented in the future are listed, then the functional profile is comprised of 'Essential Now' and 'Essential Future' and/or optional functionality. Finally, the vendor adds conformance criteria for each function, inheriting some criteria directly (without

change) from in the Functional Model. But can also add new criterion to reflect added system features. If all children of a function have the same new criterion, that criterion would be moved to the parent function as overarching, and applicable to all the children. This is appealing in that, the vendor has the opportunity to list all the current functionality and if desired, indicate future plans. In essence, this is similar to a vendor Conformance Statement (a concept most vendors are already familiar with). A vendor may create multiple functional profiles.

2.7.2 Sample Functional Domain Profile Conformance Clauses

To aid functional profile developers in developing a conformance clause for their functional profile, as required by Section 6.1 rule #3, the following examples are offered. Note: in these examples, the keywords 'shall', 'should', and 'may' are capitalized and bold. This is a convention to draw attention to the keywords.

Conformance clause for a care-setting functional domain profile

This functional domain profile defines the conformance requirements for EHR systems and derived functional domain profiles. To conform to this functional profile, all 'Essential Now' functions **SHALL** be implemented. 'Essential Now' functions are considered mandatory functions. An EHR system is conforming if it implements all the functions designated as 'Essential Now' and the mandatory conformance criteria associated with that function. A derived functional domain profile is conforming if it follows the Rules for functional profiles.

Mandatory conformance criteria are indicated by the keyword 'shall**'**. Optional conformance criteria are indicated by the keywords 'should' or **'**may'.

EHR systems **SHALL** provide a Conformance Statement structured according to the rules and policies defined in this functional profile.

Conformance clause for an application

E-Application is an application that if included in a care-setting specific system **SHALL** conform to this functional profile. E-Application is an application that has a defined set of attributes of which a minimum set of functions is required of any system claiming this e-Application functionality. Two levels of conformance are designated:

- Core Conformance is comprised of the functions in the minimal set of functions that are designated as 'Essential Now'.
- Advanced Conformance comprises the entire minimal set of functions (i.e., all 'Essential Now' as well as those designated 'Essential Future' functions).

A system **MAY** claim conformance to either the Core or Advanced Conformance levels, if it implements all the mandatory criteria for the functions at the conformance level for which the claim is being made.

Functions designated with the priority 'Essential Now' indicate core functionality. These functions are required to be implemented in order to claim conformance to E-Application, regardless of the level of conformance (i.e., core or advanced) to which the claim is made.

Functions designated with the priority 'Essential Future' indicate advanced functionality. These functions are required to be implemented in order to claim advanced level conformance. 'Essential Future' functions become mandatory 18 months after publication of this functional profile and thus, required for immediate implementation in order to claim conformance at either the core or advanced levels.

Conformance clause for a vendor system functional domain profile

Conformance is defined for My-EHRsystem. All functions in this functional profile are mandatory, are deemed as 'essential now', and **SHALL** be implemented in order to conform to this functional profile.

Conformance clause for a community of interest functional companion profile

Conformance is defined for BuyMyDiabetesEHR. To conform to this functional companion profile, all functions labeled as 'essential now' **SHALL** be available and have been implemented, , and all functions labeled 'essential now' in the Long Term Care or Ambulatory domain profile must also be available and implemented. Functions labeled 'essential future' are optional, in that they are present for informational purposes only and **MAY** be implemented in future functional companion profiles.

2.8   Interpreting and Applying a Conditional 'SHALL' (Reference)

Conformance criteria in the FM and those created can be structured in the simple format an Actor followed by normative verb followed by action or property. For example: The system **SHALL** capture demographic information as part of the patient record.

However, there are two conditional forms for which if the condition is true, then the following text must apply. One is If/Then. If condition, then Actor followed by normative verb followed by action. If the condition is not met (i.e., false) then ignore the rest of the sentence. For example, IF data is exchanged with internal or external systems, THEN the system **SHALL** conform to function IN 5.1 (Interchange Standards)

The other is a 'Dependent Shall' format. Actor followed by normative verb followed by action/interaction followed by 'according to scope of practice, organizational policy or jurisdictional law'. For example, The system **SHALL** enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional law.

The following example of a Functional Model 'dependent shall' criterion will be used to illustrate conditional concepts throughout this section.

> *Functional Model criterion: The system **SHALL** enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional laws.*

2.8.1 General Concepts

The purpose of the 'dependent shall' is to allow functional profiles to constrain a Functional Model 'shall' criteria based on situational conditions such as policy and legal implications. Specifically, the 'dependent shall' criteria in the Functional Model are 'shall' criteria + a dependency, where the dependency is defined by:

- Scope of practice which applies to the EHRs user's scope of practice and refers to best practices within the user's discipline – which may be care setting specific or not.
- Organizational policy which refers to a plan or course of action intended to influence and determine decisions, actions, and other matters of a group of persons organized for a particular purpose within an association and structure through which individuals cooperate systematically to conduct business.
- Jurisdictional law which refers to the territorial range of authority or control with the power, right, or authority to interpret, apply, and declare the body of rules and principles governing the affairs of a community and enforced by a a political authority; a legal system.

The structure of the 'dependent shall' criteria in the Functional Model is the same as the 'shall' criteria except with the addition of the phrase "in accordance with scope of practice, organizational policy or jurisdictional law" or other appropriate grammatical tie-in words (e.g., based on rather than in accordance). Note that all three dependencies are present in the Functional Model 'dependent shall' criteria.   It is the functional profile that narrows it to any one dependency or any combination of the three.   Moreover, in the functional profile, the specific

scope of practice, organizational policy, and/or jurisdictional law which necessitates evoking the 'dependent shall' is explicitly identified.

For example: (derived from the Functional Model criterion above)

> *Functional Model criterion: The system SHALL enable EHR-S security administrators to grant authorizations in accordance with HIPAA.*

The difference between a 'shall' criterion and a 'dependent shall' criterion is shown in Table 1 below.

	'SHALL' Criterion	**'Dependent SHALL' Criterion**
Be present in the functional profile	Yes, either verbatim or modified (e.g., constrained or refined)	Yes, verbatim. If dependency exists, add additional criteria reflecting the dependency.
Implemented by EHR systems	Yes.	Situational - only implement if the dependency exists. Specifically, EHR system does not implement the 'dependent shall' criterion (as copied from the FM), but does implement additional 'shall' criteria created to reflect the dependency.

Table 1 Differences between 'shall' and 'dependent shall'

2.8.2 Rationale for 'Dependent SHALL'

The reason for using a 'dependent shall' in the Functional Model is to highlight these criteria and bring them to the attention of the reader – both developers of functional profiles as well as other users. These criteria are considered to be special cases, where there are one or more dependencies that affect these criteria, across multiple care settings. Using the 'dependent shall' ensures that developers of all functional profiles address the criterion and consciously decide whether the criterion in question is applicable, based on the stated dependency.

Regardless of whether a dependency exists or not, the 'dependent shall' is copied verbatim into the functional profile. The reasons for this are:

* Adherence to the rule that a 'shall' criterion is always inherited by the functional profile.
* Consistency with handling the 'dependent shall' under all conditions (i.e., when there are dependencies and when there are not.
* Retention of the 'dependent shall' so that it is present for derived profiles.
* Retention of the 'dependent shall' so that it remains effective for this profile if future requirements change (i.e., the dependency may not be applicable at this present time, but may be applicable in the future due to changes in scope of practice, organizational policy or jurisdictional law.

2.8.3 How to Apply the 'Dependent SHALL'

The way to interpret and apply a 'dependent shall' criterion in a functional domain profile is as follows:

* Copy the criterion into the functional profile.
* Review the criterion and determine if any of the dependencies are applicable to the functional profile.
* Dependency exists

  If one or more dependencies are applicable to the functional profile (e.g., there are jurisdictional legal requirements), add one or more 'shall' criteria that refine and further constrain the 'dependent shall' with respect to the dependencies.

For the new criteria, add an explanation and/or citing for the dependency. For example, jurisdictional legal requirements for this functional profile are defined by Federal Regulations (see 45 CFR Parts 160, 162 and 164 – The HIPAA Security Rule. The explanation or citing may be in an appendix. It is likely that multiple criteria will reference the same explanation or citing.

Examples:

Functional Profile criteria

1. The system SHALL enable EHR-S security administrators to grant authorizations to principles in accordance with HIPAA*.

2. The system SHALL enable EHR-S security administrators to grant authorizations for roles in accordance with 42 CFR Part 2*.

Dependency Explanation

*For a U.S. realm functional profile, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as other jurisdictional legal requirements or other more stringent requirements would be applied to 'dependent shall' criteria in the functional profile.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	Yes	Mandatory	Copy SHALL from FM
		Mandatory	Add additional criteria to reflect the dependencies. Use 'shall'.
		Mandatory	Add explanation or citing
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 2 Summary of actions when dependency exists

2. No Dependency exists

If no dependency is applicable to the functional domain profile (i.e., there are no scope of practice, organizational policies or jurisdictional legal requirements that apply), then document the rationale for deciding that no dependencies apply. This explanation may be in an appendix. It is likely that this explanation will apply to multiple 'dependent shall' criteria.

FM	Dependency Applicable?	Applicability	Functional Profile
Dependent SHALL	No	Mandatory	Copy SHALL from FM
		Mandatory	Add explanation
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 3 Summary of actions for when no dependencies

- Add additional criteria – regardless of whether a dependency exists or not.

It is always permissible for a functional profile to add new criteria. Add new criteria that are derived from the 'dependent shall'. Use any keyword: 'shall', 'should' or 'may' (see Section 3) in these new criteria.

Examples:

*1. The system **SHOULD** enable EHR-S security administrators to grant authorizations to principals.*

*2. The system **MAY** enable EHR-S security administrators to grant authorizations for roles.*

*3. The system **SHOULD** enable EHR-S security administrators to grant authorizations within contexts.*

*4. The system **SHALL** enable EHR-S security administrators to grant authorizations for roles for organizations with 10 employees or more.*

2.9 Definitions (Reference)

Additional terms are listed in the HL7 EHR-WG Functional Model Glossary.

Term	Description
Base functional profile :	An existing domain or companion functional profile from which new functional profiles are created/derived.
Conformance:	The fulfillment of a product, process, or service of specified requirements.
Conformance criteria:	Requirements indicating the behavior, action, capability that constitutes implementation of the function.
Conformance clause:	A section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance.
Conformance Statement:	A description of the function in an EHR system that have been implemented. It reflects the degree to which an EHR system has met the functionality has met the functional profile's requirements and may include optional functions and information.
Derived functional profile:	A functional domain or companion profile that is created from a base functional profile, (i.e., child functional domain profile to children's hospital domain profile).
Extension:	The ability for an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile.
Functional profile:	A subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR systems or healthcare delivery settings or narrow operation requirements.
Informative functional profile:	A registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process.
Inherited criterion:	All the conformance criteria listed in a parent function will be inherited by all its children functions,
Registered functional profile:	A functional profile that has successfully completed HL7 EHR Work Group registration process and review.
Situational criterion:	Criterion that is required if the circumstances given are applicable. (IF/Then or Dependent SHALL)