

NCPDP-HL7 Pharmacy/Pharmacist Provider Functional Profile Work Group

Pharmacy/Pharmacist Provider Functional Profile

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Chapter Two: Conformance Clause

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Chapter 2 Introduction (Reference)

This profile is based upon the HL7 EHR-S Functional Model, Release 1.1 dated June, 2009, available at <http://www.hl7.org/ehr> and incorporates the model's conformance chapter here by reference with a few extensions as described below. Key to the Functional Model and derived profiles is the concept of *conformance* which may be defined as “*verification that an implementation faithfully meets the requirements of a standard or specification*”. A profile can be said to conform to the functional model if it adheres to the defined rules identified by the functional model specification. The Pharmacist/Pharmacy Provider EHR-S Functional Profile adheres to the defined rules of the EHR-S Functional Model. Similarly, an EHR system may claim conformance to the Pharmacist/Pharmacy Provider EHR-S Functional Profile if it meets all the requirements outlined in this profile.

2.1 Functional Priority

The Pharmacist/Pharmacy Provider EHR-S Functional Profile Workgroup recognizes that clinical computing is an evolving field, and that many of the desired functions of EHR systems are not currently available. Nevertheless, it is important for functional profiles to outline major trends and articulate a vision for functionality (especially interoperability) for the future. Furthermore, the delineation of potential functions for future implementation and adoption should guide vendors in system development, and help purchasers develop and articulate to vendors a strategic vision for future functional requirements.

Each function in the profile is assigned a single priority as follows:

EN	Essential Now	Indicates that the implementation of the function is mandatory and SHALL be implemented in EHR systems claiming conformance to this profile.
EF XXX	Essential Future	Indicates that the function has significant importance but is not widely available. The function will become mandatory and SHALL be implemented in EHR systems claiming conformance to this profile by the end of the year identified.
O	Optional	Indicates that, while the function may have value to some organizations, it is not viewed as being essential.
N/A	Not Applicable	Function not applicable in the nursing home setting and rejected for purposes of the Pharmacist/Pharmacy Provider EHR-S Functional Profile.

2.2 Normative Language

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 1, February 2007 Chapter 2: Conformance Clause:

SHALL	Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to' and 'must'.
SHALL NOT	Indicates a prohibited action. Synonymous with 'prohibited' and 'must not'.
SHOULD	Indicates an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
MAY	Indicates an optional, permissible action. Synonymous with 'is permitted'.

2.3 Claiming Conformance

To claim conformance to this functional profile, an EHR system or derived profile must include as functions at least all those indicated as **ESSENTIAL NOW** and all the criteria within those functions that are designated as **“SHALL”**.

Systems claiming conformance to this Profile SHALL	<ul style="list-style-type: none"> Implement all functions designated Essential Now. Fulfill (i.e., meet or satisfy) all the SHALL criteria for each implemented function.
Systems claiming conformance to this Profile MAY	<ul style="list-style-type: none"> Implement functions designated Essential Future. Fulfill any of the SHOULD or MAY criteria associated with an implemented function
Systems claiming conformance to this Profile SHALL NOT	<ul style="list-style-type: none"> Negate or contradict defined functionality of this profile when including additional functionality beyond what is specified in this profile.
Derived profiles claiming conformance to this Profile SHALL	<ul style="list-style-type: none"> Inherit all functions designated Essential Now Inherit all SHALL criteria for functions included in the derived profile Follow the rules for profiles in Chapter 2, Section 6.1 and for creating new functions in Chapter 2, Section 6.3 of the HL7 EHR-S Functional Model standard.
Derived profiles claiming conformance to this Profile MAY	<ul style="list-style-type: none"> Change SHOULD and MAY criteria to SHALL, SHOULD or MAY criteria

2.4 Applying the Conformance Requirements (Reference)

In some instances a **“SHALL”** criterion in a function may require conformance with another function in the profile that has a different timing priority (i.e. a criterion in an Essential Now (EN) function may require conformance with a function designated as Essential Future (EF) 2011). This situation would arise when HL7 requirements regarding profiles adopting mandatory requirements from the Functional Model did not harmonize well with timing priorities for functions identified by profile developers. It is important to understand that the priority timing of a referencing function **DOES NOT** supersede the timing priority established for the referenced function. Examples include:

Example #1 (Referencing Function EN, Referenced Function EF)	
Referencing Function	
ID/Name:	DC.3.2.3 (Support for Communications Between Provider and Patient . . .)
Priority:	Essential Now
“SHALL” Criteria for This Function:	<ul style="list-style-type: none"> There are 5 “SHALL” criteria for function DC.3.2.3 found at criteria #1, 2, 3, 5, and 10. Of these, only criterion #10 requires conformance to another function within the profile. Specifically, criterion #10 states “The system SHALL conform to function IN.1.4 (Patient Access Management)”.
Referenced Function	
ID/Name:	IN.1.4 (Patient Access Management)
Priority:	Essential Future 2010
Result	
<ul style="list-style-type: none"> The SHALL criteria for function DC.3.2.3 found at criteria #1, 2, 3, and 5 are expected to be implemented at the time conformance is claimed with this profile. Conformance with DC.3.2.3 criterion #10 will not be expected until 2010. 	

Example #2 (Referencing Function EF, Referenced Function EN)	
Referencing Function	
ID/Name:	DC.2.2.2 (Support Consistent Healthcare Mgt of Patient Groups or Populations)
Priority:	Essential Future 2012
"SHALL" Criteria for This Function:	<ul style="list-style-type: none"> There are 4 "SHALL" criteria for function DC.2.2.2 found at criteria #1, 2, 3 and 5. The following criteria require conformance to other functions within the profile. Specifically, Criterion #1 states "The system SHALL conform to DC.2.2.1.2 (Support for Context-Sensitive Care Plans, Guidelines, Protocols)" o Criterion #5 states "The system SHALL conform to function S.2.2.2 (Standard Report Generation)"
Referenced Functions	
ID/Name:	DC.2.2.1.2 (Support for Context-Sensitive Care Plans, Guidelines, Protocols)
Priority:	Essential Now
ID/Name:	S.2.2.2 (Standard Report Generation)
Priority:	Essential Now
Result	
<ul style="list-style-type: none"> Function DC.2.2.1.2 (Support for Context-Sensitive Care Plans, Guidelines, Protocols) is Essential Now, and the SHALL criteria found at DC.2.2.1.2 criteria #1, 6, 7 and 8 are expected to be implemented at the time conformance is claimed with this profile. Function S.2.2.2 (Standard Report Generation) is Essential Now and the SHALL criteria found at S.2.2.2 criteria #1 and 4 are expected to be implemented at the time conformance is claimed with this profile. Function DC.2.2.2 (Support Consistent Healthcare Management of Patient Groups or Populations) is Essential Future, and the ability to support context-sensitive care plans/guidelines/protocols, or generate standard reports, related to consistent healthcare management of patient groups or populations will not be expected until 2012. 	

2.5 Standardizing Terms in Function Criteria (Reference)

Additional clarification is necessary to understand the standardized nomenclature used to describe the functions of a system. The following chart, adapted from the EHR-S FM *How to Guide for Creating Functional Profiles*, illustrates the hierarchy of nomenclature. For example, "capture" is used to describe a function that includes both direct entry "create" and indirect entry through another device "input". Similarly, "maintain" is used to describe a function that entails reading, updating, or removal of data.

Manage				
Capture		Maintain		
Input Device (External)	Create (Internal)	Read (Present)	Update	Remove Access
		View Report Display Access	Edit Correct Amend Augment	Obsolete Inactivate Destroy Nullify Purge

2.6 Components of the Pharmacist/Pharmacy Provider Functional Profile Outline (Reference)

Each function in Pharmacist/Pharmacy Provider EHR-S Functional profile is identified and described using a set of elements or components as detailed below.

ID	Type	Priority	Name	Statement /Description	See Also	Conformance Criteria	Row #	FM Source		
								ID #	Criteria #	Criteria Status

This is the unique outline identification of a function. Functions inherited from the HL7 EHR-S Functional Model retain the ID assigned in the model. New functions added by the authors of the Pharmacist/Pharmacy Provider EHR-S Functional Profile are underscored and shown in blue font.

- *Direct Care functions are identified by 'DC' followed by a number (Example DC.1.1.3.1;DC.1.1.3.2).*
- *Supportive functions are identified by an 'S' followed by a number (Example S.2.1; S.2.1.1).*
- *Information Infrastructure functions are identified by an 'IN' followed by a number (Example IN.1.1; IN.1.2).*

Function Type

Indication of the line item as being a header (H) or function (F).

Function Priority

Indication that implementation of the function is Essential Now (EN), Essential Future (EFxxxx), Optional (O), or Not Applicable (N/A). The definitions for these priorities are found above.

Function Name

The name of the Function (*Example: Entity Authentication*). Functions inherited from the HL7 EHR-S Functional Model retain the Function Name as stated in the model. Names for new functions added by the authors of the Pharmacist/Pharmacy Provider EHR-S Functional Profile are underscored and shown in blue font.

Function Statement

Brief statement of the purpose of this function (*Example: Authenticate EHR-S users and/or entities before allowing access to an EHR-S*). Functions inherited from the HL7 EHR-S Functional Model retain the Function Statement as shown in the model. Statements for new functions added by the authors of the LTC-NH EHR-S Functional Profile are underscored and shown in green font.

Description

Detailed description of the function, including examples if needed (*Example: Both users and applications are subject to authentication. The EHR-S must provide mechanisms for users and applications to be authenticated. Users will have to be authenticated when they attempt to use the application, the applications must authenticate themselves before accessing EHR information managed by other applications or remote EHR-S'...*) Functions inherited from the HL7 EHR-S Functional Model retain the portions of the Description shown in the model that are relevant to the nursing home setting, with additional industry-specific explanation being underscored and shown

in blue font. Descriptions for new functions added by the authors of the Pharmacist/Pharmacy Provider EHR-S Functional Profile are underscored and shown in green font.

See Also

This element is intended to identify relationships between functions.

Conformance Criteria

This element displays valuable statements used to determine if a particular function is met (*Example: The system SHALL authenticate principals prior to accessing an EHR-S application or EHR-S data*). Modifications to conformance criteria inherited from the HL7 EHR-S Functional Model are underscored and shown in blue font. Conformance criteria added to functions inherited from the functional model are indicated by an alpha designation (e.g. criterion #4a) and are underscored and shown in blue font. This numbering method allowed developers to display criteria in a logical sequence - there is no relationship implied in regards to other criterion for the function. Finally, for new functions added to the Pharmacist/Pharmacy Provider EHR-S Functional Profile, criterion are underscored and shown in blue font.

Row #

This element is provided to help users when navigating the various sections (i.e., a user can reference row #38 of the IN section versus stating function IN.1.6, criterion #5).

FM Source – ID #

This element is intended to assist with tracing profile content back to the HL7 EHR-S Functional Model. The column displays the ID# for the source function from the model, or is blank if the function was added by the authors of the Pharmacist/Pharmacy Provider EHR-S Functional Profile.

FM Source – Criteria #

This element is intended to assist with tracing profile content back to the HL7 EHR-S Functional Model. The column displays the number for the source criterion from the model, or is blank if the criterion was added by the authors of the Pharmacist/Pharmacy Provider EHR-S Functional Profile.