

Guidance for Pharmacy Use of HL7 EHR Functional Profile

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1. INTRODUCTION

Since 2011, the NCPDP ePrescribing and Related Transactions Work Group (WG11) NCPDP – HL7 Pharmacist/Pharmacy Provider Functional Profile Task Group has been tasked to identify Electronic Health Record (EHR) functionality for pharmacists and pharmacy systems. As the Office of the National Coordinator (ONC) defined EHR certification for meaningful use (MU) incentives for promoting interoperability, this task group focused on meeting certification requirements for pharmacy EHRs. Health Level Seven International (HL7®) provides standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services.

According to HL7®, “The EHR-S FM is a list of all functions that COULD be present in EHR systems and criteria for achieving that function. Any given EHR-S will perform one or more functions (i.e., a subset) from the FM list (i.e., the superset), depending on the purpose of the system. The select subset of functions and the criteria for conforming to these functions characterize the EHR-S capabilities and are referred to as a “functional profile”. The functions and conformance criteria will vary across functional profiles, depending on the operational needs of the system, i.e., what the system is in place to accomplish.”¹ This applies to EHR pharmacy systems. Instructions can be located on the [HL7.org](http://hl7.org) website for instructions on accessing HL7 Standards.²

The Electronic Health Record System Function Model Release 2 builds on Release 1.1 of the model, offering a more comprehensive set of functions and criteria. The work is informed by industry advances/directions, regulatory changes, learning from work from functional profiles, and participation by the international community. The work is also balloted through six standards organizations including: International Organization for Standardization (ISO), European Committee for Standardization (CEN), International Health Terminology Standards Development Organisation (IHTSDO), Clinical Data Interchange Standards Consortium (CDISC), Global Standards One (GS1) and Health Level Seven (HL7®).

The WG11 NCPDP – HL7 Pharmacist/Pharmacy Provider Functional Profile Task Group met to review the criteria related to medication and pharmacy-related activities contained in the Functional Profile (FP) to support the MU 2015 EHR test criteria. This profile is based on the EHR-System Functional Model (FM) Release 2 (R2), which incorporates all of the pharmacy related elements identified in the Pharmacy/Pharmacist Provider EHR-S Functional Profile R1 along with functions and criteria from other profiles. The MU certification requirements were mapped to the EHR-S FM and where necessary additional criteria were added. Since system vendors must code to these criteria to have a certified EHR, it is believed adoption of the MU EHR-S FP would meet the needs of pharmacy as well as eliminate the need for vendors to develop two separate profiles.

Some NCPDP members participated in the review of the ISO/HL7 Electronic Health Record (EHR) System Functional Model (FM) Release 2 conformance criteria related to ONC/NIST 2015 Edition Meaningful Use (MU) Test Procedure and provided the pharmacy perspective into the final balloted version. Considerable objection was raised to “Meaningful Use”³ as it was felt this connotes the pharmacist’s eligibility for

¹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=409

² http://www.hl7.org/documentcenter/public_temp_7752CF8E-1C23-BA17-0CBB6CA3E84B7601/gforge_include/hl7_eula.html

³ <https://www.federalregister.gov/documents/2018/08/24/2018-18297/request-for-information-regarding-the-21st-century-cures-act-electronic-health-record-reporting>

provider status and adoption incentives. It was thought this would cause confusion for both system vendors and the pharmacy industry. A suggestion was to create guidance for the industry.

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2. PURPOSE

The purpose of the document is to provide guidance to pharmacy system vendors to incorporate Electronic Health Record functionality using the [HL7 EHR-S Functional Profile: Meaningful Use, Release 1 - US Realm](#) (MU EHR-S FP) and demonstrate the value for adoption by the pharmacy industry.

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3. AUDIENCE

The audiences for this guidance document are the pharmacy system architects and developers of healthcare information technology (health IT) systems in the US Realm to meet health IT certification requirements for EHR system functionality to enable interoperability.

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4. OVERVIEW

As pharmacy systems evolve to collect and share clinical information, their systems need to adopt HL7 EHR functional conformance criteria to exchange this information in an interoperable way. The Office of the National Coordinator for Health Information (ONC) has defined EHR certification criteria to meet interoperable exchange within the healthcare ecosystem. Functional Profiles, Conformance Criteria and Business Requirements defined by HL7 are important concepts for pharmacy system vendors to understand when developing EHRs for pharmacy systems to facilitate interoperability.

As an example, when pharmacy system vendors programmed their systems to accept an electronic prescription, there were certain certification scenarios and criteria required to ensure that the exchange of information occurs in an interoperable way.

Functional Profiles

Functional profiles help to manage a master list of functions. A full Functional Model will not necessarily apply to any single HL7® Electronic Health Record- System (EHR-S) implementation. Typically, an EHR system does not conform directly to the entire Functional Model; instead it conforms to one or more Functional profiles. According to HL7, “Functional profiles are the expression of usable subsets of, or modifications or additions to, functions and criteria of the EHR-S Functional Model.”⁴ The act of creating a Functional Profile is to support a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Functional Model to meet specific requirements.

Conformance Criteria

The Functional Profile contains a list of functions, each of which may include one or more Conformance Criteria. Conformance Criteria are a set of requirements which allow the implementation to claim conformance to the related functions. The language and format used to express a conformance criterion is outlined within the [HL7 EHR-S Functional Profile: Meaningful Use, Release 1 - US Realm \(MU EHR-S FP\)](#) and is summarized below.

SHALL	Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with ‘is required to’ and ‘must’.
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’.

⁴ http://wiki.hl7.org/images/d/dd/EHRS_FM-MU_FP-2015_Edition-Overview-Dec2017.docx

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The following rules govern when elements must always be present, may never be present or only be present in certain circumstances.⁵

Value	Description	Comment
R	Required	A conforming sending application shall populate all "R" elements with a non-empty value. Conforming receiving application shall process (save/print/archive/etc.) or ignore the information conveyed by required elements. A conforming receiving application must not raise an error due to the presence of a required element but may raise an error due to the absence of a required element. Any element designated as required in a standard HL7 message definition shall also be required in all HL7 message profiles of that standard message.
RE	Required but may be empty	The element may be missing from the message but must be sent by the sending application if there is relevant data. A conforming sending application must be capable of providing contents for all "RE" elements. If the conforming sending application knows the required values for the element, then it must send that element. If the conforming sending application does not know the required values, then that element will be omitted. Receiving applications will be expected to process (save/print/archive/etc.) or ignore data contained in the element but must be able to successfully process the message if the element is omitted (no error message should be generated because the element is missing).
O	Optional	This code indicates that the Usage for this element has not yet been defined. A usage of 'Optional' may not be used in 'implementation' profiles (no-optionality profiles). Conformance may not be tested on an Optional field. Narrower profiles may be defined based on this profile, and may assign any usage code to the element
C	Conditional	This usage has an associated condition predicate. If the predicate is satisfied: A conformant sending application must always send the element. A conformant receiving application must process or ignore data in the element. It may raise an error if the element is not present. If the predicate is NOT satisfied: A conformant sending application must NOT send the element. A conformant receiving application must NOT raise an error if the condition predicate is false and the element is not present, though it may raise an error if the element IS present.
CE	Conditional but it may be empty	This usage has an associated condition predicate. If the predicate is satisfied: If the conforming sending application knows the required values for the element, then the application must send the element. If the conforming sending application does not know the values required for this element, then the element shall be omitted. The conforming sending application must be capable of knowing the element (when the predicate is true) for all "CE" elements. If the element is present, the conformant receiving application shall process (display/print/archive/etc.) or ignore the values of that element. If the element is not present, the conformant receiving application shall not raise an error due to the presence or absence of the element. If the predicate is not satisfied: The conformant sending application shall not populate the element. The conformant receiving application may raise an application error if the element is present.

Contained within the following table are conformance usage codes specific to allowable conformance usage designations.

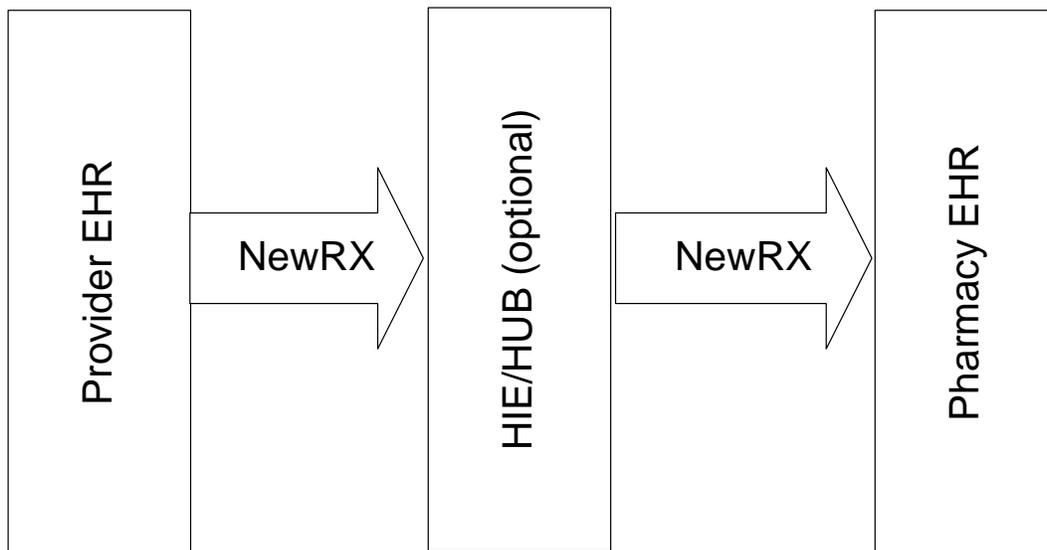
⁵[http://wiki.hl7.org/index.php?title=Conformance Implementation Manual#v2.x: Optionality.2C Usage and Interversion compatibility](http://wiki.hl7.org/index.php?title=Conformance_Implementation_Manual#v2.x:_Optionality.2C_Usage_and_Interversion_compatibility)

HL7 Optionality	Allowed Conformance Usage	Comment
R - Required	R	
O - Optional	R, RE, O, C, CE, X	O is only permitted for constrainable profiles
C - Conditional	C, CE, R	
X – Not Supported	X	
B – Backward Compatibility	R, RE, O, C, CE, X	O is only permitted for constrainable definitions
W - Withdrawn	R, RE, O, C, CE, X	

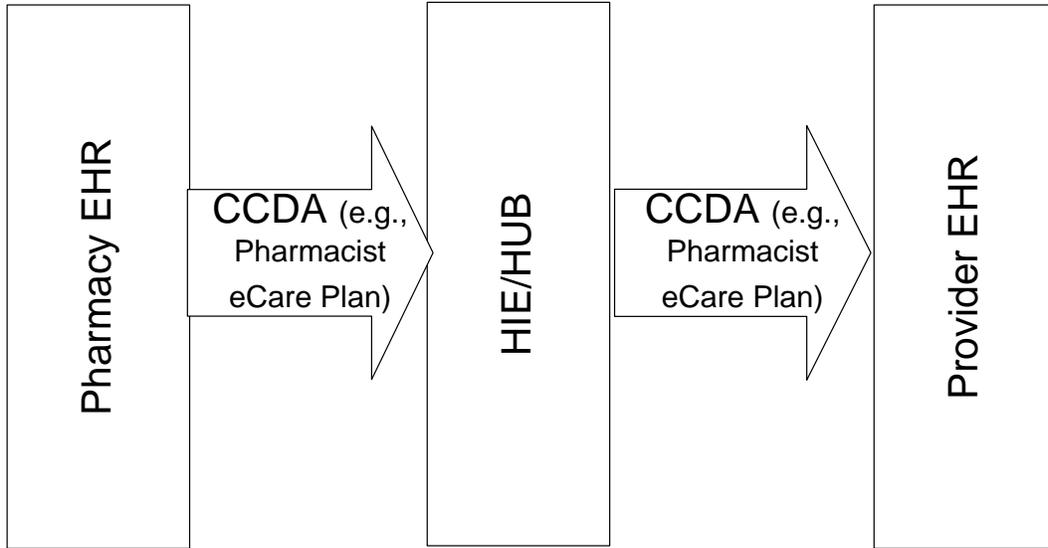
Business Requirements

Certification and Conformance requirements are vital for pharmacies that wish to successfully exchange information with various trading partners. Although pharmacies are primarily on the receiving end of information exchange, it is important for pharmacies to follow the certification and conformance criteria process. Current regulatory requirements do not necessarily apply to pharmacy, but contractual agreements normally require the criteria to be met.

Provider EHR to Pharmacy EHR Flow Chart



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5. DISCUSSION

It is important for pharmacy system vendors to understand the certification requirements for the [HL7 EHR-S Functional Profile: Meaningful Use, Release 1 - US Realm](#) (MU EHR-S FP) which includes ONC Test Procedures for 2015, soon to be 2019 EHR Certification Requirements.

Background on ONC Test Procedures

The ONC Health IT Certification Program is a voluntary certification program established by ONC to provide for the certification of health IT. Requirements for certification are established by standards, implementation specifications and certification criteria adopted by the Health and Human Services Secretary and supports the availability of certified health IT for its recommended and mandated use under other federal, state and private programs. The Program is run as a third-party product conformity assessment blueprint for health information technology (health IT) based on the principles of the International Standards Organization (ISO) and International Electrotechnical Commission (IEC) framework.

The program was launched in 2010 to support the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) administered by the Centers for Medicare & Medicaid Services (CMS). While the EHR Incentive Programs continue to require the use of certified health IT, the use of certified health IT has spread to other government and non-government programs. The program also supports interoperability, interchangeability and quality of care improvement. The program has released several editions of certification criteria and the most recent editions of certification criteria outline include more vigorous functional and interoperability requirements.

ONC collaborates with other organizations that it evaluates, approves, and authorizes to perform these certification functions on its behalf. The program defines the technical requirements for health IT and the process by which health IT may become certified and maintain its certification. Certification and conformance requirements may be done through an entity that is authorized to certify:

- ONC-ACB (ONC-Authorized Certification Body): Certifies health IT based on test results supplied by ONC-ATLs; posts results on the Certified Health IT Product List (CHPL); and is responsible for conducting surveillance of certified health IT.
- ONC-ATL (ONC-Authorized Testing Laboratory): A National Voluntary Laboratory Accreditation Program (NVLAP)-accredited testing laboratory that performs health IT testing to determine conformance with ONC's standards and certification criteria according to the ONC-approved test method

More information about the ONC certification can be found on the HealthIT.gov website.⁶

ONC Test Procedures Related to Pharmacy

Documentation for the ONC [2015 Edition Health Information Technology \(Health IT\) Certification Criteria Test Criteria, 2015 Edition Base Electronic Health Record \(EHR\) Definition, and ONC Health IT Certification Program Modifications Final Rule](#) includes a number of defined test procedures for evaluating

⁶ <https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program>

conformance to the ONC criteria. The 2015 Edition Test Method includes Test Procedures, Test Tools and Test Data and is listed by certification criterion number. The list below contains examples of [pharmacy related test procedures](#):

1. [Test Procedure for §170.315\(a\)\(1\) Computerized Provider Order Entry – Medications](#)
2. [Test Procedure for §170.315\(a\)\(4\) Drug-Drug, Drug-Allergy Interaction Checks for CPOE](#)
3. [Test Procedure for §170.315\(a\)\(6\) Problem List](#)
4. [Test Procedure for §170.315\(a\)\(7\) Medication List](#)
5. [Test Procedure for §170.315\(a\)\(8\) Medication Allergy List](#)
6. [Test Procedure for §170.315\(a\)\(10\) Drug Formulary and Preferred Drug List](#)
7. [Test Procedure for §170.315\(b\)\(1\) Transitions of Care](#)
8. [Test Procedure for §170.315\(b\)\(3\) Electronic Prescribing](#)
9. [Test Procedure for §170.315\(b\)\(9\) Care Plan](#)
10. [Test Procedure for §170.315\(e\)\(3\) Patient Health Information Capture](#)
11. [Test Procedure for §170.315\(f\)\(1\) Transmission to Immunization Registries \(Alternative Test Method Updated 12/18/2017\)](#)
12. [Test Procedure for §170.315\(g\)\(6\) Consolidated CDA Creation Performance](#)

Although ONC has identified other test procedures than listed above, these are the test procedures that may be pertinent to pharmacy management systems looking to share information with other providers' EHRs. The test procedures listed above are detailed enough for pharmacy management system vendors to evaluate if their organization wants to undergo EHR certification with their trading partners. ONC is working on 2019 test procedures. To date these are not finalized. The requirements will be finalized in the ONC Final Rule to Support Seamless and Secure Access to, Exchange of, and Use of (Electronic Health Information) EHI, which is expected to be published in late 2019.

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