APPENDIX

During the development of the LTC EHR-S Functional Profile, members of the LTC community discussed whether the Profile should reference specific standards, or whether the Profile and its supporting documentation should remain generic with statements that require compliance/conformance "in a standard manner" or "adhere to industry standards." Members of the LTC community recommended:

i. identifying the recognized standard setting entities and making generic references to complying with standards; and
ii. in some instances, identifying the specific standards needed for certain functions or criteria in the Profile, when such standards are particularly important and/or unique to LTC.

Complying with Industry Standards

As a matter of general principle, the expectation is that the LTC-NH EHR-S Functional Profile will require compliance with applicable industry standards approved, accepted, endorsed, or regulated by the following entities:

- Recognized Healthcare Information Technology Standards Panel (HITSP) standards.
- Standards endorsed through the Consolidated Health Informatics (CHI) Initiative, accepted by the Secretary of Health and Human Services (HHS), and required for use in all future federal health information systems acquisitions.
- Standards required for use by the Centers for Medicare and Medicaid Services (CMS).
- Standards that are widely accepted by the industry or industry groups.

The following table provides the reader with some information about the preceding standard setting entities/activities.

STANDARD SETTING ENTITIES/ACTIVITIES	
Key Standard Setting Entities/Activities	**Comment**
HITSP	Health Information Technology Standards Panel (HITSP) is a public-private standards harmonization collaborative. HITSP has identified several widely accepted, consensus-based HIT standards to enable and support the development and use of interoperable HIT products in several healthcare domains, some of which will be useable by nursing home electronic health record systems (EHR-S) such as HITSP EHR Lab Results Reporting v2 and Consumer Empowerment v2.1. The HITSP endorsed HIT standards can be found at: http://www.hitsp.org. The LTC/NH EHR-S Functional Profile shall require use of applicable HITSP standards.

Key Standard Setting Entities/Activities	Comment
CHI	The Consolidated Health Informatics (CHI) Initiative began in 2001 as part of the President's Management Agenda. The CHI Initiative was a collaborative effort to identify and adopt Federal Government-wide interoperable HIT standards to be implemented by federal agencies and enable the Federal Government to exchange electronic health information. Through the CHI Initiative 27 HIT content and messaging standards were endorsed, including standards for patient assessments. The CHI reports specifying the specific standards that have been endorsed can be found at: http://www.hhs.gov/healthit/chiinitiative.html. The National Committee for Health and Vital Statistics (NCVHS) and the Secretary of HHS accepted these 27 CHI standards, and the Department of HHS has published two Federal Register notices concerning the Federal Government's use of CHI standards. The first notice was published on 12/23/2005 for the CHI standards that had been accepted as of that date. On December 17, 2007 another Federal Register notice was published announcing the acceptance of the CHI Disability and Assessment standards and indicated that the "Federal Government will require all future federal health information acquisitions to be based on CHI standards when applicable and as permitted by law, whether system development occurs within the Agency or through use of contractor services" (http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-6058.htm). The LTC/NH EHR-S Functional Profile shall require use of applicable CHI standards when HITSP has not yet accepted standards in a domain that is important to /needed by LTC. As described below, the LTC/NH EHR-S Functional Profile shall specifically reference and require conformance with the CHI Patient Assessments standards.
CMS Required Standards	1. **Health Insurance Portability & Accountability Act (HIPAA)** The LTC/NH EHR-S Functional Profile shall require conformance with HIPAA mandated standards and requirements. 2. **e-Rx final rule, April 7, 2008** requirements are: - The National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1 (for the exchange of new prescriptions, changes, renewals, cancellations, fill status notification, medication history, and certain other transactions between prescribers and dispensers). - The National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard, Version 1.0, for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors. - The National Provider Identifier (NPI) to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

Key Standard Setting Entities/Activities	Comment
	3. **CMS e-Rx Interim Final Rule (IFR) (6/23/2006)** (does <u>not</u> require the application of e-prescribing standards to e-prescribing on behalf of nursing home residents). The e-prescribing standards in this IFR are: • National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 5.1 or 8.1 (for the exchange of new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers). • Accredited Standards Committee (ASC) X12N 270/271 Version 4010A1 (for the exchange of eligibility information between prescribers and Medicare Part D sponsors). • NCPDP Telecommunication Standard Version 5.1 (for the exchange of eligibility inquiries and responses between dispensers and Medicare Part D sponsors). 4. **The CMS e-Rx Final Rule (11/7/2005)** provides that entities may use Health Level Seven (HL7) standards or the NCPDP SCRIPT standard to conduct internal electronic prescription transactions. The LTC-NH EHR-S Functional Profile shall <u>not</u> require conformance with the CMS e-RX Final Rule (4/7/08), the e-RX Interim Final Rule (6/23/2006) or the e-Rx Final Rule (11/7/2005) as nursing homes are excluded from the requirements.

Standards widely accepted by industry:
 	
1. **Integrating the Healthcare Enterprise (IHE)** Patient Care Coordination (PCC) Technical Framework
 	
2. **E-prescribing in Nursing Homes**
	1. **IHE PCC standards include:**
	
	• Continuity of Care Document (CCD):
	   – Continuity of Care Record (CCR),
	   – HL7 CDA -- Clinical Document Architecture.
	• Clinical Document Architecture (CDA).
	• HL7 Care Record Summary.
	• Logical Observation Identifiers Names and Codes (LOINC).
	• Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT).
	• Basic Patient Privacy Consents (BPPC).
	
	2. **E-prescribing in Nursing Homes:**
	
	• NCPDP SCRIPT Standard Version 10.2.
	• ASC X12N 270/271 Version 004010X092A1.
	• NCPDP Formulary and Benefits Standard version 1.0.
	• NCPDP Telecommunication Standard Version 5.1.
	
	As described below, the LTC/NH EHR-S Functional Profile shall specifically reference and require conformance with certain IHE standards and industry accepted nursing home e-prescribing standards.

NOTE: Members of the LTC community also acknowledge that some of the standards that have been recognized by the preceding entities are not applicable to the LTC-NH EHR-S Functional Profile either because the nursing home EHR-S Functional Profile

does not embed functions/criteria that would require certain standards (e.g., HITSP Emergency Responder standards), or because the standards needed to support certain functions have not yet been required by CMS (e.g., e-prescribing in nursing homes).

Requiring Compliance/Conformance with Specific Standards in the LTC-NH EHR-S Functional Profile

Members of the LTC community recommended that the LTC-NH EHR-S Functional Profile reference and require compliance/conformance with the following specific standards that are particularly important and/or unique to LTC:

- HL7 Continuity of Care Document (CCD).
- Consolidated Health Informatics (CHI) Disability and Patient Assessment Standards.
- e-Prescribing Standards applicable to Nursing Homes.

These standards and their importance to LTC providers are described below.

HL7 Continuity of Care Document (CCD)

HL7 standards include standards for health information exchange (e.g., exchange of results and documents). The HL7 Clinical Document Architecture (CDA) is an HL7 exchange standard by which a wide array of documents can be exchanged. The CDA can support the electronic exchange of both text-based and coded documents. One type of document that can be exchanged using the CDA is the Continuity of Care Document (CCD). The CCD is the exchange standard for documents such as transfer/discharge documents. The CCD allows for the exchange of all and/or some of the following content:

Payers	Advanced Directives
Healthcare Providers	Supports (persons/family)
Social History	Family History
Medical Equipment	Plan of Care
Encounters	Functional Status
Problems	Alerts
Medications	Immunizations
Vital Signs	Results
Procedures	

Because persons are frequently transferred to/discharged from nursing homes, members of the LTC community thought that it was important that the LTC-NH EHR-S Functional Profile require/suggest the use of the CCD as the standard to support nursing home transfers/discharges. The CCD has been recognized by HITSP (as the exchange standard for other documents) and recognized by the Certification Commission for Health Information Technology (CCHIT) as an exchange standard for CCHIT certified physician office EHR-S.

There are several criteria in the LTC-NH EHR-S Functional Profile that specifically point to the use of the CCD as the standard that SHALL or SHOULD be used to support particular functions/criterion in the LTC-NH EHR-S Functional Profile regarding the exchange of transfer, discharge, and referral documents.

Consolidated Health Informatics (CHI) Disability and Patient Assessment Standards

In 2006, the CHI Initiative endorsed HIT standards to format, standardize the content of, and exchange federally-required assessment instruments or specific assessment findings from these federally-required instruments. (The link to all CHI reports is: http://www.hhs.gov/healthit/chiinitiative.html. Scroll down to Full Reports item #24 for the report entitled Disability and Assessment Forms.) The CHI patient assessment standards are:

1. Clinical LOINC® representation of federally-required assessment: (i) questions and answers, and (ii) assessment forms that include functioning and disability content as CHI standards.

2. CHI Endorsed Vocabulary Content:
    a. International Classification of Functioning, Disability and Health (ICF) as a CHI-endorsed standard for the functioning and disability domains;
    b. CHI-endorsed vocabulary (e.g., SNOMED-CT) for exact and "usefully related" content matches with federally-required patient/client assessments and other functioning and disability content.

3. HL7® (Health Level Seven®), Version 2.4 and higher messaging and Clinical Document Architecture (CDA) to exchange patient and client assessments and other standardized functioning and disability content.

In July 2007, the Secretary of HHS accepted the CHI standards for Disability and Assessments instruments, stating that, "these standards will be used by all Federal agencies in implementing new, and as feasible, when updating existing health information technology systems" (http://www.ncvhs.hhs.gov/070731lt.pdf). In December 2007, HHS published a Federal Register Notice stating that the "Federal Government will require all future federal health information acquisitions to be based on CHI standards when applicable and as permitted by law, whether system development occurs within the Agency or through use of contractor services" (http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-6058.htm).

Given (i) the importance of federal assessment requirements in nursing homes (i.e., used to calculate payment rates, monitor facility quality, and develop care plans) and (ii) that health information technology products, including EHR products, have been designed to support the production and exchange of federally-required assessments, the LTC-NH EHR-S Functional Profile indicates that systems SHOULD provide the

ability to exchange federally mandated assessment data in conformance with CHI format and content standards.

e-Prescribing Standards in Nursing Homes

The Medicare Modernization Act (MMA) established the Medicare Part D prescription drug benefit. The MMA requires prescriptions for covered Part D drugs for Part D enrolled individuals that are transmitted electronically be transmitted in accordance with e-prescribing standards. The MMA required initial standards be implemented not later than September 1, 2005 and that final standards must be promulgated not later than April 1, 2008.

CMS has published several final e-prescribing rules (i.e., CMS e-Rx Final Rule (4/7/2008), CMS e-Rx Interim Final Rule (6/23/2006), and CMS e-Rx Final Rule (11/7/2005)). CMS has excluded nursing homes from being required to use these e-prescribing standards because of questions concerning the applicability of these standards to nursing homes.

The MMA required pilot testing of standards that (at the time of initial e-prescribing rulemaking) were not ready for adoption. The Agency for Healthcare Research and Quality (AHRQ) and CMS sponsored five e-prescribing pilots, including a pilot in LTC (i.e., nursing homes). The purpose of the AHRQ/CMS pilots was to determine which (if any) additional e-prescribing standards were ready for adoption, including which standards for e-prescribing in nursing homes were ready for adoption. The report of LTC/nursing home e-prescribing pilot can be found at: http://healthit.ahrq.gov/erxpilots.

The evaluation of the LTC/nursing home pilot and the CMS Report to Congress (both of which are also available at the same website referenced above) found with respect to e-prescribing in nursing homes that: "*Analysis shows that e-prescribing can be supported, with some technical accommodations to the standards, in long-term care facilities for Part D implementation.*"

In November 2007, ANSI approved the NCPDP SCRIPT V10.2 standard. The NCPDP SCRIPT V10.2 provides many of the necessary technical accommodations to this standard that were identified as needed through the AHRQ/CMS pilot.

Specifically, the NCPDP SCRIPT V10. 2 provides for the following (Note: NCPDP SCRIPT V10.2 includes functionality approved in the NCPDP SCRIPT V10.1. Therefore, the table below describes both NCPDP SCRIPTV10.1 and V10.2):

NCPDP SCRIPT 10.1 and 10.2		
Version	**ANSI Approval**	**Changes from Prior Version**
NCPDP SCRIPT 10.1	September, 2007	• CENSUS Update Transaction was added. The Census Update Transaction is originated by the facility in a long term care environment. • Support for the Long-Term Care (LTC) Medication Change Process was added. • For LTC settings, a new transaction type of "Resupply Request" was added, which looks like a Refill Request, but no response is necessary. • Sections throughout the document were updated to include the new request message of CENSUS, the LTC Medication Change Process, and the Resupply Request. • Field values were added to the REQ Segment for the CENSUS transaction. *(Admit; Change; Discharge -- Expired; Discharge -- Return Not Anticipated; Discharge -- Return Anticipated; Discharge -- Other)*. • Fields added to the REQ Segment for the CENSUS transaction. • In the COO Segment, new field values were added for the CENSUS transaction. • In the COO Segment, Party Name became a composite. • In the COO Segment, **Ø7Ø** Party Name (Group Name) is available for use (was shaded). • In the COO Segment, Address is now available for use (was shaded) and is used for the responsible party's address. • In the COO Segment, Insurance Type, coded is now available for use (was shaded), and values added *(Primary, Secondary; Tertiary, Unknown, Private Pay)*. • In the COO Segment, Communication Number has been added. • For Long Term Care (LTC) Medication Change Process, in the UIH Segment, trace number assigned by sender. • In the REQ Segment, the following values have been added *(Significant Change; Frequency Change, Insignificant Change)*. • In the DRU Segment, an enhancement was made for Medication History Response transactions. • For Resupply Request transaction, additional notes have been made. • DRU Ø2Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier uses the same base list (Unit of Measure X-12 DE 355), but uses a subset list for this field. See the NCPDP *External Code List.*

Version	ANSI Approval	Changes from Prior Version
		• DRU Ø6Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier added a new value for number of refills remaining on a prescription, for use in Medication History Responses.
NCPDP SCRIPT 10.2	November, 2007	• For LTC -- In the DRU Segment, the following fields were added *(Needed no later than; Time Zone; Needed no later than reason)*. • Section *"Sign"* was added to *"Numeric Representation"* to provide information about the use of the negative sign in the Time Zone Difference Quantity. Section *"Time Zone"* was added to *"Requirement Designation".*

Given the approval by the American National Standards Institute (ANSI) of the NCPDP SCRIPT V. 10.2 standard and the demonstrated functionality of this standard in the AHRQ/CMS e-prescribing pilot, the LTC-NH EHR-S Functional Profile references and requires conformance with NCPDP SCRIPT V.10.2 (as well as the ASC X12N 270/271 V. 004010X092A1+ and NCPDP Telecommunication Standard V. 5.1 as required by CMS in the Medicare Part D e-prescribing requirements).

In addition, consistent with the CMS e-prescribing rule, the LTC-NH EHR-S Functional Profile references and permits the use of either the NCPDP SCRIPT or HL7 standards for prescribing transactions that are internal to the nursing home.

LONG-TERM CARE-NURSING HOMES EHR-SYSTEMS FUNCTIONAL PROFILE: RELEASE 1

Files Available for This Report

Main Report
HTML: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1.htm
PDF: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1.pdf

Direct Care Functions
HTML: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-dcf.htm
PDF: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-dcf.pdf

Supportive Functions
HTML: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-sf.htm
PDF: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-sf.pdf

Information Infrastructure Functions
HTML: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-iif.htm
PDF: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-iif.pdf

APPENDIX: HIT Standards
HTML: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-A.htm
PDF: http://aspe.hhs.gov/daltcp/reports/2008/LNEHRSFP1-A.pdf