

Via Electronic Submission to: https://www.healthit.gov/isa/recent-isa-updates

October 1, 2018

Office of the National Coordinator Department of Health and Human Services Hubert H. Humphrey Bldg., Suite 729D 200 Independence Ave., SW Washington, DC 20201

Re: 2018 Interoperability Standards Advisory Review Comment Period

Dear Sir or Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the 2018 Interoperability Standards Advisory comment period.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC), developing the national health information technology (HIT) framework since 2010. The Collaborative is supportive of the proposed standards for clinical health IT interoperability purposes.

Pharmacists provide patient-centered care and services, maintain various secure patient care records, and as part of the integrated health care team, they are directly involved with other health care providers and patients in various practice settings. Pharmacists are users of health IT and are especially supportive of interoperability standards incorporating HL7, SNOMED CT, LOINC, RxNorm, and NCPDP SCRIPT, and NCPDP Real Time Formulary and Benefits (currently under development). The Collaborative supports use of these particular standards which are important to pharmacists for allergy reactions, immunization historical and administered, immunization registry reporting, medications, medication allergies, patient problems, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing (including new versions).

The following are our comments regarding the 2018 Interoperability Standards Advisory.

Section I: Vocabulary Code Set/Terminology Standards

Allergies and Intolerances Representing Patient Allergies and Intolerances; Medications

Comment:

The Pharmacy HIT Collaborative supports using RxNorm and SNOMED CT; however, we ask for clarification as to why MED-RT (formerly NDF-RT) has been removed as a standard/implementation specification, as it was included in the final 2017 ISA and is currently included under "Representing Patient Medications." We recommend that it be returned.

Sex at Birth, Sexual Orientation and Gender Identity Representing Patient Gender Identity

Comment:

The Pharmacy HIT Collaborative supports using LOINC and SNOMED CT; however, we ask for clarification as to why HL7 Version 3 Null Flavor was removed for 2018 review; it was added to the final 2017 ISA.

Section II: Content/Structure Standards and Implementation Specifications

Admission, Discharge, and Transfer

Sending a Notification of a Patients Admission, Discharge and/or Transfer Status to Other Providers

Comment:

The Pharmacy HIT Collaborative supports using HL7 2.5.1 (or later) ADT message and IHE Patient Administration Management (PAM) Integration Profile.

Admission, Discharge, and Transfer

Sending a Notification of a Long Term Care Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy

Comment:

The Pharmacy HIT Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6

Care Plan Documenting and Sharing Care Plans for a Single Clinical Context

Comment:

The Pharmacy HIT Collaborative supports the balloted drafts of HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 and HL7 Resource Care Plan (v3.0.1). The Collaborative also supports HL7 Fast Healthcare Interoperability Resources (FHIR), STU3, which is in development.

Care Plan

Sharing Patient Care Plans for Multiple Clinical Contexts

Comment:

The Pharmacy HIT Collaborative supports the balloted draft IHE Dynamic Care Team Management (DCTM), Rev. 1.1 Trial Implementation.

Care Plan

Documenting and Sharing Medication-Related Care Plans by Pharmacists

Comment:

The Pharmacy HIT Collaborative appreciates the ONC taking our recommendation and adding NCPDP Pharmacist eCare Plan Version 1.0 Guidance on the Use of the HL7 CDA Consolidated Templates for Clinical Notes R2.1 Care Plan and HL 7 CDA R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 – US Realm, Volume 1 to the final 2018 version. The Collaborative also recommends adding Pharmacist Care Plan FHIR Implementation Guide to the standard implementation/specifications.

Care Plan

Sharing Patient Care Teams for Care Planning in Multiple Clinical Contexts

Comment:

The Pharmacy HIT Collaborative supports the balloted draft IHE Dynamic Care Team Management (DCTM), Rev. 1.1 Trial Implementation.

Clinical Decision Support Shareable Clinical Decision Support

Comment:

The Pharmacy HIT Collaborative supports the addition of the balloted drafts of: HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 2; HL7 FHIR Profile: Quality (QI Core), DSTU Release 1; HL7 Version 3 Standard: Decision Support Service, Release 2; HL7 Implementation Guide Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard Trial Use; HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), DSTU Release 1, HL7 FHIR Profiles: Quality Improvement Core (QI Core), Release 2; and HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3.

Clinical Quality Measurements and Reporting Sharing Quality Measure Artifacts for Quality Reporting Initiatives

Comment:

The Pharmacy HIT Collaborative supports combining the previous Sections II-D and II-E into a single Section II-D, and the addition of the balloted editions: HL7 Version 3: Representation of the Health Quality Measures Format (eMeasures) DSTU Release 2.1; HL7 FHIR Profile: Quality, Release 1; HL7 Cross-Paradigm Specification: Clinical Quality (CQL) Language, Release 1, STU Release 1.1; HL7 Version 3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF), Release 1.4 DSTU (based on HAMF 2.1 - US Realm); HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQM)F, Release 1.1 DTSU 2 (based on HQMF 2.1 - US Realm); HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQM)F, Release 1.1 DTSU 2 (based on HQMF 2.1 - US Realm); HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQM)F, Release 2 DTSU 32 (based on HQMF 2.1 - US Realm). The Collaborative also supports HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR) and HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3, which are in development.

Electronic Prescribing Allows a Prescriber to Request or Cancel Prior Authorization Medications

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPDP SCRIPT Standard, Implementation Guide Version 2013101.

Electronic Prescribing

Allows a Prescriber to Request a Patient's Medication History from a State Prescription Drug Monitoring Program

Comment:

The Pharmacy HIT Collaborative supports the use of NCPDP SCRIPT Standard, Implementation Guide Versions 10.6, as well as the move to NCPDP SCRIPT Standards, Implementation Guide, Version 2017071 and HL7 FHIR Implementation Guide, US Meds STU2 as soon as participants can be ready to implement such a change. We also recommend including NCPDP SCRIPT Standard Implementation Guide Version 2013101.

Electronic Prescribing Allows a Prescriber or Pharmacy to Request a Patient's Medication History

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPDP Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing Allows a Prescriber or a Pharmacy to Request a New Prescription

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPD Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing

Allows a Pharmacy to Request Additional Refills

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPD Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing

Allows a Pharmacy to Request a Change to a Prescription

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPD Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing

Allows a Prescriber to Cancel a Prescription

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPD Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing Allows a Pharmacy to Notify a Prescriber of Prescription Fill Status

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. The Collaborative supports the use of NCPDP Script Standard, Implementation Guide, Version 10.6.

Electronic Prescribing Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer

Comment:

The Pharmacy HIT Collaborative supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. We also recommend including NCPDP SCRIPT Standard Implementation Guide Version 2013101.

Electronic Prescribing

Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing

Comment:

The Pharmacy HIT Collaborative supports the use of Structured Codified Sig Format Implementation Guide Version 2.1. The Collaborative also supports the move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change.

Patient Education Materials

A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge from Online Resources

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 Version 3 Standard: Context-Aware Knowledge Retrieval Application (Infobutton), Knowledge Request, Release 2; HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Conext-Aware Knowledge Retrieval (Infobutton) Domain, Release 1; and HL7 Version Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.

Patient Identification Management; Name Change to Patient Demographic Record Matching

Comment:

The Pharmacy HIT Collaborative supports the name change.

Public Health Reporting Reporting Cancer Cases to Public Health Agencies

Comment:

The Pharmacy HIT Collaborative supports the addition of HL7 Clinical Document Architecture (CDA), Release 2.0, Final Edition, as well as the balloted drafts HL7 CDA Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 (US Realm) and IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation.

Public Health Reporting Case Reporting to Public Health Agencies

Comment:

The Pharmacy HIT Collaborative supports the balloted drafts of HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm), DSTU Release 2.1 (with errata); HL7 CDA Release 2 Implementation Guide: Reporting to Public Health Case Reporting, Release 1, DSTU Release 1.1 (US Realm), the Electronic Initial Case Report (eICR); HL7 FHIR Implementation Guide: Structured Data Capture (SDC) STU2; and HL7 CDA R2 Implementation Guide: Reportability Response Release 1, STU Release 1.0 (US Realm).

Public Health Reporting Electronic Transmission of Reportable Lab Results to Public Health Agencies

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 2.5.1; HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification; the balloted drafts of HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory to Public Health, Release (US Realm), Draft Standard for Trial Use, Release 1.1; and emerging implementation specification HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 STU Release 2 (US Realm), which is in development.

Public Health Reporting Exchanging Immunization Data with Immunization Registries

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 2.5.1 and HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 and 1.5.

Research

Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements

Comment:

The Pharmacy HIT Collaborative supports the use of IHE-RFD (Retrieve Form for Data Capture), HL7 Clinical Document Architecture (CDA), Release 2.0, Final Edition, and CDISC Pharmacogeneomics/genetics (PGx) Implementation Guide.

Research

Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators

Comment:

The Pharmacy HIT Collaborative supports the use of IHE-RFD (Retrieve From for Data Capture) and balloted drafts of IHE-DSC (Drug Safety Content) and IHE-CPRC (Clinical Research Process Content).

Research

Complete Disease Registry Forms and Submit to Reporting Authority (ACC)

Comment:

The Pharmacy HIT Collaborative supports use of CDISC Clinical Data Acquisition Standards Harmonization (CDASH), IHE-RFD (Retrieve Form for Data Capture) and HL7 Clinical Document Architecture (CDA), Release 2, Final Edition.

Segmentation of Sensitive Information Data Segmentation of Sensitive Information

Comment:

The Pharmacy HIT Collaborative supports the use of Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1; HL7 Clinical Document Architecture (CDA), Release 2.0, Final Edition and IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P). The Collaborative also supports Consent2Share FHIR Consent Profile Design, which is in development.

Summary Care Record

Support a Transition of Care or Referral to another Health Care Provider

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 Clinical Document Architecture (CDA), Release 2.0, Final Edition; the balloted drafts of: HL7 Consolidated CDA Release 1.1 (HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU

Release 1.1, US Realm), HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1, and IHE Patient Care Coordination Technical Framework Supplement 360 Exchange Closed Loop Referral, Rev. 1.1, Trial Implementation; and NCPDP Specialized Standard.

Section IV: Models and Profiles

Functional Models EHR Interoperability with the HIT Ecosystem

Comment:

The Pharmacy HIT Collaborative supports the use of ISO/HL7 EHR System Functional Model, Release 2, aka, EHR-SFM (published by HR7 2014, ISOP 2015)

Functional Profiles Interoperability for Public Health Services

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 Public Health Functional Profiles (published 2015), suite of nine FPs for specific public health services/domain, based on ISO/HL7 10781 EHR-S FM

Information Models

Information Model for Interoperability of Behavioral Health

Comment:

The Pharmacy HIT Collaborative supports the use of HL7 Version 3 Domain Analysis Model: Behavior Health Record, Release 2.

Section V: Administrative Standards & Implementation Specifications

Administrative Transactions to Support Clinical Care Referral Certification and Authorization for Pharmacy Transactions

Comment:

The Pharmacy HIT Collaborative supports the use of NCPDP Telecommunications Standard Implementation Guide, Version D, Release 0.

Health Care Eligibility Benefit Inquiry and Response from Retail Pharmacy Coverage

Comment:

The Pharmacy HIT Collaborative supports the use of NCPDP Telecommunications Standard Implementation Guide, Version D, Release 0.

The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and ten associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *2018 Interoperability Standards Advisory* comment period.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at <u>shelly@pharmacyhit.org</u>.

Respectfully submitted,

Shelly Spired

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