September 23, 2019

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: 2019 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 2019 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 documenting allergies (including medications, food, and environmental intolerances and reactions), immunizations (historical and administered), immunization registry reporting (query/response), 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 2019 Interoperability Standards Advisory.
Section I: Vocabulary Code Set/Terminology Standards

Allergies and Intolerances
Representing Patient Allergic Reactions

Comment:
The Pharmacy HIT Collaborative supports using LOINC and SNOMED CT. We also ask that RxNorm be included for use, as it is included in “Representing Patient Allergies and Intolerances; Medications.”

Allergies and Intolerances
Representing Patient Allergies and Intolerances; Medications

Comment:
The Pharmacy HIT Collaborative supports using Rx Norm and SNOMED CT. We also ask that RxNorm be included as a standard for “Representing Patient Allergic Reactions.”

Family Health History
Representing Patient Family Health History

Comment:
The Pharmacy HIT Collaborative supports using LOINC and SNOMED CT.

Health Care Providers, Family Members and Other Caregivers
Representing Provider Role in Team Care Settings

Comment:
The Pharmacy HIT Collaborative supports using SNOMED CT.

Health Care Providers, Family Members and Other Caregivers
Representing Relationship Between Patient and Another Person

Comment:
The Pharmacy HIT Collaborative supports using HL7 V3 Vocabulary.

Immunizations
Representing Immunizations – Administered

Comment:
Immunizations
Representing Immunizations – Historical

Comment:
The Pharmacy HIT Collaborative supports using HL7 Standard Code Set CVX – Clinical Vaccines Administered; HL7 Standard Code Set MVX – Manufacturing Vaccine Formulation; and RxNorm Vaccine Clinical Drug 2.16.840.1.113762.1.4.1010.8.

Laboratory
Representing Laboratory Tests

Comment:
The Pharmacy HIT Collaborative supports using LOINC and SNOMED CT.

Medications
Representing Patient Medications

Comment:
The Pharmacy HIT Collaborative supports using RxNorm and National Drug Code (NDC).

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

Comment:
The Pharmacy HIT Collaborative supports using LOINC, SNOMED CT, and HL7 Version 3 Null Flavor. The Collaborative appreciates ONC taking our suggestion to reinstate HL7 Version 3 as a standard for this interoperability need. It was initially removed from the 2018 ISA.

Social, Psychological, and Behavioral Data
Representing Financial Resource Strain

Comment:
The Pharmacy HIT Collaborative supports using LOINC.

Tobacco Use (Smoking Status)
Representing Patient Tobacco Use (Smoking Status)

Comment:
The Pharmacy HIT Collaborative supports using LOINC and SNOMED CT.
Section II: Content/Structure Standards and Implementation Specifications

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

Comment:

Admission, Discharge, and Transfer
Sending a Notification of a Long Term Care Patient’s Admission, Discharge, and/or Transfer Status to Another Provider

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

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

Comment:
The Pharmacy HIT Collaborative supports the balloted draft HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Trial Use, Release 2.1; emerging standard HL7 Fast Health Care Interoperability Resources (FHIR), STU3; and emerging implementation specification HL7 Resource Care Plan (v1.0.2).

Additionally, the Collaborative recommends adding the following:


Standards Process Maturity: Final
Implementation Maturity: Production
Adoption Level: 1
Federally Required: No
Cost: $
Test Tool Availability: No
Available: Spring 2020
Care Plan
Documenting and Sharing Medication-Related Care Plans by Pharmacists

Comment:

Additionally, the Collaborative recommends adding the following:

Standards Process Maturity: Final
Implementation Maturity: Production
Adoption Level: 1
Federally Required: No
Cost: $
Test Tool Availability: No
Available: Spring 2020

Care Plan
Domain or Disease-Specific Care Plan Standards

Comment:

Additionally, the Collaborative recommends adding the following:

Standards Process Maturity: Final
Implementation Maturity: Production
Adoption Level: 1
Federally Required: No
Cost: $
Test Tool Availability: No
Available: Spring 2020

Care Plan
Sharing Patient Care Plans for Multiple Clinical Contexts

Comment:
The Pharmacy HIT Collaborative supports the balloted draft IHE Dynamic Planning (DCP), Rev 1.2 Trial Implementation.

Care Plan
Sharing Patient Care Teams in Multiple Clinical Contexts

Comment:
The Pharmacy HIT Collaborative supports the balloted draft IHE Dynamic Planning (DCP), Rev 1.1 Trial Implementation.

Care Plan
Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims

Comment:
The Pharmacy HIT Collaborative supports the balloted draft IHE: Clinical Decision Support Order Appropriations Tracking (CDS-OAT).

Care Plan
Provide Access to Appropriate Use Criteria

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts CDS Hooks Services and HL7 FHIR Clinical Reasoning Module, FHIR STU Release 3.

Clinical Quality Measurement and Reporting
Reporting Aggregate Quality Data to Quality Reporting Initiatives

Comment:
Clinical Quality Measurement and Reporting  
Reporting Patient-level Quality Data to Quality Reporting Initiatives

Comment:  

Data Provenance  
Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners

Comment:  

Diet and Nutrition  
Exchanging Diet and Nutrition Orders Across the Continuum of Care

Comment:  
The Pharmacy HIT Collaborative supports the balloted drafts HL7 Version Standard: Diet and Nutrition, STU Release 1 and HL7 FHIR Nutrition Order Resource.

Drug Formulary & Benefits  
The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit to Prescribers Systems

Comment:  
The Pharmacy HIT Collaborative supports using NCPDP Formulary and Benefits v3.0.

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

Comment:  
Electronic Prescribing
Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription

Comment:

Electronic Prescribing Allows the Pharmacy to Respond to Request Additional Refills

Comment:

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

Comment:

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

Comment:

Electronic Prescribing Allows a Prescriber to Cancel a Prescription

Comment:
Electronic Prescribing
Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing

Comment:
The Pharmacy HIT Collaborative supports using Structured and Codified Sig Format Implementation Guide Version 2.1 and NCPDP SCRIPT Standard, Implementation Guide, Version 2017071. The Collaborative also recommends that e-prescribing vendors adopt logic that results in a prescription that calculates a weight-based dose to suggest a measurable dose (e.g., rounded to the +/- 5-10% of the calculated dose). Measurable does should be based on home dosing tool precision. For example, a weight-based dose calculation may result in instructions to give a child 4.7mL amoxicillin 400mg//5mL (375mg) when the measurable dose should be 5mL (400 mg is still a safe dose and easier to measure with a 5mL or 10mL oral syringe).

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

Comment:

Electronic Prescribing
Allows a Prescriber to Request a Patient’s Medication History from a State Prescription Drug Monitoring Program (PDMP)

Comment:

Family Health History (Clinical Genomics)
Representing Family Health History for Clinical Genomics

Comment:
Family Health History (Clinical Genomics)
Healthy Weight

Comment:

Images
Format of Medical Imaging Reports for Exchange and Distribution

Comment:
The Pharmacy HIT Collaborative supports using Digital Imaging and Communications in Medicine (DICOM) and PS3 2.0 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture.

Images
Format of Medical Imaging Reports for Data Exchange and Distribution

Comment:
The Pharmacy HIT Collaborative supports using Digital Imaging and Communications in Medicine (DICOM).

Laboratory
Identify Linkages Between Vendor IVD Test Results and Standard Codes

Comment:
The Pharmacy HIT Collaborative supports using LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results.

Laboratory
Ordering Labs for a Patient

Comment:
The Pharmacy HIT Collaborative supports balloted draft HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 (US Realm) and using HL7 2.5.1.

Laboratory
Receive Electronic Laboratory Test Results

Comment:
The Pharmacy HIT Collaborative supports balloted drafts HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm [HL7
Laboratory Support the Transmission of a Laboratory’s Directory of Services to Health IT

Comment:
The Pharmacy HIT Collaborative supports balloted draft HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 (also referred to as eDOS, (Electronic Directory of Service) and the use of HL7 2.5.1.

Medical Device Communication to Other Information Systems/Technologies Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies

Comment:
The Pharmacy HIT Collaborative supports using IHE-PCD (Patient Care Device Profiles) and ITU H810, H811, H812, H812.5, and H813.

Patient Education Materials Clinical Information systems to Request Context-Specific Clinical Knowledge from Online Resources

Comment:

Patient Identification Management Patient Demographic Record Matching

Comment:
The Pharmacy HIT Collaborative supports the balloted draft Implementation Guide for Expressing Context in Direct Messaging, and the use of HL7 2.5.1, IHE-PDQ (Patient Demographic Query), and IHE-PIX (Patient Identifier Cross-Reference).

Patient Preference/Consent Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Health Care Providers
Comment:
The Pharmacy HIT Collaborative supports the balloted draft IHE Advanced Patient and Consents (APPC); the development of emerging specifications HL7 FHIR Consent Resource and HL7 Contract Resource; and the use of IHE Basic Patient Privacy Consents (BPPC) and HL7 Implementation Guide for CDA Release 2: Consent Directives, Release 1.

Public Health Reporting
Case Reporting to Public Health Agencies

Comment:

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

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts HL7 Version 2.51 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) and HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 (US Realm), and the use of HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Erata and Clarifications and ELR 2.51 Clarification Document for EHR Technology Certification.

Public Health Reporting
Exchanging Immunization Data with Immunization Registries

Comment:
The Pharmacy HIT Collaborative supports using HL7 2.5.1 Implementation Guide for Immunization Messaging, Releases 1.4 and 1.5.

Public Health Reporting
Reporting Cancer Cases to Public Health Agencies
Comment:

Public Health Reporting
Sending Health Care Survey Information to Public Health Agencies

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts HL7 Implementation Guide for CDA R2: National Health Care Surveys (NHCS), Releases 1, 1.1, and 1.2 (US Realm), and using HL7 Clinical Document Architecture (CDA), Release 2.0, Final Edition.

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

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts IHE-DSC (Drug Safety Content) and IHE-CPRC (Clinical Research Process Content), and using IHE-RFD (Retrieve Form for Data Capture).

Summary Care Record
Support a Transition of Care or Referral to Another Health Care Provider

Comment:

Unique Device Identification
Defining a Globally Unique Device Identifier
Comment:
The Pharmacy HIT Collaborative supports the implementation specification development HL7 Harmonization Pattern for Unique Device Identifiers.

Unique Device Identification
Transmitting a Unique Device Identifier

Comment:
The Pharmacy HIT Collaborative supports the implementation specification development HL7 Harmonization Pattern for Unique Device Identifiers.

Section III: Standards and Implementation Specifications for Services/Transport/Exchange

“Push Exchange”
An Unsolicited “Push” of Clinical Health Information to a Known Destination and Information System User

Comment:
The Pharmacy HIT Collaborative supports the use of Direct (Applicability Statement for Secure Health Transport v1.2); IHE-XDR (Cross-enterprise Document Reliable Interchange); IG for Direct Edge Protocols; XDR and XDM for Direct Messaging Specification; ITU H810, H811, H812, and H813; and the balloted draft of Implementation Guide for Expressing Context in Direct Messaging v1.1.

“Push Exchange”
An Unsolicited “Push” of Clinical Health Information to a Known Destination Between Systems

Comment:
The Pharmacy HIT Collaborative supports the balloted draft HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2; and the use of SOAP-B Secure Transport Requirements Traceability Matric (RM) version 1.0 specification; Direct (Applicability Statement for Secure Health Transport v1.2); eHealth Exchange Specification Messaging Platform; eHealth Exchange Specification: Authorization Framework; eHealth Exchange Specification: Document Submission; IHE-XDR (Cross-Enterprise Document Reliable Interchange); and HL7 Fast Healthcare Interoperability Resources (FHIR).

“Push Exchange”
Medical Device Communication to Other Information Systems/Technologies

Comment:
The Pharmacy HIT Collaborative supports the use of ITU H810, H811, H812, and H813.
“Push Exchange”
Medical Device Communication to Other Information Systems/Technologies

Comment:
The Pharmacy HIT Collaborative supports the use of IEEE 11073-10101-2004 Health Informatics Point-of-Care Medical Device Communication, Part 10101: Nomenclature; IHE-PCD (Patient Care Device Profiles); and ITU H810, H811, H812, and H813.

“Push Exchange”
Remote Patient Monitoring to Support Chronic Condition Management, Patient Education, and Patient Engagement

Comment:
The Pharmacy HIT Collaborative supports the use of ITU H810, H811, H812, and H813.

“Push Exchange”
Representing Path Traversal Expressions

Comment:
The Pharmacy HIT Collaborative supports the balloted draft HL7 Fast Healthcare Interoperability Resources (FHIR) – FluentPath, STU 1, Release 1.

Clinical Decision Support Services
Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts HL7 Version 3 Standard: Decision Support Services, Release 2; HL7 Implementation Guide Decision Support Service, Release 1, US Realm, Draft Standard for Trial Use; HL7 FHIR Profile: Quality Improvement Core (QI), Release 1, STU 3; HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 2; CDS Hooks Services; IHE-GAO (Guideline Appropriate Ordering).

Clinical Decision Support Services
Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care

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: Context-Aware Knowledge Retrieval (Infobutton), Release 4;

**Consumer Access/Exchange of Health Information**

**Patient Exchanging Secure Messages with Care Providers**

**Comment:**
The Pharmacy HIT Collaborative supports the balloted draft of HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3 and the use of Direct (Applicability Statement for Secure Health Transport v1.2).

**Consumer Access/Exchange of Health Information**

**Push Patient-Generated Health Data into Integrated EHR**

**Comment:**
The Pharmacy HIT Collaborative supports the balloted draft of HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3 and the use of Direct (Applicability Statement for Secure Health Transport v1.2).

**Consumer Access/Exchange of Health Information**

**Remote Patient Authorization and Submission of EHR Data for Research**

**Comment:**
The Pharmacy HIT Collaborative supports the balloted draft of HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3

**Consumer Access/Exchange of Health Information**

**View, Download, and Transmit Data from EHR**

**Comment:**

**Healthcare Directory, Provider Directory**

**Listing of Providers for Access by Potential Exchange Partners**

**Comment:**
The Pharmacy HIT Collaborative supports the balloted drafts of Validated Healthcare Directory Implementation Guide Home; IHE-IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation; HL7 Argonaut
Provider Directory Implementation Guide Version 1.0.0; and IHE Mobile Care Services Discovery (mCSD).

Patient Identification Management
Exchanging Patient Identification Management Within a Community

Comment:
The Pharmacy HIT Collaborative supports the balloted draft IHE-Patient Identifier Cross-reference PIX for Mobile (PIXm), and the use of IHE-PDQ (Patient Demographic Query), IHE-PIX (Patient Identifier Cross-Reference), and IHE-XCPD (Cross Community Patient Discovery).

Public Health Exchange
Transport for Immunization Submission and Query/Response

Comment:

Query
Data Element Based Query for Clinical Health Information

Comment:
The Pharmacy HIT Collaborative supports the balloted drafts HL7 Argonaut Data Query Implementation Guide Version 1.0.0, IHE Mobile Cross-Enterprise Document Data Element Extraction (mXDE) Profile, and IHE Query for Existing Data for Mobile (WEDm).

Query
Query for Documents Outside a Specific Health Information Exchange Domain

Comment:

Query
Query for Documents Within a Specific Health Information Exchange Domain
Comment:
The Pharmacy HIT Collaborative supports the balloted drafts IHE-MHD (Mobile Access to Health Documents), IHE-PIXm (Patient Identifier Cross-Reference for Mobile), IHE-PDQm (Patient Demographics Query for Mobile), and the use of IHE-XDS (Cross-enterprise document sharing), IHE-PDQ (Patient Demographic Query), and IHE-PIX (Patient Identifier Cross-Reference).

Section IV: Administrative Standards and Implementation Specifications

Administrative Transactions – Non-Claims
Health Care Eligibility Benefit Inquiry and Response for Retail Pharmacy

Comment:

Administrative Transactions to Support Clinical Care
Health Care Attachments to Support Claims, Referrals, and Authorizations


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

Comment:

Health Care Claims and Coordination of Benefits
Health Care Claims or Equivalent Encounter Information for Retail Pharmacy Claims
**Comment:**

**Health Care Claims and Coordination of Benefits**
**Health Care Claims or Equivalent Encounter Information for Pharmacy Retail Supplies and Professional Services**

**Comment:**

**Operating Rules to Support Administrative Transactions**
**Operating Rules to Support Electronic Prescribing Transactions**

**Comment:**
The Pharmacy HIT Collaborative supports the use of NCPDP Operating Rules for the X12 270/271 Transactions in Electronic Prescribing v1.0.

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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 nine 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.

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the 2019 Interoperability Standards Advisory comment period.

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

Respectfully submitted,

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