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Office of the National Coordinator for Health Information Technology  
Department of Health and Human Services  
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Washington, DC 20201

**Re: [RIN 0955-AA06] Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability**

Dear Dr. Tripathi:

On behalf of its membership, the Pharmacy Health Information Technology Collaborative (PHIT) is pleased to submit comments for the proposed rule *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)*.

PHIT has been involved with the federal agencies, including the Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) and the Centers for Medicare & Medicaid Services (CMS), in developing the national health information technology (HIT) framework for implementing secure access of electronic health information to improve health outcomes since 2010.

Pharmacists provide essential, patient-centered care services to their patients, including Medicare and Medicaid beneficiaries. Pharmacists use health IT, provider directories, telehealth, e-prescribing (eRx), electronic medical record (EMR)/electronic health record (EHR) systems, and certified EHR technology (CEHRT) to help manage patients' health needs. PHIT supports the use of these systems, which are important to pharmacists in working with other health care providers to deliver longitudinal person-centered care planning, medications used, and transmit patient information related to overall patient care, transitions of care, medication lists, medication allergies, patient problem lists, smoking status, and social determinants of health (SDOH). Pharmacists also use health IT for reporting to public health agencies (e.g., immunization reporting), clinical decision support services/knowledge artifacts, checking drug formularies checking, and comprehensive medication management (CMM).

## Comments

PHIT is supportive of the proposed requirements for HTI-2 and supports the recommendations the National Council of Prescription Drug Programs (NCPDP) and the Health IT Advisory Committee (HITAC) are submitting for this proposal. We also ask ASTP/ONC to consider ways to promote and incentivize the utilization of certified health IT beyond the CMS incentive programs, as these pertain to just a fraction of HIT users. All participants in the health data exchange ecosystem, including pharmacies who are excluded from the incentive programs and entities using electronic health information (EHI) exchange, should be provided with support, education, and incentives to adopt standardized certified health IT.

### **New and Revised Standards and Certification Criteria (page 17)**

#### *i. The United States Core Data for Interoperability Version 4 (USCDI v4)*

PHIT supports the adoption of USCID v4 and the January 1, 2028 expiration for USCDI v2.

#### ***SMART App Launch 2.2***

PHIT supports the adoption of Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) SMART Application Launch Framework Implementation Guide release 2.2.0 (SMART v2.2 Guide) in § 170.215(c)(3) and the January 1, 2028 expiration date of the SMART v2 Guide in § 170.215(c)(2).

### **Electronic Prescribing**

#### ***§ 170.315(b)(3)(ii)(A)(10): Electronic prior authorization transactions (pages 91 and 576)***

PHIT supports requiring PAINitiationRequest, PAINitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and the new PANofication in § 170.315(b)(3)(ii)(A)(10) for the electronic prescribing certification criterion at the time a health IT developer presents a health IT module for certification using NCPDP SCRIPT standard versions 2023011 and 2017071.

#### ***§ 170.315(b)(3)(ii)(D): Signatura (Sig) (pages 95 and 581)***

PHIT supports requiring a health IT module certified to the electronic prescribing criterion to enable a user to enter, receive, and transmit structured and codified prescribing instructions with the NCPDP SCRIPT standard versions 2023011 and the NCPDP Structured and Codified Sig Format Implementation Guide. These instructions are essential for accurate prescription labeling, appropriate patient counseling and education from a pharmacist, and optimal medication use.

#### ***RxNorm and National Drug Codes (NDC) (pages 98 and 582)***

PHIT supports removing existing reference to RxNorm, September 8, 2015 Release and requiring the use of at least one of the more recent releases of the RxNorm code at the time a health IT developer presents a health IT module for certification using the NCPDP SCRIPT standard version 2023011.

Updating to the more current RxNorm will ensure all health IT modules use the same code sets and can communicate with pharmacy data systems more effectively, as well as significantly benefiting prescribers, pharmacists, payers, and patients to help improve the quality of health care and aligning with Medicare Part D.

***§ 170.315(b)(3)(ii)(B): Race and Ethnicity (page 100)***

PHIT supports the proposal, as recommended by ASTP’s Pharmacy Interoperability and Emerging Therapeutics Task Force, that a health IT module certified in electronic prescribing must enable a user to exchange race and ethnicity information for a patient when performing certain prescription-related electronic transactions, if using NCPDP SCRIPT standard version 2023011.

***Base EHR Definition (page 102)***

PHIT supports including “real-time prescription benefit” certification criteria in 170.315(b)(4) in the Base EHR definition in § 170.102 and “electronic prescribing” certification criterion in § 170.315(b)(3) to the Base EHR definition.

***Multi-factor Authentication (page 103)***

PHIT supports that after January 1, 2028, a health IT module certified must meet the multi-factor requirements specified for user-facing authentication. PHIT agrees with ASTP that this update is in line with industry information security best practice and will better protect electronic health information.

***c. Real-Time Prescription Benefit Standard (pages 111 and 583)***

As noted in our June 20, 2023 comments on HTI-1, PHIT (and NCPDP) supported adopting Real-Time Prescription Benefit (RTPB) standard version 13 rather than version 12 for use as part of the certification criterion. RTPB version 13 should also be required for medication and vaccines covered by pharmacy benefit managers (PBMs). It appears ASTP plans to allow health IT modules certified to use either RTPB 12 or 13. To ensure the current RTPB version becomes the standard, PHIT recommends that ASTP add a target expiration date for using RTPB 12, as it has done with other proposed standards of this rule.

***d. Sending and Receiving Real-Time Prescription Benefit Information (page 112)***

See previous RTPB comment.

### ***Formulary and Benefit (page 116)***

PHIT supports the adoption of HL7 FHIR Da Vinci – Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, version 2.0.1 – STU2, in § 170.215(m)(i), as well as it being referenced as part of the “patient access API” certification criterion.

### **11. Revised End-User Device Encryption Criterion (page 121)**

PHIT supports the new server-side encryption requirement in § 170.315(d)(7)(iii) that must be met on and after January 1, 2026 for storing all personally identified information. PHIT also supports HITAC’s recommendation that the term “server-side” be replaced with “health IT storage.”

### **13. Health IT Modules Supporting Public Health Data Exchange (pages 128 and 664)**

PHIT supports revising the current certification criteria related to public health by adding criterion for bidirectional exchange with a Prescription Drug Monitoring Program (PDMP) and adopting new criteria for health IT for public health, standardized FHIR-based API for public health data exchange, and computerized provider order entry – laboratory. PHIT agrees that the multi-pronged approach proposed will harmonize data exchange across the industry.

#### **d. Revised Certification Criteria for Health IT Modules Supporting Public Health Data Exchange (page 143)**

PHIT supports revising § 170.315(f)(1) – Immunization registries – Bi-directional exchange as proposed and updating to HL7 v2.51 Immunization Messaging Implementation Guide release 1.5 with a January 1, 2028 expiration date.

#### **ii. § 170.315(f)(9) and (29) – Prescription Drug Monitoring Program (PDMP) Databases– Query, receive, validate, parse, and filter (pages 163 and 660)**

PHIT supports the adoption of new certification criterion and functional requirements to enable and improve the bidirectional interaction and electronic data exchange between health IT modules and PDMP databases, as well as adding functional certification criteria. PDMP is particularly important for pharmacists, especially bidirectional interstate exchange, to be able to query and receive PDMA data in an interoperable manner.

#### **iii. § 170.315(f)(21) Immunization information – Receive, validate, parse, filter, and exchange – response (page 178)**

PHIT supports the adoption of new certification criterion and requirements for health IT for public health, as well as the proposed requirements to enable health IT for public health to receive electronic immunization information transmitted through a method that conforms to Simple Object Access Protocol (SOAP)-based transport.

Regarding ASTP's request for comment about SMART Health Cards, PHIT believes health IT for public health should support patient access using SMART Health Cards for Immunizations Criteria.

**v. § 170.315(f)(23) Reportable laboratory test values/results – Receive, validate, parse, and filter (page 184)**

PHIT supports the proposed requirements in § 170.315(f)(23)(i) to receive electronic reportable laboratory test values/results transmitted at a minimum through a method that conforms to the standards specified. ASTP may want to consider updating transmission requirements to HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5, US Realm, May 2024, LRI\_PH\_COMPONENT\_V3.

**ii. Provider access API – client (§ 170.315(g)(31)) and Provider access API – server (§ 170.315(g)(32)) (page 285)**

PHIT supports the adoption of certification criteria and time periods proposed that would enable a health care provider access to information on a patient's claim, including access to clinical information maintained by the payer from sources other than claims, such as laboratory results, clinical data from documents formatted in accordance with the Common Clinical Data Architecture (C-CDA), information from admit, discharge and transfer (ADT) messages, information received from immunization registries, and information related to medications from pharmacy networks.

PHIT also supports requiring a health IT module support the ability to interact with a Payer Data Exchange (PDex) Server for all the corresponding client capabilities for requirements described in the "PDex Server CapabilityStatement" and HL7 FHIR Profiles, Resources, as well as support the corresponding client capabilities described in the "US Core Server CapabilityStatement."

**iii. Payer-to-payer API (§ 170.315(g)(33)) (page 292)**

PHIT supports the adoption of payer-to-payer API (application programming interface) certification criterion to specify requirements for health IT modules that can be used by payers to support electronic exchange between payer systems when patients transition between payers and requiring health IT modules to meet these requirements by December 31, 2027.

**iv. Prior authorization API – provider (§ 170.315(g)(34)) and prior authorization API – payer (§ 170.315(g)(35)) (page 295)**

PHIT supports the adoption of prior authorizations API – provider certification, which establishes requirements for health IT modules that can be used to facilitate a provider's request of coverage information and request for a prior authorization decision.

PHIT also supports the adoption by reference of all certification criteria based on HL7 FHIR Da Vinci Burden Reduction IGs, as well as the adoption of CRD IG version 2.01 – STU2, CDS Hooks, workflow triggers for decision support interventions certification criterion, et al.

#### **v. Provider directory API – health plan coverage (§ 170.315(g)(36)) (page 310)**

PHIT supports adoption of a provider directory API – health plan coverage certification criterion, as based on HL7 FHIR Da Vinci Payer Data Exchange Plan Net (PDex Plan Net) IG, version 1.1.0 – STU1.1, which specifies technical requirements for health IT modules that can enable publishing information regarding the providers that participate in a payer’s network.

#### **C-CDA Reconciliation and Incorporation Through Certified Health IT Measure (page 321)**

PHIT supports requiring developers to submit responses on specific data classes and elements from C-CDA documents obtained and subsequently reconciled and incorporated through manual and automated processes.

PHIT also supports the data classes and elements that ASTP intends to list in the measurement specific sheet as technical updates: Substance (Medication) and Substance (Drug Class) in the Allergies and Intolerances data class, patient goals and social determinants of health (SDOH) goals in the Goals data class; immunizations in the immunizations data class; values/results in the Laboratory data class; medications in the Medications data class; unique device identifier – implantable for a patient's implantable device(s) in the Medical Devices data class; assessment and plan of treatment in the assessment and Plan of Treatment data class, and problems and SDOH problems/health concerns in the Problems data class.

#### **IV. Information Blocking Enhancements (page 391)**

PHIT notices that ASTP proposes incorporating the PHSA section 3000 definitions of “laboratory” and “pharmacist” into the health care provider definition for information blocking, which is understandable based on previous ONC interpretations of health care providers. Although ASTP’s “interpretation of these types of health care providers has always relied on the 42 U.S.C. 300jj(10) and (12) definitions of ‘laboratory’ and ‘pharmacist,’” does this mean that pharmacists are now formally “actors” under the information blocking rule rather than potential actors? Does this change to the health care definition only apply only to the information blocking or is the definition applicable to other sections of this proposed rule? Clarification by ASTP would be appreciated.

Regarding the proposed description of interference (page 399), PHIT believes it is necessary to say “access, exchange, or use” of electronic health information (EHI). Removing the word “exchange” and saying “access or use” of EHI is not sufficient and changes the meaning and intent of the description. Exchanging information is not the same as accessing and using information. Accessing information is one sided and only involves retrieving or

obtaining information, while exchanging information implies a two-way flow where information is shared.

#### **a. Application of “Interference” to TEFCA Requirements (page 400)**

PHIT believes the discussion presented gives assurance to actors interested in participating in the Trusted Exchange Framework and Common Agreement (TEFCA) that complying with the requirements of TEFCA as a Qualified Health Information Network (QHIN), participant, or subparticipant would unlikely constitute interference under the information blocking definition.

#### **V. Trusted Exchange Framework and Common Agreement (page 479)**

PHIT supports the proposed exchange requirements for QHINs in § 172.201(b) to ensure the data sharing infrastructure is private and secure.

#### **13. Health IT Modules Supporting Public Health Data Exchange**

##### ***§ 170.315(f)(1) Immunization registries – Bidirectional exchange (page 601)***

PHIT supports revising the current certification criterion for “Transmission to immunization registries” to reference the most current HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 2.0.

##### ***§ 170.315(f)(3) Reportable laboratory results – Transmission to public health agencies – and Laboratory Orders – Receive and validate (page 609)***

PHIT supports adopting HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 4 - US Realm (LOI) and incorporating it by reference; HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (ELR), and referencing the latest versions of SNOMED CT, LOINC, and UCUM.

#### **Workflow triggers for decision support interventions (page 683)**

PHIT supports adopting HL7 Clinical Decision Support (CDS) Hooks FHIR Implementation Guide version 2.0 in § 170.215(f) as a mandatory compliance prerequisite to facilitate API-driven workflow triggers for decision support interventions in § 170.315(j)(20) and §170.315(j)(21).

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members. PHIT’s membership is composed of the key national pharmacy associations involved in health IT, the National Council for Prescription Drug Programs, and 12 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, PHIT's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-centered care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, PHIT 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](http://www.pharmacyhit.org).

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On behalf of PHIT, thank you again for the opportunity to comment on *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)*.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at [shelly@pharmacyhit.org](mailto:shelly@pharmacyhit.org).

Respectfully submitted,



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