Via Electronic Submission to: www.regulations.gov

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Office of Policy
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building
C Street, SW
Washington, DC 20201

RIN: 0955-AA03; Proposed Rule HTI-1: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Dear Dr. Lipinski:

On behalf of its membership, the Pharmacy Health Information Technology Collaborative (PHIT) is pleased to submit comments for *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Rule.* PHIT has been involved with the federal agencies, including the Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) 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 provide longitudinal person-centered care planning, needed medications, and transmit patient information related to overall patient care, transitions of care, immunization, medication lists, medication allergies, allergy reactions, 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, drug formulary checking, and comprehensive medication management (CMM).

Comments

PHIT supports the recommendations the National Council of Prescription Drug Programs (NCPDP) is submitting for this proposal.

C. New and Revised Standards and Certification Criteria (pages 54-70)

PHIT supports ONC's proposal to update the United States Core Data for Interoperability (USCDI) standard in §170.213 by adding the newly released USCDI v3 and setting January 1, 2025 as the expiration date for USCDI v1. Of particular benefit to health care providers, especially pharmacists, are the data elements included in USCDI v3 that were not part of USCDI v1: social determinants of health (SDOH); clinical notes; clinical tests; encounter information; health insurance information; health status assessments; laboratory; medications, including fill status and indications; patient demographics; and problems.

2. C-CDA Companion Guide Updates (page 70)

PHIT supports the adoption of Health Level 7 (HL7®) CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 3 – US Realm and understands that HL7 working on updating the C-CDA R2.1 Companion Guide (Release 4) for USCDI v3.

3. "Minimum Standards" Code Sets Updates (pages 70-76)

PHIT supports incorporating by reference throughout §170.207 the various code sets updates, particularly those relevant to pharmacy: SNOMED CT US Edition (March 2022); LOINC Database version 2.72 (February 16, 2022); RxNorm (July 5, 2022) Full Monthly Release; CVX-Vaccines Administered (June 15, 2022); NDC – Vaccine NDC Linker (updates through July 19, 2022); and CDC Race and Ethnicity Code Version 1.2 (July 2021).

4. Electronic Case Reporting (pages 77-93)

PHIT supports requirements that align with the functionalities included in the specified Clinical Document Architecture (CDA) and Fast Healthcare Interoperability Resources (FHIR)-based Implementation Guides (IGs) discussed in the proposal for the purpose of electronic case reporting to public health agencies.

5. Decision Support Interventions and Predictive Models (pages 94-210)

PHIT understands that the current criterion for clinical decision support (CDS) will be replaced and renamed as the decision support interventions (DSIs) certification criterion and recategorized as part of the care coordination criteria in §170.315(b). PHIT would support updates that ensure users know when race, ethnicity, SDOH, and other data salient to health equity are used by a DSI, including predictive DSIs.

Artificial Intelligence, Algorithms, and Predictive Models in Healthcare (page 98)

Clinician trust in artificial intelligence (AI) and machine learning (ML)-based predictive DSI will be crucial for adoption. PHIT believes that advances in predictive modeling based on AL/ML have the potential for improving clinical care, including pharmacist provided person-centered care, and patient outcomes provided predictive DSI is unbiased; trustworthy; fair, appropriate, valid, effective, and safe (FAVES) when applied to medications; and the information from these models is presented in an effective manner for sound decision making.

To ensure that predictive DSI is not biased, developers of AI/ML and certified health IT with health IT modules need to address issues, such as health equity, information privacy and security, patient safety, and data stewardship, including data de-identification, to prevent algorithmic bias. Algorithmic bias, which is not new, can exacerbate social inequities in health care.[1] Although a number of intervention risk management requirements for predictive DSI are proposed in this rulemaking, including submitting "real world testing plans and results," the proposal does not appear to address or require equity in testing in these plans for AL/ML across patient population to limit potential biases, particularly those biases pertaining to race and ethnicity, which are directly related to health care inequities and SDOH.

"AI utilizes algorithms to assess data from the world, make representation of that data, and use that information to make an inference."[2] Among the worldwide data accessed is health care data, which may not necessarily be an equitable and accurate representation of certain patient populations in the United States. These algorithms that use evidence-based data for medications, clinical trials, may be the basis for population bias. In their 2019 paper, "Artificial intelligence and algorithmic bias: implications for health systems," Panch, Mattie, and Atun define "algorithmic bias in the context of AI and health systems as: 'the instances when the application of an algorithm that compounds existing inequities in socioeconomic status, race, ethnic background, religion, gender, disability, or sexual orientation to amply them and adversely impact inequities in health systems.'"[3]

Health care and health care systems will face challenges in addressing algorithmic biases especially as it relates to medications. Federal guidance, requirements, and harmonization are needed to address this.

[1] Katherine J. Igoe, "Algorithmic Bias in Health Care Exacerbates Social Inequities – How to Prevent It," Harvard T.H. Chan School of Public Health, March 12, 2021. https://www.hsph.harvard.edu/ecpe/how-to-prevent-algorithmic-bias-in-health-care/
[2] Ibid.
[3] Trishan Panch, Heather Mattie, and Rifat Atun, "Artificial intelligence and algorithmic bias: implications for health systems," Journal of Global Health, December 9, 2019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875681/

2. Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities (pages 334-40)

PHIT and the National Council for Prescription Drug Programs (NCPDP) support adopting Real-Time Prescription Benefit (RTPB) standard version 13 rather than version 12, as proposed, for use as part of the certification criterion. Additionally, we support adoption of NCPDP RTPB for clinical purposes and follow NCPDP's recommendations. Adoption of an RTPB standard must not prohibit or block use by a pharmacist.

Although we agree with the importance of interoperability within the certification program, without incentives provided on the pharmacy side, PHIT supports voluntary certification.

iii. Requirements for Use of NDC or RxNorm Codes (pages 341-44)

PHIT and NCPDP supports use of both NDC and RxNorm Codes. We also support accurate NDC-RxNorm mapping.

v. Patient Specific Benefit Information (pages 346-47)

PHIT supports NCPDP's recommendations in this area. Additionally, we support patient demographic/information data class identified in USCDI version 3.

vi. System and Workflow Integration (pages 347-49)

PHIT supports system workflow and integration to reduce the clinician's burden, as well as NCPDP's additional recommendations in this area.

vii. Real Time Prescription Benefit Certification Scope (pages 349-51)

As stated previously, PHIT and NCPDP supports adoption of RTBP version 13 rather than version 12.

d. Health IT Ecosystem for Pharmacy Interoperability and Formulary Benefit Management (pages 351-354)

PHIT supports NCPDP's recommendations in this area.

3. FHIR Standard (page 356-58)

PHIT supports the FHIR standard. The Pharmacist eCare Plan is FHIR ready, as shown by ONC's "Documenting and Sharing Medication-Related Care Plans by Pharmacists."

b. Clinical Decision Support (CDS) Hooks Request for Information (pages 353-61)

PHIT supports the use of CDS hooks. The potential uses of CDS hooks is discussed in PHIT's paper, "Optimized clinical decision support (CDS) using FHIR-based CDS Hooks." Critical to the use of CDS hooks is making sure the ML process and AI has the ability to ensure patient safety and bias against adverse events can be identified. Additionally, CDS hooks allows pertinent data to be accessible within the clinician's workflow in the appropriate time to reduce clinician burden.

c. FHIR Standard for Scheduling Request for Information (pages 360-62)

PHIT supports the FHIR standard for scheduling. Many pharmacies are currently using scheduling as a result of needed vaccination appointments during Covid-19.

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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. PHIT's membership is composed of the key national pharmacy associations involved in health IT, the National Council for Prescription Drug Programs, and 13 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.

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On behalf of PHIT, thank you again for the opportunity to comment on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Rule.*

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

Respectfully submitted,

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