March 21, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-0053-P
P.O. Box 8013
Baltimore, MD 21244-8013

> **CMS-0053-P: Administrative Simplification: Adoption of Standards for Health Care Attachments and Electronic Signatures, and Modification to Referral Certification Authorization Transaction Standard**

Dear Administrator Brooks-LaSure

On behalf of its membership, the Pharmacy Health Information Technology Collaborative (PHIT) is pleased to submit comments for *CMS-0053-P: Administration Simplification: Adoption of Standards for Health Care Attachments and Electronic Signatures.*

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

III.3. Proposed Adoption of X12N Standards for Health Care Attachments Transaction Standards

PHIT supports the adoption of the X12N standards proposed for health care attachments transactions, particularly X12N 278 Version 6020 to replace X12N 278 Version 5010, as Version 6020 expands the drug authorization segment, which includes fields necessary to identify a drug, specify quantity of drug requested, specify drug dosage requested, and accommodate related codes. Version 5010 does not enable entities to supply this additional information.

PHIT also agrees with CMS's interpretation that the Affordable Care Act's (ACA) "mandate as referencing the then-current standards (the X12 Version 5010) did not specifically require a static standard in perpetuity, as that would be incongruent with the HIPAA standards paradigm."

III.B. Proposed Adoption of Health Level 7 (HL7) Implementation Guides for Health Care Attachment Information

PHIT supports the adoption of the three proposed HL7 implementation guides, as HIPAA standards for the attachment information included in health care attachments transactions and for a transmission from a health care provider to a health plan, and for digital signatures:

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1 – Introductory Material, June 2019 with Errata;
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2 – Introductory Material, June 2019 with Errata; and
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1, March 2017.

III.C. Electronic Signatures (HL7 Implementation Guide)

PHIT supports the of adoption HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegations of Rights, Release 1.

V.D.11. Conclusion: Pharmacies

PHIT agrees with the conclusion and assumption in Section V.D.11 that "pharmacies would generally not be impacted by the changes in this proposed rule." If necessary, pharmacies use NCPDP standards and clinical information or C-CDA attachments that can be attached to NCPDP SCRIPT or SPECIALIZED standard transactions. However, as pharmacist

provided services and care coordination continue to expand, if a payer requires a pharmacy to support health care attachments and digital signatures for pharmacy provided services submitted, the pharmacy may need to support these transactions at the request of the payer. PHIT hopes that CMS will take this into consideration in future rulemaking.
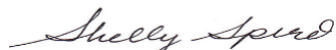
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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. PHIT's membership is composed of the key national pharmacy associations involved in health IT, the National Council for Prescription Drug Programs, and 14 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 *CMS-0053-P: Administration Simplification: Adoption of Standards for Health Care Attachments and Electronic Signatures.*

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

Respectfully submitted,

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