Via Electronic Submission to: https://www.regulations.gov

June 16, 2025

Stephanie Carlton
Deputy Administrator, Centers for Medicare & Medicaid Services
Steven Posnack
Acting Assistant Secretary for Technology Policy, Acting National Coordinator for Health Information Technology
Department of Human Services
Attention: CMS-0042-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: [RIN 0938-AV68; CMS-0042-NC] Request for Information; Health Technology Ecosystem

Dear Deputy Administrator Carlton and Acting Assistant Secretary Posnack:

On behalf of its membership, the Pharmacy Health Information Technology Collaborative (PHIT) appreciates the opportunity to submit comments regarding the *Request for Information; Health Technology Ecosystem*.

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 (ASTP/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 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 and guidance on safe medication use. Pharmacists transmit patient information related to overall patient care, transitions of care, medication lists, medication allergies, patient problem lists, tobacco use 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, and comprehensive medication management (CMM).

Comments

C. Providers

1. Digital Health Apps

As pharmacy practice is an integral part of the health care system, PHIT supports the use of interoperable health information technology (health IT), which includes digital health apps and electronic health records (EHR), to improve patient safety and outcomes, provide better and more timely access to health information needed by patients and providers, and integrate pharmacy health IT into the national health IT infrastructure. It is critical that health IT, as well as future CMS and ASTP/ONC proposals, enable pharmacists to improve public health, prevent chronic disease progression, and ensure that electronic health information and access are available to support the pharmacist's optimized role in health care delivery. In this regard, PHIT encourages CMS and ASTP/ONC to examine the Pharmacist eCare Plan, as well as the HL7 FHIR Standard Medication Profile (SMP) Implementation Guide.

The eCare Plan "is an interoperable standard that allows for pharmacy technology providers to have a common method of exchanging information related to care delivery, including patient goals, health concerns, active medication list, drug therapy problems, laboratory results, vitals, payer information, and billing for services."[1] Care planning is an essential part of patient-centered care services provided by pharmacists. The eCare Plan allows pharmacists to identify and address a patient's health care barriers.[2]

The HL7 FHIR SMP Implementation Guide "defines a way to transmit medication/drug information (as prescription or orders or records of a patient receiving some kind of medication/drug). As a patient travels through the healthcare system (such as from hospital to nursing facility to home) this guide shows how the medication/drug information can be sent electronically with the patient to enable *medication reconciliation*." [3] Ensuring an updated and accurate patient's medication profile is available to providers in transition of care and emergency situations is essential to patient safety.

PR-2: Obstacles

Although health IT has advanced, barriers exist and affect adoption, access by patients and providers, security, and privacy.

The government has spent millions of dollars over the years to get medical and other health professions to exchange health information electronically[4], including providing incentive programs established in 2011 (e.g., CMS Incentive EHR program), and yet, inconsistencies in

[1] https://www.ecareplaninitiative.com/
[2] Erin Hmielewski, "The Pharmacist eCare Plan: Expanding Patient-Centered Care." April 30, 2020. https://www.pharmacyowners.com/the-pharmacist-ecare-plan
[3] https://www.hl7.org/fhir/us/smp/index.html
[4] Andrew Muchmore, "Government rules led electronic records astray. It's time to reimagine them." STAT Health Tech. March 27, 2020. https://www.statnews.com/2020/03/27/government-rules-led-electronic-health-records-astray-its-time-to-reimagine-them/

various rules and interpretations by the agencies and departments involved are contributing to EHRs not living up to their potential. Interoperability still is not fully where it needs to be, including issues with data at the point of care (e.g., medical errors, costs, lack of transparency, outdated practices that govern data exchange, siloed and fragmented data[5]). EHR systems must be able to share information between all relevant systems.

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Community pharmacy, also referred to as "retail pharmacy", excels at electronic exchange of prescription claims data which means patients have real-time coverage and cost share information at the point of care. The lack of recognition as providers in the Social Security Act and, subsequently, the lack of access to incentive funds afforded to other providers, has contributed to slower adoption of electronic systems to document clinical care and subsequently exchange health information. Ironically, as one of the most accessible health care providers in the country, pharmacists were deemed ineligible for the CMS EHR Incentive Program (now called Medicare Promoting Interoperability Program) because they are not defined as health care providers under Section 1171 of the Social Security Act – the governing law used for CMS programs. This also affects pharmacists practicing in a health care system who must approach documentation for care covered by federal programs different from Medicaid/commercial/other payers. This oversight needs to be corrected, and pharmacists need to be recognized as providers by the federal government as they are by many Medicaid programs and private/commercial health plans across the country. This is a significant, but easily removed, barrier that must be addressed.

Identity verification can be a burden for providers, as well as for individuals exercising the right to access their records, particularly when needing to share information with another provider or caretaker. Ensuring security and protecting privacy could be done easily through the electronic systems used by covered health care providers and health plans if set up to reduce identity burden. Such systems, ideally, should be certified EHR technology (CEHRT) through the ASTP/ONC HIT and CMS Certification Programs and adhere to those standards. Pharmacists must be included in identity verification and not left out, as often happens.

An often-overlooked aspect is an individual's access to the electronic tools needed for accessing digital health information. Not all people own smartphones and computers or have access to adequate and affordable internet service, especially in rural areas. This is particularly true for many seniors and low-income individuals. Community pharmacies are a key portal into the health care system for patients, especially people with technology and other communication barriers.

PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)?

[5] Mika Newton, "All health care problems are data problems." September 10, 2024. https://www.medicaleconomics.com/view/all-health-care-problems-are-data-problems

It is crucial for health care delivery that all data in an EHR system be accessible for exchange regardless of storage format; all formats must be accessible and readable. Access to all patient data, including those in formats noted in this question, allows providers to make informed decisions, avoid errors, and provide more personalized and effective treatment plans. In this regard, EHR interoperability is especially important for better workflows, reducing ambiguity and errors, and providing seamless data transfer among EHR systems and health care stakeholders (e.g., providers, patients).

There are more than 67,000 community (retail) pharmacies in the United States; nearly 19,000 of those are independent pharmacies. HIPAA (Health Insurance Portability and Accountability Act) security rule safeguards for fax machines used by pharmacies are followed. "Fax machines remain the most prevalent form of communication for transmitting care records and prescriptions," according to ASTP/ONC,[6] though progress is slowly being made in moving away from fax machines. A subset of those pharmacies participate in a clinically integrated network of pharmacies, such as CPESN USA, and all have the systems and processes in place to document clinical encounters and produce a FHIR-based care plan.

Faxes are a secure and reliable way to transmit patient information and prescriptions, especially when secure transmission is crucial. Fax machines are not subject to cyberattacks. The primary reason that fax machines continue to be used in health care is the challenges with interoperability between different EHR systems; interoperability is not where it needs to be.

2. Data Exchange

PR-5: FHIR APIs

PHIT supports all the FHIR APIs (Fast Healthcare Interoperability Resources Application Programming Interfaces) listed in PR-5 (a-i). PHIT is an active participant with Health Level Seven International (HL7), FHIR's developer, and provides feedback on standards being developed. PHIT also published a paper on the potential uses of CDS hooks, "Optimized clinical decision support (CDS) using FHIR-based CDS Hooks."

PR-6: TEFCA (Trusted Exchange Framework and Common Agreement)

PHIT supports and believes TEFCA will advance provider access to health information, particularly for pharmacies. Through its work with ASTP/ONC, PHIT has provided feedback on TEFCA. Though TEFCA has only been operational since December 2023, nine designated Qualified Health Information Networks (QHINs) were approved as of April 2025. According to the Sequoia Project and the Recognized Coordinating Entity (RCE), 1,633 organizations were live on TEFCA (QHINs, participants, and subparticipants) and to the framework agreement as of January 2025. RCE, through its collaboration with ASTP/ONC, is responsible for developing,

[6] Lucas Mearian, "The fax is still king in healthcare – and it's not going away anytime soon." Computerworld. May 22, 2023. https://www.computerworld.com/article/1626950/the-fax-is-still-king-in-healthcare-and-its-not-going-away-anytime-soon.html

implementing, and maintaining the Common Agreement. PHIT is actively involved with the Sequoia Project Interoperability Matters Pharmacy Workgroup.

PHIT also supports the proposed exchange requirements for QHINs in § 172.201(b) to ensure the data sharing infrastructure is private and secure. ASTP/ONC issued a proposed rule for Health Data, Technology, and Interoperability Engagement, Information Sharing, and Public Interoperability (HTI-2) on September 12, 2024.

4. Information Blocking

PR-12: Removing or Revising Any of the Information Blocking Exceptions or Conditions

On September 12, 2024, ASTP/ONC released a proposed rule regarding HTI-2, which included "Section IV. Information Blocking Enhancements." PHIT noted in its October 4, 2024, comments that ASTP/ONC proposed incorporating the Public Health Service Act (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/ONC'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 to 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 for information blocking in HTI-2, 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.

Additionally, PHIT stated it believes the discussion regarding the application of interference to TEFCA requirements presented in proposed HTI-2 gives assurance to actors interested in participating in TEFCA that complying with the requirements of TEFCA as a QHIN, participant, or subparticipant would unlikely constitute interference under the information blocking definition.

PR-13: For any category of healthcare provider (as defined in 42 U.S.C. 300jj(3)), without a current information blocking disincentive established by CMS, what would be the most effective disincentive for that category of provider?

On November 1, 2023, CMS and ASTP/ONC published "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking," a proposed rule that also requested information for future rulemaking on additional

appropriate disincentives that should be considered and applied to health care providers not implicated in the proposed rule.

PHIT stated in its January 2, 2024, comments that although pharmacies and pharmacists are mentioned in the RFI's examples of possible health care providers not implicated by the proposed rule, we recommended that CMS and ASTP/ONC not proceed with establishing or applying disincentives for pharmacies until such EHR requirements and criteria for interoperability are in place for pharmacies.

Although a pharmacist and a pharmacy are defined in the health care provider term (42 U.S.C. 300-jj) used in the CMS/ASTP/ONC proposed rule, the disincentives for information blocking outlined in the proposal cannot be applied to them, as they are not participants in the EHR Incentive Program for which the proposed rule applies. Pharmacists and pharmacies are not defined as meaningful users of CEHRT (certified electronic health record technology) in the Merit-Based Incentive Payment System (MIPS) program, as they are not defined as eligible professionals nor as meaningful EHR users in the EHR Incentive Program by CMS. Since the creation of this program in 2011, PHIT has been requesting the Secretary to address this omission to include pharmacists as health care providers under Section 1171 of the Social Security Act.

A pharmacist's or pharmacy's certification and use of certified EHR in the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Program is currently voluntary because they do not receive incentives from the EHR Incentive Program for demonstrating use of CEHRT. Until EHR requirements and criteria for interoperability are identified for a pharmacist or a pharmacy, disincentives cannot be applied; only the reporting of possible information blocking by a pharmacist or pharmacy is allowed.

Future disincentives should be related to TEFCA. TEFCA establishes a universal governance, standardization, and the technical floor for interoperability, as well baseline legal technical requirements through the Common Agreement, which covers information blocking. Pharmacies will likely be part of TEFCA through their participation in QHINs, as QHINs are approved and operational and the cost of participation can be justified.

E. Technology Vendors, Data Providers, and Networks

2. Digital Identity

Based on recent developments, strengthening security with additional safeguards where cyberattacks are predominantly occurring should be the number one focus and priority of the health technology ecosystem at all levels (government and private sector). Verifiable digital credentials (VDCs) can help reduce the risk of identity-based cyberattacks; however, "though the concept seems simple, deploying VDCs and understanding their impact on security, privacy

and usability in practice can be challenging."[7] It needs to be kept in mind that the capabilities of smaller health care groups are different than those of the larger groups, as are their needs.

Cybersecurity is a major concern that needs to be addressed. Safeguarding electronic protected health information (ePHI) is paramount. The U.S. lags other countries in this area from federal and state governments to the private sector. Health care is the number one target experiencing cyberattacks.[8] The reason for this is health care data is valuable; worth a lot of money to attackers.[9] Attacks range from stealing personally identifiable information that is sold to black market operators to holding electronic health care systems and organizations hostage via ransomware; United Healthcare paid nearly $3 billion in ransom in a 2024 attack,[10] making it the largest ransom paid to date. This information, including ePHI, is not only being stolen from the private sector but also from the federal government.

Cyberattacks on health care organizations hit an all-time high in 2023.[11] In 2024, the health care industry experienced its biggest data breaches of all time with attacks on Change Healthcare (owned by UnitedHealthcare Group; largest breach), Kaiser Foundation Health Plan (second biggest), and Ascension Health (third).[12] The federal government was not immune to health care cyberattacks, as CMS reported a major breach of protected health information of 3,112,815 individuals in its system (September 2024);[13] over 940,000 were Medicare beneficiaries.[14] An earlier CMS data breach occurred in May 2023, affecting 612,000 Medicare beneficiaries.[15]

3. Technical Standards and Certification

TD-5: How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers?

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[7] Bill Fisher and Ryan Galluzo, "Digital Identities: Getting to Know the Verifiable Credential Ecosystem," National Institute of Standards and Technology, November 13, 2024. https://www.nist.gov/blogs/cybersecurity-insights/digital-identities-getting-know-verifiable-digital-credential-ecosystem

[8] "FBI Report: Health Care the Top Target by Cyber Attackers," Government Technology, June 27, 2024. https://www.govtech.com/em/safety/fbi-report-health-care-the-top-target-by-cyber-attackers

[9] "9 Reasons why healthcare is the biggest target for cyberattacks." Swivel Secure. https://swivelsecure.com/solutions/healthcare/healthcare-is-the-biggest-target-for-cyberattacks/

[10] Marianne Kolbasuk McGee, "Change Healthcare Attack Cost Estimate Reaches Nearly $2.9B,"Bank Info Security, October 16, 2024. https://www.bankinfosecurity.com/change-healthcare-attack-cost-estimate-reaches-nearly-29b-a-26541

[11] Steve Alder, "Healthcare Data Breach Statistics," *The HIPAA Journal*, January 20, 2025. https://www.hipaajournal.com/healthcare-data-breach-statistics/#:~:text=2021%20was%20a%20bad%20year,stolen%2C%20or%20otherwise%20impermissibly%20disclosed.

[12] Steve Alder, "The Biggest Healthcare Data Breaches of 2024," *The HIPAA Journal*, January 7, 2025. https://www.hipaajournal.com/biggest-healthcare-data-breaches-2024/

[13] Ibid.

[14] Esperance Becton & Stephanie Marcantonio, "Over 940,000 Medicare Beneficiaries Impacted by Data Breach," Healthcare Law Blog, October 23, 2024. https://www.sheppardhealthlaw.com/2024/10/articles/centers-for-medicare-and-medicaid-services-cms/over-940000-medicare-beneficiaries-impacted-by-data-breach/#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid,)%20and%20personally%20identifiable%20information%20(%E2%80%9C

[15] "CMS Responding to Data Breach at Contractor," CMS Newsroom, July 28, 2023. https://www.cms.gov/newsroom/press-releases/cms-responding-data-breach-contractor

FHIR endpoints could improve access to health information for patients, providers, and payers by providing a streamlined, centralized data hub for health care directory information that is accurate and verified data.

Patients could quickly retrieve their health records from various providers and payers, allowing them to become more active in their care; easily share health information with new and multiple providers across different health systems, which would improve the continuity of care; and use this information to better understand their conditions, treatment options, and compliance with their care plans, including pharmacy care plans.

Providers would have faster and more efficient access to patient information through a centralized directory, which would lead to improved clinical decision-making and reduced administrative burdens. However, as stated previously, pharmacists are still not recognized as providers under Medicare, which is a barrier that must be removed to ensure longitudinal patient care provision and pharmacy and patient level data exchange, including pharmacist provided patient care and digital health.

For payers, this would help streamline claim processing and prior authorization (important to the pharmacy practice), reduce reporting burdens with regulatory agencies and others, and improve network management, ensuring their provider networks are up to date.

HL7's National Directory of Healthcare Providers & Services (NDH) Implementation Guide (IG) provides standards and guidance for a national directory infrastructure in the US. Local directories could also use FHIR APIs to make content available to their users.[16] Some federal agencies are further along implementing FHIR capabilities than others. PHIT continues to work with the HL7 Pharmacy Work Group.

TD-7: USCDI (United States Core Data for Interoperability)

PHIT supports USCDI, as it provides a standardized set of health data classes and data elements for nationwide, interoperable, electronic health information exchange needed by pharmacists. ASTP/ONC's USCDI integrates with FHIR US Core, though not all USCDI elements are mapped, and USCDI Data Classes and Element names may differ from FHIR US Core resource names and element names.[17] PHIT actively reviews, provides feedback, and makes recommendations to ASTP/ONC for additional data classes and elements on an annual basis.

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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

[16] National Directory of Healthcare Providers & Services (NDH) Implementation Guide, HL7. https://build.fhir.org/ig/HL7/fhir-us-ndh/

[17] 3.1 USCDI, HL7 International. https://build.fhir.org/ig/HL7/US-Core/uscdi.html

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 *Request for Information; Health Technology Ecosystem*.

For more information, contact Jeff Rochon, Executive Director, Pharmacy HIT Collaborative, at jeff@pharmacyhit.org.

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