Pharmacy Health Information Technology Collaborative

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

June 3, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS 9115-P – Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers

Dear Administrator Verma:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we appreciate the opportunity to submit comments on the *Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Care Plans et al* proposed rule.

Pharmacists provide essential pharmacy and health-related services to patients. Additionally, pharmacists are users of health IT, and in particular, e-prescription and EHR systems. The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicare and Medicaid Services (CMS), in developing the national health information technology (HIT) framework and standards since 2010.

The Collaborative appreciates that CMS continues working collaboratively with ONC to develop proposed rules to advance interoperability and health care provider and patient access to health information. The following are our comments.

Application Programming Interfaces (APIs)

Although CMS is proposing to require that API technologies deployed by health plans subject to this rule use modern computing standards (such as RESTful inferfaces and XML/JSON), the Collaborative also supports adopting Health Level 7 Fast Healthcare Interoperability Resources (FHIR) DSTU2, as a baseline standard conformance requirement, and FHIR Releases 2, 3, and 4, which are also under consideration by ONC's proposed options for APIs. This would allow more flexibility for advancing FHIR-based interoperability, particularly with the Public Health Service definition of interoperability that CMS proposes to adopt.

Special Technical Approach and Standards

The Collaborative supports adopting content and vocabulary standards, particularly USCDI Version 1, for representing electronic health information (EHI), technical standards for an API by which the EHI must be made available, and aligning these with the interoperability standards proposed for adoption in the ONC 21st Century Cures Act proposed rule.

Clinical Data Including Laboratory Results

For pharmacy, the PHIT Collaborative recommends the Pharmacist Care Plan,[1] using HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1, which incorporates USCDI v1 and FHIR Release 4 for interoperable exchange of medication-related clinical data captured by pharmacists. The Collaborative supports adopting HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1 C-CDA Companion Guide to support the best practice implementation of USCDI v1 data classes. These should be available through the API, as well.

The CDA and FHIR Pharmacist Care Plan Implementation Guides project is now being balloted by HL7. "The goal of the project is to develop an electronic care plan with enhanced medication management content based on the templates in HL7 Implementation Guide for C-CDA Release 2.1: Consolidated Notes and FHIR profiles based on US Core specifications."[2] The Pharmacist Care Plan is key to the incorporation of medication-related goals and outcomes into a patient's care profile and planning. It will serve as a "standardized, interoperable document for exchange of consensus-driven prioritized medication-related activities, plans and goals for an individual needing care."[3]

The Collaborative supports the proposal at 42 CFR 422.119(b)(2)(ii) and (iii) that Medicare Advantage (MA) organizations offering MA-PD plans make available through APIs pharmacy directory data, including the number, mix, and addresses of pharmacies in the plan network, as well as formulary data, especially Part D drugs and any tiered formulary structure

[1] https://www.ecareplaninitiative.com/

[2] http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1232

[3] Ibid.

or utilization management procedure that pertains to those drugs. We believe this would also be better addressed in regulation text rather than just imposing a timeframe for this information to be made available through an API.

Routine Testing and Monitoring of Open APIs

The Collaborative supports that an API be routinely tested and monitored to ensure it is functioning properly, including assessments to verify that the API is fully and successfully implementing privacy and security features, such as, but not limited to those minimally required to comply with HIPAA privacy and security requirements.

Request for Information on Information Sharing Between Payers and Providers through APIs

While the Collaborative supports information sharing between payers and providers, some third-party applications may not have business associate agreements with payers and may not be covered under existing HIPAA liability provisions. We ask CMS to review and clarify whether there would be a security and liability issue for either the payer or provider in such cases in using open APIs.

Health Information Exchange and Care Coordination Across Payers: Establishing a Coordination of Care Transaction to Communicate Between Plans

The Collaborative supports the requirement for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs maintain a process to coordinate care between plans by exchanging, at a minimum, in the form of the USCDI Version 1 data set at the specific times specified in the proposed rule. We agree that the use of USCDI to exchange information furthers care coordination. As mentioned previously and as part of coordinated care, the Collaborative recommends the Pharmacist Care Plan, using HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 which incorporates USCDI v1, for interoperable exchange of medication-related clinical data captured by pharmacists.

Additionally, we believe CMS needs to look at this more broadly to ensure that the electronic exchange of information between pharmacists and these plans, as well as between pharmacists and eligible clinicians, eligible hospitals, and eligible CAHs occurs in an interoperable two-way process (bidirectional communication/exchange). For the long-term and post acute care settings, a three-way process is needed to include pharmacy, prescriber, facility/home care systems, and these plans.

Trusted Exchange Framework and Common Agreement (TEFCA)

The Collaborative supports requiring MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs (excluding SADP issuers) to participate in TEFCA, once the framework is fully defined, formalized, and operational. In addition to allowing broader interoperability beyond on health system or point-to-point connections among payers,

patients, and providers, participating in TEFCA is a means of providing assurances to their customers and CMS that they are not taking actions that constitute information blocking or actions that would inhibit the exchange, access, or use of electronic health information.

Information Blocking and Public Reporting

The Collaborative understands that CMS' primary focus with regard to information blocking is to require eligible clinicians, eligible hospitals, and eligible CAHs under the Medicare FFS Promoting Interoperability Program (MPIP; formerly the Medicare EHR Incentive Program) and physicians in the Physician Compare Program to attest on a CMS website that they are not information blocking. In the event that an entity states they are information blocking, CMS will report their names as a means of holding them accountable. One concern, though, is that information may be blocked at an institutional level. The CMS proposal would appear to hold the eligible clinician accountable for the institutional actions. Further, we don't believe attestation is adequate to address this issue. Providers are not likely to self-declare they are information blocking. CMS may need to develop an evaluation test for this particular area to ensure information blocking is not occurring rather than relying on provider attestation.

An additional concern is that this section of the proposed rule does not appear to address other areas where information blocking may occur, such as health information exchanges and APIs that may be used for sharing health information related to CMS programs. Although pharmacists are not eligible clinicians under some of the CMS programs, they do need access to patient health information in these programs and could limited in their access to that information. As CMS has been working collaboratively with ONC, we recommend that CMS provide assurances in the rule that ONC information blocking prohibitions would apply.

Advancing Interoperability in Innovative Models: Examples of Interoperability-Related Areas to Focus for New Model Development

The Collaborative strongly encourages CMS to review the Pharmacist Care Plan Initiative. This joint project between NCPDP and HL7, which is fully supported by the Collaborative, will serve as a "standardized, interoperable document exchange of consensus-driven prioritized medication-related activities, plans, and goals for an individual needing care."[4]

Request for Information on Policies to Improve Unique Patient Matching

The Collaborative supports efforts to identify patient matching options. We encourage CMS, as we also stated in our May 3 interoperability/information Blocking comments to ONC 's 21st Century Cures proposed rule on this topic, to look at NCPDP's Universal Patient Identifier (UPI), which was developed in partnership with Experian Health, as a solution to match and manage patient identities.[5] The NCPDP UPI leverages Experian's "expansive consumer

[4] https://www.healthit.gov/techlab/ipg/node/4/submission/1376
[5] https://ncpdp.org/Products/NCPDP-Universal-Patient-Identifier

demographic information and referential matching methodologies to identify record matches and duplicates in a patient roster file, and then assign a unique NCPDP UPI to each patient in the file."[6] The NCPDP UPI can be used across all health care entities.

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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 *Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Care Plans et al* proposed rule.

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

Respectfully submitted,

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[6] Ibid.

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