Via Electronic Submission to: www.regulations.gov

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21224-8016

Re: [CMS-9123-P] Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (PHIT), we are pleased to submit comments regarding proposed rule *CMS-9123-P Medicaid Program, et al.*

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

Pharmacists provide essential services to Medicaid and Medicare patients. Pharmacists are users of health IT, and in particular, electronic medical record (EMR)/electronic health record (EHR) systems, and are impacted by prior authorization requirements. PHIT supports the use of these electronic systems, which are important to pharmacists in working with other health care providers and insurers to provide needed medications and exchange 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, social determinants of health, and electronic prescribing.

The following are our comments regarding *CMS-9123-P Medicaid Program, et al* for proposed areas concerning improving prior authorization processes, promoting patients' electronic access to health information for Medicaid managed care plans, and health IT standards and implementation specifications.

II. A. Patient Access API

II. A. 2a. Patient Access API Implementation Guides (page 19)

PHIT supports including in the final rule these implementation guides (IGs):

- HL 7 Consumer Directed Payer Data Exchange (CARIN IG for Blue Button® IG: Version STU 1.0.0 to facilitate the exchange of claims and encounter data;
- HL7 FHIR US Core IG: Version STU 3.10. and HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG: Version STU 1.0.0 to facilitate the exchange of clinical information as defined in U.S Core Data for Interoperability (USCDI); and
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) US Drug Formulary: Version STU 1.0.1 to facilitate the exchange of current formulary information.

II. A. 2b. Additional Information (page 26)

PHIT supports requiring impacted payers to implement and maintain a FHIR-based Prior Authorization Support (PAS) application programming interface (API) that would have the capability to accept and send prior authorization requests and decisions, which could be integrated within a provider's workflow.

For future consideration, PHIT believes CMS should require payers to include information about prescription drug and covered outpatient drug pending and active prior authorization decisions via the Patient Access API, the Provider Access API, and the Payer-to-Payer API. Patients, providers, and payers need to have access to the same information, and thus we recommend this information be included in all three APIs.

II. A. 2c. Privacy Policy Attestation (pages 27-34)

As privacy and security are of the utmost importance, PHIT supports requiring impacted payers to request a privacy policy attestation from third party application (app) developers when their app requests to connect with the payer's Patient Access API and to have a process in place for making such requests beginning January 1, 2023. Ideally, app developers should attest that all privacy provisions are in place. If, however, an app developer is not able to have all provisions in place by the January 1 implementation date, then the app developer needs to attest to those that are.

II. A. 2e. Patient Access API Revisions (pages 36-37)

PHIT agrees with the language revisions using "clinical data, as defined in the USCDI version 1" and changes to require that payers make a determination to deny or discontinue access to the Patient Access API using objective, verifiable criteria that are applied fairly and consistently.

II. A. 2f. Provider Directory API Implementation Guide (pages 38)

PHIT supports requiring state Medicaid Provider Directory APIs be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0.

II. B. Provider Access

II. B. 3. Proposed Requirements for Payers: Provider Access for Individual Patient Information Access (pages 52-55)

PHIT supports requiring impacted payers to implement a Provider Access API using HL7 FHIR standards and to allow providers to have access to an individual patient's information, as well as accessing multiple patients' information at the same time, regardless of in- and out-of network payer agreements. Additionally, we support that payers implement this Provider Access API patient data approach for data maintained by the payer with a date of service by January 1, 2023.

II. B. 6c. Provider Resources (page 66)

PHIT supports requiring payers to make educational resources available to providers, including pharmacists, that describe how a provider can request patient data using the payer's Provider Access APIs in "non-technical, simple, and easy-to-understand language."

II. B. 7b. QHP Issuers on the FFEs (page 76-77)

PHIT supports requiring these new requirements for qualified health plans (QHPs) on the Federal-facilitated Exchanges (FFEs) to allow FFEs to certify only health plans that make enrollees' health information available to their providers, including pharmacists, via the Provider Access API and to use the FHIR Bulk specification for the Provider Access API. When providers have access to patient utilization and authorization information directly from their electronic health records (EHRs) or other health IT systems, they can provide higher quality of care. The more information a provider receives increases the likelihood patients will receive better care.

II. C. Documentation and Prior Authorization

II. C. 2. Electronic Options for Prior Authorization (pages 83-86)

PHIT supports the continued use of National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard electronic prior authorization (ePA) transaction for prescription drugs and devices (e.g., digital therapeutics, home blood glucose monitors, and testing supplies) and X12 Version 5010x217 278 (X12 278) for dental, professional, and institutional request for review and response for items and services. As proposed, we understand that payers are required to use X12 278 standard for electronic prior authorization transactions.

PHIT appreciates and applauds CMS' efforts to encourage providers to conduct these transactions electronically, for recognizing the need to increase transparency of the medical benefit, and proposing to increase data sharing and reduce overall patient, provider and payer burden through proposed changes to prior authorization processes. Pharmacy has already addressed these problems via the NCPDP SCRIPT Standard ePA transactions. It is imperative CMS acknowledge the progress and promise of pharmacy prior authorization automation to gain full utilization and adoption of the standard.

II. C. 3. Proposed Requirement for Payers: Documentation Requirement Lookup Service (DRLS) API (pages 86-90)

PHIT supports requiring state Medicaid and CHIP fee for service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to implement and maintain a FHIR-based RLS API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0 and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0, populated with their list of covered items and services for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request by January 1, 2023. PHIT, however, asks CMS to clarify its reasoning for not including prescription drugs and covered outpatient drugs in the list of items and services for these IGs.

CMS states, "Throughout this proposed rule, when we discuss items and services, this does not include prescription drugs and/or covered outpatient drugs. We did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this rule."

According to NCPDP, the NCPDP SCRIPT Standard ePA transactions has been adopted by nearly the entire (96%) payer industry.[1] As we note below, prior authorization determination times can take days to weeks before a patient is given a

[1] covermymeds.com/main/insights/articles/key-findings-of-the-epa-and-rtbc-national-adoption-scorecards/

needed medication. The use of NCPDP SCRIPT Standard ePA transactions for medication prior authorization significantly reduces the determination time to mere seconds, which leads to quicker access to these needed medications and improves outcomes. PHIT supports NCPDP's concern about not including drugs in these IGs and agrees that they should be included.

II. C. 4. Proposed Requirement for Payers: Implementation of a Prior Authorization Support (PAS) API (pages 90-93)

PHIT supports the implementation date of January 1, 2023. We agree with CMS' assessment that it would be valuable for payers to implement the PAS API for prior authorizations, especially a FHIR-based PAS-API, as it would enhance the overall process and increase the use of electronic prior authorizations by providers, which is low at this time, and especially if providers' management systems and EHRs make the connection to a payer's API. Maintaining a FHIR-based PAS would give the provider the capability to accept and send prior authorization requests and decisions, which could be integrated within a provider's workflow.

PHIT believes this presents CMS and ONC with an opportunity to encourage health IT developers to implement these functions within EHRs, including the potential future addition of certification criteria in the ONC Health IT Certification Program. This could also help move using ePAs by providers forward.

II. C. 4a. Requirement to Provide a Reason for Denial (pages 94-97)

As payers do not always provide consistent communication about the reasons for denials or information about what is required for approval, PHIT supports requiring impacted payers send a specific reason for denying a prior authorization request. PHIT recommends requiring the use of X12 278 HIPAA standard transaction to communicate prior authorization status information.

II. C. 4b. Program Specific Notice Requirements to Accompany Prior Authorization Denial Information – Medicaid and CHIP Managed Care (page 98)

PHIT believes requiring communication via the PAS API would enhance the current notification process.

II. C. 8. Public Reporting of Prior Authorization Metrics (page 122-127)

As proposed, PHIT supports requiring impacted payers to publicly report certain prior authorization metrics on their websites at the state level for Medicaid and CHIP

FFS, at the plan level for Medicaid and CHIP managed care, and at the insurer level for QHP insurers on the FFEs.

II. C. 10. Additional Requests for Comments (pages 127-130)

PHIT encourages CMS to look at opportunities to improve the prior authorization process, especially for pharmacists. Although ePA is available, it is not being fully used by health care providers who interact with pharmacists. A few topics for consideration and where improvements are needed:

- **Disconnect in the provider's office.** Many times, a patient is informed of the prior authorization after going to the pharmacy, as the provider is unaware that the payer requires this before the prescription can be dispensed. This can cause a delay in dispensing a medication, or result in the patient asking for another medication. Often it requires a series of phone calls to resolve.
- **Integration.** The electronic process needs to be seamless, as well as integrated into the EHR. This will be particularly critical for the advances being made in the use of cell and gene therapies. Prior authorization needs to exist within the EHR. As mentioned previously, this is an area where CMS and ONC could partner to encourage developers to add or improve this functionality.
- **Standardized forms.** All forms used for ePA need to be standardized. Additionally, it is time to start moving away from paper-driven processes. PHIT would suggest CMS partner with HL7 for developing and standardizing electronic FHIR questionnaires for ePAs.
- **Medicare Advantage (MA) Plans.** Although this proposed rule deals predominantly with the various Medicaid plans as payers, we note that Medicare Advantage plans are not specifically included in the proposed requirements, though they are mentioned in some sections. We would appreciate it if CMS could provide an explanation for specifically not including MA plans.

II. D. 2. Payer-to-Payer Data Exchange on FHIR (pages 140-142)

PHIT supports expanding Payer-to-Payer Data exchange to be conducted via a specified Health Level 7 International® (HL7) Fast Healthcare Interoperability Resources® (FHIR)-based API. PHIT also supports CMS' proposal to require impacted payers to implement the Payer-to-Payer API in accordance with the specified HL7 FHIR version 4.0.1 IGs, as well as the HL7 FHIR Bulk Data Access (Flat FHIR) specification for exchanging patient data, such as adjudicated claims and encounter data, clinical data as defined in the USCDI, and information related to pending and prior authorization decisions.

Additionally, PHIT supports requiring impacted payers to implement and maintain a Provider Access API that is consistent with the APIs finalized in the

Interoperability and Patient Access final rule (85 FR 25510) and utilize HL7 FHIR version 4.0.1. We agree with CMS that this will better facilitate the coordination of care across the care continuum.

PHIT supports requiring impacted payers to implement and maintain a FHIR-based Prior Authorization Support (PAS) API that would have the capability to accept and send prior authorization requests and decisions, which could be integrated within a provider's workflow.

II. D. 4. Enhancing the Payer-to-Payer Data Exchange: Payer-to-Payer API (pages 148-159)

PHIT agrees that it would be valuable for payers to share pending and active prior authorization decisions with providers, including pharmacists. PHIT supports requiring this Payer-to-Payer API to be able to share specified data conformant with the HL7 FHIR Bulk Data Access (Flat FHIR).

II. D. 6. Extensions and Exemptions for Medicaid and CHIP (pages 160-167)

As states may face unique circumstances that would not apply to other impacted payers, PHIT supports the proposed, limited, implementation extensions and exemptions.

II. E. Adoption of Health IT Standards and Implementation Specifications (pages 173-188)

PHIT supports adoption of implementation specifications for APIs based on the HL7 FHIR Release 4 base standard adopted by the ONC.

III. Requests for Information

III. A. Patient Engagement and Provider Discretion: FHIR Utility (page 191)

PHIT supports the use of FHIR-based APIs that engage the patient and provider in the data segmentation decision process, particularly with regard to protecting a patient's privacy.

III. B. Electronic Exchange of Behavioral Health Information (pages 196-200)

Pharmacists can impact mental health outcomes by providing patients with education about psychiatric drugs, evaluating medication lists for drugs that may alter a patient's mental status, and improving medication adherence through side-effect

monitoring.[2] Paramount for doing this is sharing behavioral health information between the behavioral health provider and the pharmacist. The most efficient and cost-effective way to share this information is electronically. Critical to this is ensuring that EHRs and prior authorization systems are integrated and accessible to facilitate better electronic health data exchange and bidirectional communication.

There are levers CMS could consider. FHIR-based APIs is one that could be leveraged. Another possibility is CMS implementing some type of incentive program (e.g., payment) to encourage the adoption and use of EHRs, particularly, certified EHRs, by behavioral health providers and pharmacists. Just as with behavioral health providers, pharmacists also were not included as eligible professionals in the meaningful use of certified EHR technology. Given CMS' interest in this area, an opportunity is presenting itself to CMS.

III. D. 1. Reducing Burden and Improving Electronic Information Exchange of Prior Authorizations (pages 200-203)

Barriers within the existing system impede pharmacists' abilities to receive prior authorizations, disrupt workflows, and delay the dispensing of needed medications and providing certain pharmacist services to patients. These barriers have a substantial and continual negative impact on patient care outcomes. Pharmacists need a means to have real-time access to prior authorizations and providers' systems, which they currently do not have.

Many of the processes used today are manual and paper-based, which rely on fax machines and other fax technology for sending the prior authorization. Manual processes are time consuming, costly, a burden to providers, and use extra staff to ensure payment is authorized and completed. These processes often involve unreasonable wait times to receive the prior authorization (some have taken one month or longer). For critically ill patients, such wait times could represent a serious threat to their recovery.

As an example, state regulations require that long-term care facilities receive medications right away or within a specified time. Some of those prescription medications may require prior authorization before they are dispensed. Any delay in receiving those medications not only could make the facility non-compliant, but also could be harmful to the patient. Delay issues may involve a problem in faxing, readability of the fax, or denial of the prior authorization without explanation. Resolving these issues, including obtaining an explanation for a denial or having the

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[2] Moore, Catherine H.; Powell, Brandon, D; Kyle, Jeffrey A., "The Role of the Community Pharmacists in Mental Health," *U.S. Pharmacist*, November 15, 2018. https://www.uspharmacist.com/article/the-role-of-the-community-pharmacist-in-mental-health#:~:text=Community%20pharmacists%20can%20have%20an,for%20drugs%20that%20may%20alter

denial reversed, may take numerous phone calls and exchanging multiple faxes, which is time consuming, adding more time to the delay and cost to the facility.

Similar issues arise at the community pharmacy level regarding prescription medications and pharmacist services. Pharmacists provide certain services, such as diabetes education, that may require prior authorization. The pharmacist needs to be connected or have access to the system with the provider to receive the prior authorization; however, in many cases the pharmacist's system isn't connected. Additionally, as mentioned in II. C. 10. above, a patient is informed of the prior authorization after arriving at the pharmacy for a medication, as the provider is unaware that the payer requires this before the prescription can be dispensed. This can cause substantial delays in dispensing a medication or result in the patient asking for another medication, both of which impede patient care and may lead to significant negative care outcomes.

The best resolution to reduce burden is to move into a fully, interoperable, integrated, ePA system. An electronic system is not only quicker and more efficient, it also provides a tracking mechanism, which a manual system does not provide. In addition to the FHIR-based APIs outlined in this proposed rule, PHIT recommends CMS consider including FHIR-based Clinical Decision Support (CDS) resources. Applications, such as CDS Hooks, trigger content to a clinician's or payer's workflow and pharmacist services in real-time, enhancing the ability to answer questions and resolve issues.

III. D. 2. Future Electronic Prior Authorization Use in the Merit-Based Incentive Payment System (MIPS) (pages 203-207)

As noted in III B. above, pharmacists were not included as eligible professionals in the meaningful use of certified EHR technology incentive program, even though they are health care providers and meaningful users of EHRs. Implementing an inclusive, incentive program for health care providers, including pharmacists, would encourage greater adoption and use of EHRs.

III. E. Reducing the Use of Fax Machines (pages 207-209)

Fax machines and online fax technology are still used. The use of fax technology is outdated, prone to malfunction, open to security risks, and incurs unnecessary expenses. The technology is inefficient, unreliable, and decelerates pharmacy workflow. Faxes may be difficult to read, which may be exacerbated by a physician's illegible handwriting or malfunctions in one machine or another.

With today's technology and advancements in electronic prior authorization, CMS is in the perfect position to aid in developing a strategy to move health care

providers away from faxing. CMS taking the lead, and working with stakeholders, to establish timeframes and possible incentives to discontinue the use of faxes, especially for prior authorizations, would help streamline this process and move toward truer interoperability.

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PHIT is overseen by 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, NCPDP, and 13 associate members encompassing e-prescribing, health information networks, pharmacy quality development organizations, pharmacy companies, system vendors, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health IT, 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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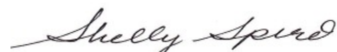
On behalf of PHIT, thank you again for the opportunity to comment on *CMS-9123-P Medicaid Program, et al.*

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

Respectfully submitted,



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