



January 4, 2021

[Submitted electronically via www.regulations.gov]

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
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, Proposed Rule

To Whom it May Concern:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the proposed rule for the Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes.

APhA is the largest association of pharmacists in the United States and the only organization advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, physician offices, clinics, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

In the Interoperability and Patient Access final rule (85 FR 25510), CMS finalized policies impacting Medicare Advantage organizations, state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans (QHPs) on the federally facilitated exchanges (FFE). CMS finalized policies in that rule requiring those impacted payers to build and maintain application programming interfaces (APIs) to increase patient access and data exchange and improve interoperability in health care. In this proposed rule, CMS is proposing certain policies to expand upon those foundational policies for state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs.

However, CMS did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this proposed rule, nor does it address the prior authorization challenges pharmacists encounter in dealing with Medicaid and these related health plans on a

daily basis. Accordingly, to assist CMS' efforts APhA offers the following comments and recommendations.

General Comments - Standardize and Streamline Prior Authorization

APhA commends CMS for taking steps to improve the prior authorization process for medical procedures which will help lead to more standardization and reduced administrative burden. As CMS is aware, prior authorization and other utilization management tools (e.g., quantity limits, step therapy) can pose administrative hurdles that delay patient access to medical services or their medication(s). There is a significant need for CMS to take a more standardized approach to prior authorization policies to improve patient access and reduce significant administrative burden on health care practitioners, including pharmacists. In January 2017, APhA partnered with the American Medical Association (AMA) and a number of other health care organizations to create 21 principles to reform prior authorization and utilization management requirements.¹ In addition, APhA along with the American Hospital Association (AHA), America's Health Insurance Plans (AHIP), AMA, Blue Cross Blue Shield Association (BCBSA) and Medical Group Management Association (MGMA) released a consensus statement on improving the prior authorization processes which offered opportunities for improvement in prior authorization programs and processes.² Accordingly, APhA strongly recommends CMS continue to utilize work completed by key stakeholders and incorporate these 21 consensus principles and consensus statement into prior authorization policies.

Pharmacists are the health care practitioner patients see most frequently and, in some circumstances, can play a more expansive role in helping streamline prior authorization requests based on their medication expertise and knowledge about a patient. However, plans generally require the prescriber to submit the prior authorization request. While APhA is very sensitive to policies that place additional burdens on pharmacists, especially when those requirements are not covered by payers, there may an opportunity to better utilize pharmacists and proactively provide pharmacists with easier access to information about a patient's prior authorization request.

To address several of these issues, APhA requests CMS implement a more standardized approach to prior authorization and other utilization management requirements that would be more user-friendly and function more efficiently. Currently, each plan and PBM has different requirements for prescribers and pharmacists when a medication requires prior authorization. While some requirements are similar, even minor variability makes it more difficult for prescribers and pharmacists to complete the prior authorization in accordance with a plan's or pharmaceutical benefit manager's (PBMs) specific policies. When documentation issues occur, valuable, unreimbursed additional time is spent by health care practitioners to identify why a

¹ AMA, American Academy of Child and Adolescent Psychiatry, American Academy of Dermatology, American Academy of Family Physicians, American College of Cardiology, American College of Rheumatology, American Hospital Association, American Pharmacists Association, American Society of Clinical Oncology, Arthritis Foundation, Colorado Medical Society, Medical Group Management Association, Medical Society of the State of New York, Minnesota Medical Association, North Carolina Medical Society, Ohio State Medical Association and Washington State Medical Association. . Prior Authorization and Utilization Management Reform Principles. January 25, 2017. Available at: <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-with-signatory-page-for-slsc.pdf>

² APhA, American Hospital Association, America's Health Insurance Plans, AMA, Blue Cross Blue Shield Association and Medical Group Management, Consensus Statement on Improving the Prior Authorization Process, available at: <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>

prior authorization request was not accepted and then to resolve the issue. All these additional steps delay patient's access to their medically necessary services or prescribed medications and detract from the practitioner's capacity to provide care directly to the patient.

Comments on Provisions of the Proposed Rule

II. A. 2b. Additional Information

As stated above, while not included in the proposed rule, CMS is requesting comment for possible future consideration and rulemaking on whether or not impacted payers should be required to include information about prescription drug and/or covered outpatient drugs pending and active prior authorization decisions with the other items or services proposed via the Patient Access API, the Provider Access API, or the Payer-to-Payer API. CMS also asks for the role Pharmacy Benefit Managers (PBMs) should play in this process.

Require Payers to Include Information about Prescription Drug and Covered Outpatient Drug Pending and Active Prior Authorization Decisions Via All Three APIs

For future consideration, APhA believes CMS should require payers to include information about prescription drug and covered outpatient drug pending and active prior authorization decisions via all three APIs. Patients, providers, and payers need to have access to the same information.

Prior authorization requirements and drug formulary changes can have a direct impact on patient care by creating a delay or altering the course of treatment. In order to ensure that patients and health care providers are fully informed while purchasing a product and/or making care decisions, utilization review entities need to be transparent about all coverage and formulary restrictions and the supporting clinical documentation needed to meet utilization management requirements.

Accordingly, CMS should require all of Medicaid, CHIP and QHPs to publicly disclose, in a searchable electronic format, through the three APIs, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual prescription drugs and covered outpatient drugs. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process. Additionally, plans should clearly and seamlessly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy override request. All efforts should be in coordination with CMS' recent final transparency rule which applies to all plans subject to section 2715A of the public health service act.³

³ HHS. Trump Administration Finalizes Rule Requiring Health Insurers to Disclose Price and Cost-Sharing Information. October 29, 2020, available at: <https://www.hhs.gov/about/news/2020/10/29/trump-administration-finalizes-rule-requiring-health-insurers-disclose-price-and-cost-sharing.html>

It is also important for CMS to be aware of issues related to prior authorization that are unique to community pharmacists. Often, pharmacists will inform their patients that a prescription requires prior authorization and communicate with a patient's prescriber regarding prior authorization needs. However, information about prior authorization may not be easily determined by the pharmacist, and pharmacists may spend additional time contacting the plan or PBM for more information. Pharmacists may initiate the prior authorization process by contacting the prescriber, often using automation, fax or telephone. After this, pharmacists are often kept in the dark regarding the status of the prior authorization. Most pharmacies attempt to process prescriptions requiring prior authorization on a daily basis until the claim is accepted, incurring transaction fees with each attempt. It is also common for patients, who have been informed by their prescriber that the prior authorization has been approved, to arrive at the pharmacy expecting their prescription to be filled, when the pharmacy is not aware of the approval. It should be clear that imposing prior authorization requirements should not be a way to direct patients to a different pharmacy than that of the patient's choice. Implementing policies that require pharmacies to be informed when prior authorizations have been approved would improve timely access to care and efficiencies within the pharmacy.

Technology Needs for Improving Pharmacist Participation in Prior Authorization Processes

Pharmacists' access to electronic medical record (EMR)/electronic health record (EHR) systems, is fundamental to ensuring all members of the patient care team can assist in streamlining prior authorization requirements and lowering the administrative burden on providers. Pharmacists' access to EHRs is necessary for real-time interactions 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.

Our members continue to have concerns that while CMS and private payors have established frameworks to encourage collaboration and team-based care, depending on the practice, pharmacists are frequently blocked from the exchange of relevant clinical information included in EHRs. Such restrictions impede the ability of CMS and patients to benefit from coordinated, team-based care. Therefore, APhA strongly suggests CMS develop policies that facilitate the exchange of relevant health information between the appropriate members of the health care team in order to streamline prior authorization, care coordination and billing among Medicaid, CHIP and QHPs in the states.

II. A. 2f. Provider Directory API Implementation Guide

APhA supports requiring state Medicaid Provider Directory APIs be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0. However, pharmacists may not uniformly be listed as Medicaid providers. As CMS understands, it is generally recognized in the health care field and verified by industry surveys conducted by credentials verification organizations and other entities that between 20-40 percent of the time provider directories in both the private and public sector are inaccurate or out-of-date. To address this situation, credentials verification

organizations are attempting to use a variety of strategies, including technological innovations, telephonic interventions, penalties, etc. Pharmacist and pharmacy-specific directories currently suffer from the same shortcomings as physician and other health provider directories with missing, inaccurate or out-of-date data. As pharmacists are being recognized in more and more states as health care providers with expanded scope and payment authority, the maintenance of accurate directories of pharmacists with accurate information is critical. However, presently pharmacists are facing challenges in effectively documenting and making their professional credentials available for use by public and private payer entities.

To address this situation, APhA, through a subsidiary entity Pharmacy Profiles LLC, has launched a nationwide platform designed to securely centralize a database of U.S. pharmacist providers and their advanced credentials. The system is designed to automate the retrieval of professional credentials information on pharmacists, verify that information, and engage pharmacists regularly to keep it up-to-date. Pharmacy Profiles works in collaboration with industry partners to effectively coordinate and share information leveraging and linking to existing databases. The Pharmacy Profiles system intends to enable pharmacists to manage all of their professional information in one place and participate as seamlessly as possible in provider directories going forward. With CMS' increasing recognition of the valuable contributions pharmacists make to improved patient care, APhA would welcome a meeting with CMS to further discuss Pharmacy Profiles and its benefits to Medicaid, CHIP and QHP plans.

II. B. Provider Access

II. B. 3. Proposed Requirements for Payers: Provider Access for Individual Patient Information Access

APhA 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. We recommend CMS specifically noting that pharmacists are included as providers in this context.

II. B. 6c. Provider Resources

APhA 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

APhA supports new requirements for QHPs 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 EHRs or other health IT systems, they can provide higher quality care. The more information a

provider receives, the better care patients will receive. This in turn will allow providers to spend more time with their patients.

II. C. 10. Additional Requests for Comments

In addition to our general comments above to standardize and streamline prior authorization, APhA encourages CMS to look at opportunities to improve the prior authorization processes for medications for pharmacists. Although electronic prior authorization 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 the patient asking for another medication. Often it requires a phone call 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 workflows need to exist within the EHR. 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 electronic prior authorization need to be standardized. Additionally, it is time to start moving away from paper-driven processes. APhA suggests CMS partner with HL7 for developing and standardizing electronic FHIR questionnaires for electronic prior authorizations.
- **Pharmacists' patient care services.** As pharmacists are increasingly recognized as providers in state Medicaid and other payer plans, any prior authorization requirements for patients to receive pharmacists' services should be consistent with those of other health care providers. Prior authorization should not be required for pharmacists for a specific service if it is not required for other providers.
- **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. APhA and our partners would appreciate if CMS could provide an explanation for specifically not including MA plans.

II. D. 4. Enhancing the Payer-to-Payer Data Exchange: Payer-to-Payer API

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

III. Requests for Information

III. B. Electronic Exchange of Behavioral Health Information

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 improve medication adherence through side-effect monitoring.⁴ 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 an incentive program (e.g., payment) to encourage the adoption and use of EHRs, particularly, certified EHRs, by behavioral health providers and pharmacists.

III. D. 1. Reducing Burden and Improving Electronic Information Exchange of Prior Authorizations

Barriers within the existing system impede pharmacists’ abilities to receive prior authorizations, disrupt workflows, and delay the dispensing of needed medications and the provision of pharmacists’ patient care services to patients. Pharmacists need a means to have real-time access to information about prior authorizations and from 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, use extra staff to make sure payment is authorized and done, costly, and a burden to providers. 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 be onerous.

As an example, state regulations require that long-term care facilities receive medications right away or within a specified time. Some prescription drugs 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 getting an explanation for a denial or having the 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, as well, regarding prescription drugs and pharmacist services. Pharmacists provide certain services, such as diabetes education, that may

⁴ 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>

require prior authorization. The pharmacist needs to be in the system with the provider to receive the prior authorization, but many times the pharmacist is not able to connect with the provider's system. Additionally, a patient is informed of the prior authorization for a medication 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 having the patient ask for another medication. Often it requires a phone call to resolve, or the pharmacist will send the patient back to the provider to request another medication.

The best resolution to reduce burden is to move into a fully interoperable, integrated, electronic prior authorization system, incorporating pharmacists. An electronic system is not only quicker and more efficient, it also provides a tracking mechanism, which a manual system does not.

In addition to the FHIR-based APIs outlined in this proposed rule, APhA recommends CMS consider including FHIR-based CDS Hooks. CDS Hooks trigger content to a clinician's or payer's workflow 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)

As CMS understands, 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. However, since the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was signed into law, CMS has stated every MIPS eligible clinician must attest that the certified EHR technology used was “[i]mplemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers”, [including pharmacists] (as defined by 42 U.S.C. 300jj(3))⁵, including unaffiliated providers, and with disparate CEHRT and health IT vendors.”⁶ However, pharmacists are frequently blocked from the exchange of relevant clinical information which is critical to maximize the benefit of coordinated team-based care, including safe and appropriate medication use; adherence for the elderly and other populations; medication reconciliation; wellness and prevention; chronic disease management programs; and case management for beneficiaries with multiple medications that require complex medication dosing regimens. Therefore, APhA strongly recommends CMS require that pharmacists are granted access to relevant patient information through interoperable HIT and certified EHRs under Medicare to improve patient care and help practitioners deliver effective care. After CMS makes such clarification, APhA would consider supporting the addition of a future MIPS improvement activity on use of electronic prior authorization.

⁵ See 42 U.S.C. 300jj(3) defining health care provider as “The term “health care provider” includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, [1] emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy ... and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.” Available at: <https://www.law.cornell.edu/uscode/text/42/300jj>.

⁶ See, CMS. Quality Payment Program. The Merit-based Incentive Payment System (MIPS) Advancing Care Information Prevention of Information Blocking Attestation: Making Sure EHR Information is Shared. Pg. 3. October 2017. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/ACI-Information-Blocking-fact-sheet.pdf>.

Thank you for the opportunity to provide feedback on the proposed rule. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

A handwritten signature in black ink that reads "Ilisa BG Bernstein". The signature is written in a cursive style with a horizontal line at the end.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs