March 13, 2023

The Honorable Chiquita Brooks-LaSure,
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-0057-P: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure:

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of health technology and data to improve health outcomes and lower costs.

HIA, and our members, have done tremendous work to improve interoperability, efficiency, and healthcare delivery while reducing the burden within the healthcare system for all involved. We applaud the thoughtful and comprehensive policies the Centers for Medicare and Medicaid Services (CMS) has put forward in this proposed rule and encourage CMS to adopt our recommendations as you work to finalize the proposals. The comments and recommendations below are from HIA and do not reflect the individual views of our member organizations.

General Comments:

Interoperability

The U.S. Department of Health and Human Services (HHS) has proposed and finalized several rules to advance the interoperability of the U.S. healthcare system since the enactment of the 21st Century Cures Act over six years ago. With the ever-increasing capabilities of technology deployed in this space, the ability for clinicians, payers, hospitals, patients, and others to share information continues to increase. But we still have a long way to go. Officials in the Office of the National Coordinator for Health Information

Technology (ONC) report that about 70 percent of healthcare organizations continue to use the fax machine as a primary method of communication.[1]

To better understand the needs of the healthcare system with regard to interoperability and to develop solutions to the issues faced by patients, providers, technology companies, pharmacies, and plans, HIA released our Interoperability Report including 21 specific solutions in six different policy areas. Specific to the focus of this rule, we urge you to consider policies that would:

- Reduce patient friction and provider burden by requiring detailed plan coverage information at the point of care, including pharmacy, medical services, and prior authorization information, and incentivizing its use; and
- Allow patients to request all covered entities help find and share their health information to improve care coordination.

Electronic Prior Authorization

CMS and Congress have both taken critical steps in migrating prior authorization (PA) processes from traditional phone and fax to digital and electronic methods, and for good reason. Electronic prior authorization (ePA) streamlines traditional PAs by reducing friction in the system, alleviating the burden for providers, and improving the timeliness of necessary treatments for patients. Research shows that switching to real-time ePA could save more than $400 million and reduce the time a provider takes to complete a transaction by 15 minutes on average.[2]

HIA believes that improving PA processes will benefit nearly every actor in these transactions, and we applaud CMS for moving forward and building upon the work done in the Medicare Part D and Medicare Advantage Prescription Drug programs. When implementing ePA in other areas, we ask you to prioritize policies that are standards-based and real-time, as these are foundational needs for achieving seamless exchange that will improve the patient's care and experience. While outside the scope of this proposed rule, we urge you to consider expanding standardized ePA for drugs in addition to the items and services included here to ensure patients have access to both the medications and services they need.

While HIA generally agrees with CMS on the implementation date of January 1, 2026, we note that certain sectors of the healthcare system have much lower technology adoption, such as the behavioral health industry. We recommend that CMS explore ways to promote technology adoption, provide additional guidance, or create exemptions in these sectors in advance of implementation.

Specific Comments

As stated earlier in this preamble, the proposals in this proposed rule do not apply to any drugs. However, we also request comments on whether we should consider policies to require impacted payers to include information about prior authorizations for drugs, when the payer covers drugs, via the Patient Access API, the Provider Access API, and the Payer-to-Payer API. We request comments on how future rulemaking to make information about prior authorizations for drugs available through these APIs might interact with existing prior authorization requirements and standards.[3]

[1] https://news.bloomberglaw.com/health-law-and-business/health-care-clings-to-faxes-as-u-s-pushes-electronic-records
[2] https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf
[3] 87 Fed. Reg at 76245.

We support the expansion of ePA for prescriptions into the programs and APIs covered in this proposal, though we recognize that this is outside the scope of this proposed rule. Prescription information is a critical part of a patient's healthcare record, and that information needs to be available and known to the patient, provider, and payer. Where possible, the regulations should align with those put into place to implement ePA for Medicare Part B, Part D, and MA-PDs as many impacted plans have already implemented the tools and data flows for those programs. Additionally, CMS should do everything it can to improve the implementation of real-time benefit tools, including adding cost-sharing information to the Provider Access API.

The NCPDP SCRIPT Standard is, and has been, the recognized standard for e-prescribing, and, as noted in the proposal, the NCPDP Telecommunications Standard is the HHS-adopted standard under the provisions of HIPAA for prescription prior authorization transactions. These standards should remain the federally-named standards for these transactions and be updated to the proper versions as necessary. The relevant Standards Development Organizations are collaborating on crosswalks and integrations to enable additional functionality. We encourage CMS to consider the resources needed to develop and transition to APIs for the standards in use today. Most standards funding through ONC is based on FHIR development at HL7. If industry-wide interoperability is a shared goal, ONC should fund all relevant SDOs (X12 and NCPDP) to develop the standards necessary to transition to APIs. While many in the healthcare industry share the CMS and ONC goal of having widely adopted FHIR-based APIs in the spaces covered under this proposal, many existing workflows do not have current FHIR functionality. Replacing existing standards and the workflows and systems built around them would be disruptive, costly, and take years to implement. HHS needs to consider how to appropriately guide the industry through required updates, including by providing resources to develop, adopt, and implement these standards and functionalities.

We are proposing that, beginning January 1, 2026, MA organizations and applicable integrated plans, Medicaid FFS programs, and CHIP FFS programs must provide notice of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than 7 calendar days for standard requests. We also propose that Medicaid FFS and CHIP FFS programs must provide notice of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than 72 hours for expedited requests unless a shorter minimum time frame is established under state law.[4]

HIA appreciates the proposed timelines for routine and urgent or expedited requests to shorten the response times for prior authorizations to seven calendar days for standard requests and 72 hours for expedited review. We understand that these timeframes aim to balance the plan's work on making the determination, communicating between the plan and provider, and getting the determination to the patient as expeditiously as possible. As technology and the interoperability among systems continues to improve and the percentage of PAs submitted as ePA increases, we encourage CMS to consider revisiting and shortening these timeframes in the future as much as the technology allows to quickly get patients the care and services they need and payers the information they require. HIA believes that one day these transactions can be automated, but there is much work to be done in the industry and at the federal level to make that a reality.

According to this proposal, the Prior Authorization Requirements, Documentation, and Decision (PARDD) API "would allow a provider to query the payer's system to determine whether a prior authorization was required for certain items and services and identify documentation requirements. The API would also automate the compilation of necessary data for populating the HIPAA-compliant prior authorization transaction and enable payers to provide the status of the prior authorization request,

[4] 87 Fed. Reg. at 76296.

including whether the request has been approved or denied."[5] Once the real-time nature of the transaction standards is combined with automation, these timelines should be able to adjust to near real-time for providers and patients using this information. HIA urges the Department to work toward this shared goal of automation and immediately available data while working with each facet of the industry to ensure adequate resources to achieve this goal.

Information Required to be Included in the Patient and Provider Access APIs

The CMS proposal calls for specific information to be included in the Patient and Provider Access APIs such as prior authorization status, the date of the approval or denial, and when the authorization ends, but also requires supporting materials that are important for patients and providers to understand the full scope of why that decision was made. Supporting materials like lab results, clinical data, and a specific reason for a denial, are necessary for patients and providers to make the best medical decisions. Much of this information should already be cataloged and included in the request, and we encourage CMS to work with impacted payers to ensure these data fields are both clarified and standardized where possible to ensure information is consistent across sources. We understand that in some cases the amount of information or the size of the files may hinder the data exchange more than it would be of value to the end user. We urge CMS to work with plans, providers, and patients to determine the balance that should be included in the requirements and provide the needed clarification and guidance to all parties.

Medicare Fee-For-Service (FFS)

While not directly covered in the proposal, CMS indicates in the preamble to the proposed rule its intent to ensure that Medicare FFS beneficiaries benefit from the eventual policies finalized and seeks comment on how these proposals could apply to Medicare FFS in the future. To accelerate interoperable data exchange, we believe that data should flow between all CMS programs, including Medicare Parts A and B and Medicare Advantage. A common, streamlined API could align with the ONC's Trusted Exchange Framework and Common Agreement (TEFCA), further accelerating the nation toward health data interoperability. This would enable MA plans to serve beneficiaries better, improve health outcomes, and ensure that the data MA plans provide to patients and providers includes the patients' data from periods when they were beneficiaries of Medicare FFS.

Thank you for your careful consideration of our comments and your continued work to improve our healthcare delivery system.

Sincerely,

Brett Meeks
Executive Director

[5] *Id*. At 76289.