Submitted March 23, 2022 electronically at: www.regulations.gov

Alex Baker,
Office of Policy
Office of the National Coordinator for Health Information Technology

RE: RIN 0955–AA04

Dear Mr. Baker,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in Health Insurance Portability and Accountability ACT (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in Medicare Modernization ACT (MMA).

NCPDP submits the following comments in response to RIN 0955-AA04: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria.

ONC Health IT Certification Program

The Certification Program currently addresses electronic prior authorization for medications as part of the ''electronic prescribing'' certification criterion at 45 CFR 170.315(b)(3). On May 1, 2020, ONC published in the Federal Register the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (21st Century Cures Act final rule). In this rule, ONC adopted the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 2017071, for electronic prescribing and specified electronic prior authorization as optional transactions which health IT developers may support in their products (85 FR 25678). However, the Certification Program does not yet address electronic prior authorization for other items and services that healthcare consumers may seek to obtain. Accordingly, for the purposes of this RFI, we are interested in certified health IT functions not yet included under the Certification Program that can support electronic prior authorization processes for items and services other than medications.

> **NCPDP Comment**: NCPDP thanks ONC for referencing the SCRIPT Standard for electronic prior authorization for pharmacy benefits. To increase the adoption and reduce burden, NCPDP recommends the NCPDP SCRIPT prior authorization transactions be required for the certification process. The 2020 AMA survey shows lack of physician access to electronic prior authorization (ePA) with under a quarter (24%) of physicians reporting that their electronic health record / practice management system offers ePA for prescription medications. See https://www.ama-assn.org/system/files/2021-05/prior-authorization-reform-progress-update.pdf.

Functional Capabilities for Electronic Prior Authorization in Certified Health IT
We are seeking comment on functional capabilities for electronic prior authorization that should be considered for inclusion in certified health IT. Specifically, we are seeking comment on a core set of capabilities that would enable a certified Health IT Module or Modules to:

- Identify when prior authorization is applicable for an item or service, using clinical decision support and/or user input, and for receiving notifications of changes in such applicability;
- Query a payer API for prior authorization requirements for each item and service and identify in real time specific rules and documentation requirements;
- Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system;
- Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information;
- Receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information;
- Query a payer's system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending; and
- Effectively capture and persist digital signatures (or other indications of provider review and assent), enable data integrity of documentation over time, and support other features necessary to meet payer administrative requirements associated with prior authorization transactions.

We invite further comment on whether these are the appropriate minimum capabilities needed for certified health IT systems to successfully interact with payer systems to complete key electronic prior authorization activities.

NCPDP Comment: NCPDP agrees the above are the appropriate minimum capabilities needed.

Implementation Specifications for Prior Authorization
NCPDP Comment: It is critical to recognize that submission of the actual prior authorization request is just one step in a series of steps in a workflow to get a patient on an appropriate therapy or treatment plan. Payer benefit design is increasingly complex, and many specialty medications are covered by both the medical and pharmacy benefits. The ability for a provider to have correct, accurate patient specific coverage requirement information at the point of care is critical to have a seamless experience.

It would improve the prior authorization process to harmonize, not replace, existing standards. One benefit to the prior authorization process would be to mandate NCPDP SCRIPT Prior Authorization Transactions in the existing certification requirements. In addition, the industry recognizes the need to expand and allow additional standards to be advanced for prior authorization automation under current law and HIPAA regulation, and certification should recognize this reality. It is crucial to supplement the prior authorization process with new functionalities and standards, not remove existing investments to fill gaps in the existing standards.

Healthcare Attachment Standards
NCPDP Comments: To streamline and standardize prior authorization processes, current workflows that depend on human intervention and interpretation (e.g., properly identifying the form to be completed) need to be replaced with automation and bi-directional electronic communication in real-time or near real-time. When additional information is necessary, the use of codified data elements instead of

documents better supports the desired system automation used in pharmacy benefit ePA processes. The NCPDP SCRIPT Standard purposefully limits the number of attachments to an ePA submission to ensure payers leverage the fielded, computable data in the NCPDP question set. Attachments should only be used when data cannot be acquired through a question set's response. If/when an attachment is necessary, it is critical that the transport packaging is closely associated with the ePA request from a header and metadata perspective, and that the contents of the payload can be parsed electronically. All clinical data attachments across both medical and pharmacy applications should leverage a higher degree of increased fielded and codified data.

NCPDP thanks ONC for the opportunity to comment on the RFI and for the consideration of our comments. NCPDP looks forward to continuing our work with ONC on electronic prior authorizations.

For direct inquiries or questions related to this letter, please contact:
Teresa Strickland
Technical Advisor,
Standards Development
NCPDP
standards@ncpdp.org

Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108