March 18, 2020

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

RE: NCPDP Comments to the ONC Proposed 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit 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.

NCPDP is pleased to provide to ONC the following comments regarding the 2020-2025 Federal Health IT Strategic Plan (Plan):

We are very concerned by the absence of any NCPDP standards in ONC's Plan. NCPDP standards play a critical role in how care is coordinated throughout the pharmacy industry. Widely adopted NCPDP standards, such as Telecommunication and SCRIPT play a significant role in the health information technology and pharmacy services space. We would like to better understand from ONC how you plan to leverage these adopted standards as a part of the Plan. ONC has referenced FHIR® in the Plan and while FHIR® will address some industry needs, it does not address all of the needs of the entire industry. This Plan needs to include all ANSI-approved standards used by the healthcare industry, similar to the Interoperability Standards Advisory (ISA) and not focus solely on the use of FHIR®.

While this Plan is intended to serve as a roadmap for Federal Health IT initiatives and activities, and as a catalyst for activities in the private sector, it does not align with the NCVHS recommendations. NCPDP requests the final version of the Plan incorporate the NCVHS recommendations on how to achieve greater efficiencies to improve adoption of standards under HIPAA.

NCPDP recommends ONC work with **all** ANSI-accredited SDOs that create standards using a consensus process among industry experts, but specifically NCPDP, HL7® and X12, to find standardized, workable solutions to empower patients, lower costs, deliver high-quality care and improve health for individuals, families and communities throughout the U.S.

The following comments are based on initiatives NCPDP is currently working on that are specifically addressed in the Plan.

Objective 1b: Advance healthy and safe practices through health IT

Strategies • Advance use of evidence-based digital therapeutics as treatment options for patients to prevent, manage, and treat conditions through smartphones, tablets, and other personal devices.

Comments:

NCPDP was approached by organizations in the digital therapeutics (DTx) industry to review and modify existing standards and/or create new standards for evidence-based digital therapeutics that both require an order and some type of order fulfillment by a pharmacy. In response to this request, NCPDP formed the DTx Task Group.

The NCPDP DTx Task Group is currently working to:
- evaluate and identify existing NCPDP standards that fully or partially support DTx participant data exchange;
- propose changes to existing standards; and/or
- develop new standards to support DTx requirements.

NCPDP requests ONC engage in the work involved in this task group and ultimately incorporate the work of the NCPDP Digital Therapeutics (DTx) Task Group as you finalize the Plan.

Objective 1c: Integrate health and human services information

- **Capture and integrate social determinants of health data into EHRs**

Comments:

NCPDP recommends ONC encourage EHR applications use ICD-10 or other applicable code sets to capture social determinants of health (SDOH) information. SDOH may be reported by the patient and directly entered into the EHR or reported by users of interoperable health IT, such as pharmacists, via a standards-based care plan and integrated into a patient record. The Pharmacist eCare Plan, developed by NCPDP and HL7®, is capable of exchanging information related to care delivery, including patient goals, health concerns, SDOH, medication lists, drug therapy problems and lab results.

NCPDP recommends ONC incorporate the Pharmacist eCare Plan in its final Plan.

Objective 2a: Ensure safe and high-quality care through the use of health IT

- **Continue efforts to establish identity solutions that improve patient matching across data systems.**

Comments:

NCPDP recommends ONC support industry-led efforts to have reliable identity matching. NCPDP's Universal Patient Identifier (UPI) leverages Experian's expansive consumer demographic information and referential matching methodologies to identify record matches and duplicates in a patient roster file and then assigns a unique NCPDP UPI to each patient in the file. The NCPDP UPI can be used to exchange

information amongst different healthcare entities with reliable identity matching. The joint offering addresses patient safety, financial and operational challenges across the U.S. healthcare ecosystem.

Through our real-time and interoperable Telecommunication Standard and the NCPDP SCRIPT Standard Version 2017071, NCPDP has the unique ability to propagate the UPI throughout the pharmacy system and ultimately throughout the entire healthcare ecosystem. As multiple organizations acquire the NCPDP UPI in their patient files, it can be attached to active claims in real-time transactions and then appended by other healthcare partners. The UPI can travel with a patient from provider to provider, improving patient care.

NCPDP encourages ONC to work with an ANSI-accredited SDO, such as NCPDP, to facilitate the sharing of patient matching information across disparate healthcare organizations to reduce medical errors, improve patient safety and achieve interoperability. NCPDP recommends that any identifier selected by ONC be openly available to any healthcare organization that exchanges patient data and address privacy protections. If ONC chooses not to name a specific vendor product for patient identification, NCPDP recommends ONC work with an ANSI-accredited SDO, such as NCPDP, to establish standards that facilitate the sharing of patient matching information across disparate healthcare organizations and provide the industry with a listing of endorsed identity matching services or products. Such a list could be made available in the ISA. The listing should only contain products that meet reliability standards set by ONC or industry norms.

Objective 2b: Foster competition, transparency, and affordability in healthcare

- **Support efforts to merge administrative and clinical data streams to have real-time financial data at the point of care.**

Comments:
NCPDP recommends ONC continue to work with NCPDP, HL7® and X12 to produce and promote standards that will further the exchange of electronic health information to improve interoperability and usability. The proposed Plan does not include NCPDP standards which foster competition and prescription price transparency.

NCPDP published *the Real-Time Prescription Benefit Standard Implementation Guide* (Beta version) in January 2020. The Real-Time Prescription Benefit (RTPB) Standard conveys real-time pricing and formulary information to providers by enabling the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions and alternatives, when they exist.

The NCPDP Foundation has funded a proof of concept project that is currently demonstrating the successful use of the NCPDP RTPB transactions. A final version of the standard, meant for wide-spread adoption, should be available by the end of 2020.

NCPDP recently approved a project to develop a new standard supporting consumer facing price transparency. The work of this endeavor is important as it will allow the consumer the opportunity to identify affordable options to obtain their needed medications.

NCPDP is aware of the HITAC Intersection Clinical and Administrative Data Task Force and is willing to offer subject matter expertise on clinical and administrative improvement priorities, such as prior authorization (PA) or other pharmacy workflows. We respectfully request ONC include NCPDP in these new initiatives. NCPDP and the industry have extensive experience creating and utilizing electronic prior authorization (ePA) in the prescriber's workflow.

Finally, NCPDP requests ONC include the RTPB standard and any additional related standard created in the final version of the Plan.

Objective 2c: Reduce regulatory and administrative burden on providers

Comments:
NCPDP concurs that clinicians spend a significant amount of time that is administrative, including time committed to completing PAs. Through our consensus-based process, NCPDP has created the NCPDP SCRIPT ePA transactions as a means to create efficient processes for providers, pharmacies and plans to utilize.

Efforts from industry stakeholders and policymakers have driven widespread adoption of ePA technologies – producing value, improved workflows and accelerated time to therapy. For ePA to continue having a positive impact on healthcare, provider adoption of the technology as well as improving data sharing and transparency in the process remains a key initiative.

NCPDP's Prior Authorization Workflow to Transactions Task Group continues to evaluate the needs of the industry to effectuate further adoption and utilization of the NCPDP SCRIPT ePA transactions. The Task Group is currently working on improving the process and updating these transactions.

NCPDP requests ONC include the NCPDP ePA transactions in the final Plan to reduce burden for providers and improve patient access to medications.

Objective 3a: Advance individual- and population-level transfer of health data

- **Support appropriate use of health and human services data across federal- and state-level systems to enable population health planning, analysis of quality and patient outcomes across care settings and programs, and clinical research.**

Comments:
NCPDP is beginning work on the electronic exchange of patient consent information to improve data sharing across care settings and to payers. Additionally, the Pharmacist eCare Plan, developed by NCPDP and HL7®, enables the exchange of patient information related to care delivery, including patient goals, health concerns, SDOH, medication lists, drug therapy problems and lab results across care settings and programs.

NCPDP requests ONC incorporate the Pharmacist eCare Plan and any work done by NCPDP on the exchange of patient consent information in the final Plan.

Objective 4a: Advance the development and use of health IT capabilities

- **Adopt and advance nationally endorsed standards, implementation specifications, and certification criteria through continued collaboration across public and private sectors**.

Comments:

NCPDP agrees it is important to adopt and advance nationally endorsed standards, implementation specifications and certification criteria through continued collaboration with all SDOs, including NCPDP.

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 HIPAA. The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in the Medicare Modernization Act (MMA). ONC's Plan should be more inclusive of all national standards as reflected in the 2020 Interoperability Standards Advisory (ISA).

The NCPDP SCRIPT ePA transactions have been adopted by more than 60% of pharmacy benefit managers according to the Medication Access Report recently published by CoverMyMeds (https://www.covermymeds.com/main/medication-access-report/electronic-prior-authorization/) and was named in the Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly NPRM (https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf).

We are pleased to see in the recently released *21st Century Cures Act: Interoperability, Information Blocking and ONC Health Certification Program Final Rule*, ONC calls for the voluntary certification of the NCPDP SCRIPT v2017071 ePA transactions to facilitate the electronic, expeditious, standard exchange of PA.

Standards must be properly tested and certified to ensure uniform adoption. The NCPDP Testing Tool (https://tools.ncpdp.org/erx/#/home) allows for such testing of the NCPDP SCRIPT standard and enforces ONC's certification criteria for e-Prescribing. ONC's certification requirements should align with the transactions and actors who use them as outlined in NCPDP's previous comments submitted to ONC on June 3, 2019, regarding *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule ONC 170.315(b)(11) Electronic prescribing Test Procedures* (https://www.healthit.gov/sites/default/files/page/2019-03/170_315b_11_Electronic_prescribing.pdf).

NCPDP requests ONC incorporate the SCRIPT, Telecommunication and Formulary and Benefit Standards and the NCPDP Testing tool, as well as our previously submitted comments regarding SCRIPT certification requirements into the final Plan.

Appendix A

This Plan considers the current state of health IT and the ideal future state for patients and caregivers, healthcare providers, payers, researchers, health IT developers, and other stakeholders. It also considers challenges in defining and implementing strategies. The broad scope of this Plan reflects the diverse roles federal government agencies play in health IT.

Comments:

NCPDP is concerned the Plan is not reflective of the diverse landscape of healthcare standards. NCPDP standards, which support billions of transactions annually, are notably absent from ONC's recommendations. Specifically, ONC should include references to the widely adopted Telecommunication and SCRIPT Standards, which play a critical role in implementation of other federal government agencies' Health IT programs.

NCPDP requests the final version of the Plan incorporate the NCVHS recommendations on achieving greater efficiencies to improve adoption of standards under HIPAA.

Conclusion

NCPDP thanks ONC for the opportunity to submit comments on the 2020-2025 Federal Health IT Strategic Plan. Beyond our collaboration with other SDOs, we continue our innovation in data exchange standards, building on our over 40-year history to ensure alignment between standards and support of emerging technologies in the future of healthcare. NCPDP requests ONC include pharmacy and the NCPDP standards and associated transactions as an integral part of its Health IT Federal Strategic Plan.

We look forward to working with the ONC as you execute on the final Plan and gaining a better understanding of ONC's vision regarding the role of NCPDP transactions in the future of healthcare.

For direct inquiries or questions related to this letter, please contact:
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Sincerely,

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