Date: January 25, 2019

Re: ONC 2018 Draft Strategy on Reducing Regulatory and Administrative Burden Related to the use of Health IT and EHRs

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Development Organization (SDO) consisting of more than 1,500 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 providing the following comments regarding the ONC 2018 Draft Strategy on Reducing Regulatory and Administrative Burden Related to the use of Health IT and EHRs. NCPDP recommends the Department of Health and Human Services (HHS) continue to work with ANSI-accredited SDOs that create standards using a consensus process among industry experts to find standardized, workable solutions.

# Clinical Documentation

## Strategy 2

***Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.***

ONC has previously partnered with, and supported, clinical stakeholders to enhance clinical documentation. An example of this was ONC's High Impact Pilot support of the Pharmacist eCare Plan to implement and evaluate the Pharmacist eCare Plan in hundreds of community pharmacies. The Pharmacist eCare Plan is a joint NCPDP and Health Level Seven® International (HL7®) project using Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR®) to standardize and enhance interoperability of patient medication care plans. NCPDP asks ONC to continue support of efforts to bring clinical stakeholders into the ongoing development, evaluation, and implementation of clinical documentation standards.

NCPDP also recognizes the burden experienced by clinicians in the day-to-day burden of documentation of services they provide. Collaborating with clinical stakeholders is vital to identifying best practices,

including identifying documentation, which enhances the provision and quality of care. Knowledge of the information clinicians produce and need to reference can be used to optimize the user experience.

Centers for Medicare and Medicaid Services (CMS) technical assistance may be a mechanism for sharing best practices. NCPDP believes working through various health professional organizations may achieve better dissemination as best practices are only useful when they are shared and all avenues for advancing documentation of burden-reducing best practices should be explored. These best practices may not be specifically for the clinicians and should be shared with system vendors and implementers for user interfaces, data content, and workflow.

## Strategy 3

***Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.***

The industry and the National Committee on Vital and Health Statistics (NCVHS) have repeatedly acknowledged the Prior Authorization transactions named under HIPAA (ASC X12N 278 initiated by a practitioner and Telecommunication Standard Version D.0 initiated by a pharmacist/pharmacy) are not sufficient for ePrescribing workflows. However, the NCPDP SCRIPT Standard's Electronic Prior Authorization (hereinafter referred to as ePA) transactions are better suited for the exchange of prior authorization information between providers and processors of the pharmacy benefit.

Therefore, NCPDP respectfully requests the NCPDP SCRIPT Standard Version 2017071 ePA transactions[1] be named in a regulation, as their use is currently part of the pharmacy industry's prior authorization process. Regulatory adoption of the NCPDP ePA transactions would streamline and standardize the prior authorization process nationwide. Currently, the NCPDP SCRIPT Standard ePA transactions have been implemented by more than 70% of pharmacy benefit managers[2]. The use of these transactions expedites access to therapy and improved patient outcomes by significantly reducing the approval time of prior authorizations[3] to hours instead of days.

Some benefits of adopting the NCPDP SCRIPT Standard Version 2017071 ePA transactions include:

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[1] ePA Transactions include:

1. PAInitiationRequest
2. PAInitiationResponse
3. PARequest
4. PAResponse
5. PAAppealRequest
6. PAAppealResponse
7. PACancelRequest
8. PACancelResponse

[2] epascorecard.covermymeds.com

[3] Surescripts - approvals come back in under a minute ~65% of the time, which increases efficiency for prescribers and payers and increases patient medication adherence.

- Expedites patient access to their needed medications
- Helps CMS achieve the intent of supporting innovative approaches to improving program quality, accessibility, and improvement of the beneficiary experience.
- Reduces the administrative burden for providers, pharmacists and plans by minimizing manual activities such as printing, faxing, phone calls, and mailing.
- Supports CMS's intent of establishing a framework to address the opioid epidemic.
- Improves clinical decision making for plans and providers to ascertain quickly, via real-time data exchange, the clinical efficacy of the prescribed treatment and eventual dispensing of the medication.

## Health IT Usability and the User Experience

### Strategy 3

***Promote harmonization surrounding clinical content contained in health IT to reduce burden.***

The NCPDP SCRIPT Implementation Recommendations contain the following recommendations related to harmonization of drug descriptions:

1. Information transmitted must be clear and not cause confusion in patient safety.
2. The prescriber and the pharmacist must have final review of the medication to be prescribed or dispensed.
3. EHR, electronic prescribing, and pharmacy systems are strongly encouraged to use a commercial compendia source for ePrescribing Drug Names.
4. EHR, electronic prescribing, and pharmacy systems are strongly encouraged to support timely and accurate updates for drug files from a recognized authoritative source.
5. The drug compendia use industry recognized best vocabulary, practices of vocabulary, and publication. These same practices should be followed by electronic prescribing and pharmacy vendors who do not choose to use a drug compendium.

Detailed recommendations and best practices for drug compendia, EHR, ePrescribing, and Pharmacy Systems can be found at: SCRIPT Implementation Recommendations.

Additionally, the FDA has proposed expansion of the current 10-digit, variable formatted NDC. NCPDP has provided extensive comments (NCPDP Comments FDA Future NDC Format – available upon request) to the FDA concerning the need to move to a standardized 12-digit format. A move to standardized format will promote harmonization and interoperability across system workflows. NCPDP respectfully request ONC's support in standardizing the 12-digit format of the NDC.

### Strategy 4

***Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.***

NCPDP recommends that ONC continue to work with NCPDP and other SDOs to produce and promote standards that will further enhance the exchange of electronic health information to improve interoperability and usability and to reduce administrative burdens. Further, NCPDP requests ONC's support in calling out the importance of transparency and interoperability of patient clinical information e.g. diagnosis codes, and other clinical measures. These values are currently available to be transmitted on an electronic prescription using the SCRIPT Standard. Unfortunately, clinical information is not regularly communicated to pharmacies due to lack of understanding of their value as well as EHR workflow. Without this clinical information, the pharmacist must request the prescriber to complete the PA process, adding to the prescriber's administrative burden. If the prescriber would send clinical information on an electronic prescription, the pharmacy would be able to pass these values on to the payer, avoiding patient delay in obtaining their medication.

NCPDP continues to improve previously referenced standards, such as the widely used SCRIPT and Telecommunication Standards, and the following standards to promote the electronic exchange of health information:

1. Audit Transaction Standard
2. Batch Standard
3. Benefit Integration Standard
4. Billing Unit Standard
5. Financial Information Reporting Standard
6. Formulary and Benefit Standard
7. Manufacturer Rebate Standard
8. Medical Rebate Data Submission Standard
9. Post Adjudication Standard
10. Prescription Transfer Standard
11. Product Identifiers Standard
12. Retiree Drug Subsidy Standard
13. Specialized Standard
14. Specialty Pharmacy Data Reporting Standard
15. Uniform Healthcare Payer Data Standard
16. Prescription Drug Monitoring Programs (PDMP) Reporting Standard

NCPDP is also developing new standards to meet industry needs such as the Real Time Prescription Benefit to convey real-time prescription benefit information to providers at the point of prescribing, the Medication List Transaction to report dispensed medication information to Health Information Exchanges (HIEs), and the Government Programs Encounter Reporting to support a common format among states for Managed Care Organizations to use in Medicaid encounter reporting. NCPDP continues to collaborate with other SDOs to ensure alignment between standards and support of emerging frameworks such as FHIR®.

Additionally, NCPDP encourages HHS to work closely with the Drug Enforcement Administration (DEA) to reduce burdensome Electronic Prescriptions for Controlled Substances (EPCS) requirements that may hinder adoption of EPCS, a vital tool in opioid management.

# EHR Reporting

## Strategy 1

***Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.***

NCPDP encourages HHS to work with an ANSI -accredited SDO, such as NCPDP, to utilize and/or develop national standards for reporting that support agreed upon Health IT measures.

## Strategy 2

***Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.***

NCPDP recommends a thoughtful approach to the development of any additional standards following a complete evaluation of available standards. Use of standardized code sets will improve interoperability across multiple Health IT systems as well as state-based HIEs. As previously referenced, NCPDP is currently working to standardize pharmacy data that is reported to HIEs.

# Public Health Reporting

## Strategy 1

***Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.***

NCPDP has developed the NCPDP Standards-based Facilitator Model for PDMPs, an *Interoperable Framework for Patient Safety*, which leverages best practices to address many of the challenges facing the current system today. The white paper was developed by the industry, using the same consensus-building process that NCPDP uses for developing and maintaining standards and industry guidance documents.

NCPDP's model engages the use of a national facilitator that connects to both the dispensing pharmacy (via NCPDP's Telecommunication Standard) and the prescriber (via NCPDP's SCRIPT Standard).

NCPDP's model aligns with a single "on ramp" to provide data that is operable within prescriber Electronic Health Record (EHR) systems to ensure PDMPs are more accessible and easier for healthcare providers to use while providing real-time data.

Through existing technology and standards, prescribers and pharmacists will be able to share real-time information to enable these providers to make clinical decisions prior to writing and dispensing medications for proactive intervention in order to prevent abuse or possible harm. The burden on providers is reduced by incorporating drug use information within their workflows. Prescribers and pharmacists are already using NCPDP standards in their everyday operations to send, receive, and bill for

prescriptions, making it easier for them to assess patient risk and ensure access for patients with a valid medical need.

NCPDP's model is a proactive, sustainable, interoperable solution that:

- Shares complete and accurate real-time information at the point of care anywhere in the country using existing, bidirectional and interoperable industry standards.
- Reduces burdens on providers by incorporating drug use information within pharmacy and prescriber workflows, with bidirectional communication.
- Enables proactive notification to practitioners when the PDMP data shows that a patient exhibits patterns indicative of opioid or other drugs of concern misuse.
- Allows prescribers and pharmacists to make clinical decisions prior to prescribing or dispensing opioid or other drugs of concern.
- Ensures access for patients with valid medical needs.

Interoperability among state PDMP databases, and across all Health IT systems such as EHRs, is crucial in addressing the opioid epidemic. Giving providers the ability to check patient records from across the country will limit provider and pharmacy shopping across state borders. Using a uniform set of policies and standards supports patient safety and will help curb the opioid public health crisis by alerting providers when an individual is exhibiting signs of Substance Use Disorder or patterns indicative of opioid misuse.

Additionally, NCPDP encourages HHS to work closely with the DEA to reduce burdensome EPCS requirements that may hinder adoption of EPCS, a vital tool in opioid management.

## Strategy 2

***Inventory reporting requirements for federal health care and public health programs that rely on EHR data to reduce collection and reporting burden on clinicians. Focus on harmonizing requirements across federally funded programs that impact a critical mass of health care providers.***

NCPDP encourages HHS to work with an ANSI-accredited SDO, such as NCPDP, and state PDMPs to agree on an interoperable solution within prescriber and dispenser workflows.

NCPDP approved a new standard to complement the Standards-based Facilitator Model for PDMP. The PDMP Reporting Standard will allow for reporting of supplemental data, such as who picked up/purchased the prescription, not contained within the NCPDP Telecommunication Standard. This new standard can also be used by the Facilitator to report one consolidated PDMP batch file to each state at the state's preferred frequency instead of collecting them from each individual pharmacy and the uncertainty of universal compliance, quality, and timeliness that can result.

NCPDP also encourages HHS to provide detailed guidance in instances where state privacy requirements impede electronic exchange of healthcare information and interoperability. For example, privacy

requirements in some states related to PDMPs prohibit the automated integration of information for providers requesting patient medication history on use of controlled substances.

In conclusion, NCPDP and its members would like to thank HHS for the opportunity to provide written comments on ONC's 2018 Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.

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

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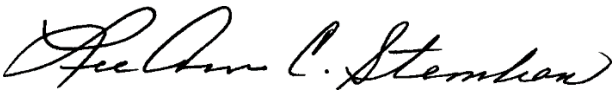
Sincerely,



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