



Date: June 3, 2019

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT
Certification Program Proposed Rule

Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: RIN: 0955-AA01, ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC
Health IT Certification Program

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 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*. NCPDP recommends ONC continue to work with ANSI-accredited SDOs that create standards using a consensus process among industry experts to find standardized, workable solutions.

Section I - B - 2 – B Electronic Prescribing

ONC:

“We propose to update the electronic prescribing (e-Rx) SCRIPT standard in 45 CFR 170.205(b) to **NCPDP SCRIPT 2017071**, which would result in a new e-Rx standard eventually becoming the baseline for certification. We also propose to adopt a new certification criterion in § 170.315(b)(11) for e-Rx to reflect these updated proposals. ONC and CMS have historically maintained complementary policies of maintaining aligned **e-Rx and medical history (MH)** standards to ensure that the current standard for certification to the electronic prescribing criterion permits use of the current Part D **e-Rx and MH** standards. This proposal is made to ensure such alignment as CMS recently finalized its Part D standards to **NCPDP SCRIPT 2017071** for **e-RX**

and MH, effective January 1, 2020 (83 FR 16440). In addition to continuing to reference the current transactions included in § 170.315(b)(3), in keeping with CMS' final rule, we also propose to require all of the **NCPDP SCRIPT 2017071 standard** transactions CMS adopted at 42 CFR 423.160(b)(2)(iv).”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071

Update all references of “e-RX and MH” to “all named transactions”

Section IV - B – 1 The United States Core Data for Interoperability Standard (USCDI)

ONC:

“Medication Data Request for Comment

The USCDI v1 “Medication” data class includes two constituent data elements within it: Medications and Medication Allergies. With respect to the latter, Medication Allergies, we request comment on an alternative approach. This alternative would result in removing the Medication Allergies data element from the Medication data class and creating a new data class titled, “Substance Reactions,” which would be meant to be inclusive of “Medication Allergies.” The new “Substance Reactions” data class would include the following data elements: “Substance” and “Reaction,” and include SNOMED CT as an additional applicable standard for non-medication substances.”

NCPDP Comments:

More information regarding ONC’s thoughts for changing any classifications would be helpful. NCPDP recommends ONC work closely with NCPDP and other SDO’s as they work to standardize code sets that would impact various standards.

Section IV - B – 2 Electronic Prescribing Standard and Certification Standard

ONC:

“We propose to update the electronic prescribing (e-Rx) SCRIPT standard used for “electronic prescribing” in the 2015 Edition to **NCPDP SCRIPT 2017071**, which would result in a new e-Rx standard becoming the baseline for certification. We propose to adopt this standard in § 170.205(b)(1). ONC and CMS have historically maintained complementary policies of aligning health IT certification criteria and associated standard for e-prescribing with the CMS Medicare Part D **e-Rx and MH** standards (75 FR 44589; 77 FR 54198). To this end, CMS has retired the current standard (NCPDP SCRIPT version 10.6) for **e-RX and MH** and adopted **NCPDP SCRIPT 2017071** as the standard for Part D **e-Rx and MH** effective January 1, 2020, conditional on ONC updating the Program to the **NCPDP SCRIPT 2017071 standard** for its e-Rx certification criterion (*see also* 42 CFR 423.160(b)(1)(v) and (2)(iv)). In addition, CMS recently sought comment regarding whether the **NCPDP SCRIPT 2017071 standard** could facilitate future reporting of the proposed Query of Prescription Drug Monitoring Program (PDMP) measure in both the 2019 Physician Fee Schedule proposed rule (83 FR 35923) and Hospital Inpatient Prospective Payment Systems (IPPS) Fiscal Year 2019 proposed rule (83 FR 20528). As summarized in the IPPS Fiscal Year 2019 final rule (83

FR 41144), CMS received comments supportive of using the **NCPDP SCRIPT 2017071** medication history transactions for PDMP queries and responses, as well as comments asking CMS to seek harmonizing of the 2015 Edition e-prescribing certification criterion to the **NCPDP SCRIPT 2017071 standard** specified in the part D program portions of the recent "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" final rule (83 FR 16440).

In addition to proposing to adopt the **NCPDP SCRIPT 2017071 standard** for the transactions that are listed in the current "electronic prescribing" criterion (§ 170.315(b)(3)), we propose to adopt and require conformance to all of the **NCPDP SCRIPT 2017071 standard** transactions CMS adopted at 42 CFR 423.160(b)(2)(iv) for **NCPDP SCRIPT 2017071.**"

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071
 Update all references of "e-RX and MH" to "all named transactions"

Section IV - B - 2 Electronic Prescribing Standard and Certification Criterion

ONC:

"2. Electronic Prescribing Standard and Certification Criterion "
 "... effective January 1, 2020 ..."

"In addition to proposing to adopt the NCPDP SCRIPT 2017071 standard for the transactions that are listed in the current "electronic prescribing" criterion (§ 170.315(b)(3)), we propose to adopt and require conformance to all of the NCPDP SCRIPT 2017071 standard transactions CMS adopted at 42 CFR 423.160(b)(2)(iv) for NCPDP SCRIPT 2017071."

NCPDP Comments:

NCPDP appreciates ONC's proposal to coordinate with CMS, regarding updating the e-Rx standard to the NCPDP SCRIPT Standard Version 2017071. Certification requirements should be in sync with CMS compliance and implementation dates.

NCPDP recommends that compliance with the certification mandates, effective January 1, 2020, focus on currently required transactions with a phased-in approach for certifying the proper implementation of newly named transactions. Certification should not be required for newly named transactions until they are more widely adopted per the Interoperability Standards Advisory (ISA). Additionally, certification requirements should be focused on applicable transactions and related practice settings, as detailed below.

Transaction Names	Transaction is currently in broad use (Y/N)	Applicable to all practice settings (Y/N)	Optional or Required for Certification (O/R)	Certification Requirement Notes
NewRx	Y	Y	R	

Transaction Names	Transaction is currently in broad use (Y/N)	Applicable to all practice settings (Y/N)	Optional or Required for Certification (O/R)	Certification Requirement Notes
NewRxRequest	N	Y	O	Certification should not be required until the transaction is more widely adopted per the Interoperability Standards Advisory (ISA).
NewRxResponseDenied	N	Y	O	Certification should not be required until the transaction is more widely adopted, per the Interoperability Standards Advisory (ISA).
RxChangeRequest	Y	Y	R	
RxChangeResponse	Y	Y	R	
CancelRx	Y	Y	R	
CancelRxResponse	Y	Y	R	
RxRenewalRequest	Y	Y	R	
RxRenewalResponse	Y	Y	R	
RxFill	Y	Y	R	
RxFillIndicatorChange	N	Y	O	Certification should not be required until the transaction is more widely adopted per the Interoperability Standards Advisory (ISA).
RxHistoryRequest	Y	Y	R	
RxHistoryResponse	Y	Y	R	
GetMessage	Y	N	O	Transaction is not necessary when transacting real time messaging; recommend certification be optional.
Status	Y	Y	R	Since the transaction is an acknowledgement, it would not contain "reason for prescription" as referenced in (b)(11)(ii) or (iii).
Error	Y	Y	R	Since the transaction is an acknowledgement, it would not contain "reason for prescription" as referenced in (b)(11)(ii) or (iii).
Verify	Y	Y	R	Since the transaction is an acknowledgement, it would not contain

Transaction Names	Transaction is currently in broad use (Y/N)	Applicable to all practice settings (Y/N)	Optional or Required for Certification (O/R)	Certification Requirement Notes
				"reason for prescription" as referenced in (b)(11)(ii) or (iii).
Resupply	Y	N	O	Transaction is applicable only to LTC practice settings. Recommend certification requirements only in LTC practice settings.
DrugAdministration	Y	N	O	Transaction is applicable only to LTC practice settings. Recommend certification requirements only in LTC practice settings.
RxTransferRequest	N	N	None	Electronic Health Record systems do not use this transaction; transfer transactions only apply to non-hospital pharmacies. Therefore, certification is not applicable and should be removed.
RxTransferResponse	N	N	None	Electronic Health Record systems do not use this transaction; transfer transactions only apply to non-hospital pharmacies. Therefore, certification is not applicable and should be removed.
RxTransferConfirm	N	N	None	Electronic Health Record systems do not use this transaction; transfer transactions only apply to non-hospital pharmacies. Therefore, certification is not applicable and should be removed.
Recertification	N	N	O	Transaction is applicable only to LTC practice settings. NCPDP recommends certification requirements only in LTC practice settings.
REMSRequest	N	N	O	Transaction needs to be adopted by a manufacturer/REMS administrator before being added to certification. Certification should not be required until more widely adopted per the Interoperability Standards Advisory (ISA).

Transaction Names	Transaction is currently in broad use (Y/N)	Applicable to all practice settings (Y/N)	Optional or Required for Certification (O/R)	Certification Requirement Notes
REMSResponse	N	N	O	Transaction needs to be adopted by a manufacturer/REMS administrator before being added to certification. Certification should not be required until more widely adopted per the Interoperability Standards Advisory (ISA).
REMSInitiationRequest	N	N	O	Transaction needs to be adopted by a manufacturer/REMS administrator before being added to certification. Certification should not be required until more widely adopted per the Interoperability Standards Advisory (ISA).
REMSInitiationResponse	N	N	O	Transaction needs to be adopted by a manufacturer/REMS administrator before being added to certification. Certification should not be required until is more widely adopted per the Interoperability Standards Advisory (ISA).

Section IV - B - 2 Electronic Prescribing Standard and Certification Criterion

ONC:

Several instances of: NCPDP SCRIPT 2017071.

NCPDP Comments:

Update all instances to: The NCPDP SCRIPT Standard Version 2017071.

Section IV - B - 2 Electronic Prescribing Standard and Certification Criterion

ONC:

“...the SCRIPT 2017071 testing tool under development is being designed.”

NCPDP Comments:

The NCPDP SCRIPT Standard Version 2017071 testing tool is currently in use for all named transactions listed below.

Transaction Names:
NewRx

Transaction Names:
NewRxRequest
NewRxResponseDenied
RxChangeRequest
RxChangeResponse
CancelRx
CancelRxResponse
RxRenewalRequest
RxRenewalResponse
RxFill
RxFillIndicatorChange
RxHistoryRequest
RxHistoryResponse
GetMessage
Status
Error
Verify
Resupply
DrugAdministration
RxTransferRequest
RxTransferResponse
RxTransferConfirm
Recertification
REMSRequest
REMSResponse
REMSInitiationRequest
REMSInitiationResponse

Section VI - B Health IT and Opioid Use Disorder Prevention and Treatment – Request for Information

ONC:

“In this section of the proposed rule, we request public comment specifically from the perspective of how our existing Program requirements and proposals in this rulemaking may support use cases related to OUD prevention and treatment and if there are additional areas that ONC should consider for effective implementation of health IT-enabled OUD prevention and treatment.”

NCPDP Comments:

NCPDP supports encouraging the use of the *NCPDP SCRIPT Standard Implementation Guide Version 2017071* Medication History transactions for PDMP queries and response.

The *NCPDP SCRIPT Standard Implementation Guide Version 10.6* Medication History transactions are named in the ONC 2018 Interoperability Standards Advisory for querying and retrieving data

from PDMP(s). The Medication History transactions are used today and integrated into current workflow. Therefore, use of these transactions could expedite provider access to PDMP data.

The *NCPDP SCRIPT Standard Implementation Guide Version 2017071* includes enhancements to the Medication History transactions as a result of the outcome of the ONC S&I Framework and requests from the industry including:

- Added a Risk Score to assist the provider in clinical decision making
- Added a Requestor Role for the person requesting PDMP data
- Clarified the identity of the person versus the entity requesting PDMP data
- Added Pharmacist ID to the requestor role to enable Pharmacies to use this transaction for PDMP
- Added the ability to identify a practitioner's multiple locations of practice
- Added ability to specify from which PDMP(s), Medication History is being requested and to identify the responding PDMP(s)

NCPDP supports additional efforts to leverage existing technology and standards for effective implementation of health IT-enabled OUD prevention and treatment.

NCPDP has developed the NCPDP Standards-based Facilitator Model for PDMP, *An Interoperable Framework for Patient Safety* that leverages best practices to address many of the challenges facing the current PDMP Systems today. This model is detailed in the white paper, entitled, [*NCPDP's Standards-based Facilitator Model for PDMP An Interoperable Framework for Patient Safety*](#). The white paper was developed by the industry, using the same consensus-building process that we use for federally mandated 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 Version 2017071).

NCPDP's model aligns with a single "on ramp" to provide data that is operable within prescriber EHR systems to ensure PDMPs are more accessible and less difficult for healthcare providers to utilize while providing real-time data to the clinician.

Through the use of 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 and to stop abuse before it starts. The burden on providers is reduced by incorporating drug abuse 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.

Interoperability among state PDMP databases, and with all health IT, 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.

Lastly, NCPDP encourages the adoption of electronic prescribing of controlled substances (EPCS) via the NCPDP SCRIPT Standard Version 2017071 as an important tool in OUD prevention. EPCS allows for improved clinical decision making at the point of prescribing and prevents diversion of fraudulent prescriptions. Additionally, in order to facilitate appropriate electronic prescribing of opioids, NCPDP understands the importance of a diagnosis code being submitted on an electronic prescription and continues to work on this requirement. This will allow the prescriber to communicate prescription-related messages to pharmacies electronically, which will assist the pharmacist in appropriate opioid dispensing. The standard currently supports the voluntary inclusion of diagnosis codes on a new prescription.

Section VI - B - 3 Emerging Standards and Innovations

ONC:

“...the NCPDP SCRIPT standard”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071

Section VI – B – 4 Additional Comment Areas

ONC:

“We further seek comment on effective approaches for the successful dissemination and adoption of standards including the **NCPDP SCRIPT 2017071 standard** (see section IV.B.2) that can support the exchange of PDMP data for integration into EHRs and also enable further adoption and use of Electronic Prescribing of Controlled Substances (EPCS). Regarding integration of health IT with PDMPs and EPCS, we believe there are real and perceived challenges and opportunities that involve policy and technical components. As we explore these issues in collaboration with industry and stakeholders, we seek comment on the priority challenges and opportunities for these topics and on any technical and policy distinctions, as appropriate.”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071

NCPDP believes that EPCS adoption should be a high priority. NCPDP encourages ONC to work closely with the Drug Enforcement Administration (DEA) to reduce burdensome EPCS requirements that may hinder adoption of EPCS, a vital tool in opioid management.

NCPDP also encourages ONC to develop rules to implement provisions of the recently enacted SUPPORT Act, which mandates EPCS and ePA for Medicare Part D Plans.

NCPDP’s model is a proactive, sustainable, interoperable solution that leverages existing industry standards to share complete and accurate real-time information at the point of care. Leveraging existing industry standards reduces burdens currently placed on providers by incorporating drug

use information within pharmacy and prescriber workflows. NCPDP's model enables proactive notification to practitioners when PDMP data shows that a patient exhibits patterns indicative of opioid misuse, allowing prescribers and pharmacists to make clinical decisions prior to prescribing or dispensing an opioid.

NCPDP approved a new standard to complement the Standards-based Facilitator Model for PDMP. The Prescription Drug Monitoring Programs (PDMP) Reporting Standard will allow for reporting of supplemental data, such as who picked up/purchased the prescription if required by a state PDMP not contained within the NCPDP Telecommunication Standard. This new standard can also be used by the Facilitator to report one clean PDMP batch file to each state on their timeframe rather than by each individual pharmacy.

NCPDP is currently developing the Dispensed Medication List transaction within the NCPDP SCRIPT Standard. This transaction is designed to become an ANSI national standard to enhance the interoperability of HIEs. This transaction will include a record of dispensing events by the pharmacy within a reporting timeframe. Reports will include data necessary for HIEs to respond to a request or inquiry on a patient's Medication History. This will allow providers to continue to retrieve a patient's prescription history using NCPDP's Medication History transaction, supplemented with data from the patient's pharmacy.

Section VI - B - 4 Additional Comment Area

ONC:

"As noted in the Hospital Inpatient Prospective Payment Systems final rule, a few commenters supported the use of NCPDP Script Standard Implementation Guide Version 2017071 medication history transactions for PDMP queries and response."

NCPDP Comments:

Update all references to: *NCPDP SCRIPT Standard Version 2017071 Implementation Guide*.
Update all references of "e-RX and MH" to "all named transactions".

Section VII - B - 5

ONC:

"Standards Version Advancement Process"

NCPDP Comments:

NCPDP supports the Standards Version Advancement Process as described in Section VII.B.5 of this preamble. In addition, a process needs to exist to deprecate and remove standards from the National Coordinator's approved list.

We suggest ONC establish a mechanism for standards developers and implementers to suggest candidate "new versions" for ONC's consideration. Ideally, the list of candidates "new versions" should be publicly viewable prior to ONC's formal consideration. With this, ONC could allow

comments prior to rulemaking which provides the opportunity for ONC to consider all points of view when developing the Proposed Rule. The process needs to include the mechanism for adopting an updated standard to the 2015 Edition Certification Criteria which would require all health IT developers participating in the Program to adopt that version.

Further, ONC should establish a timeline for rulemaking. Both ONC and the submitters of candidate "new versions" should have a clear understanding of the timeline: A cut-off date for "new versions" submitted to ONC; a target date for ONC's NPRM; and a target date for publication of the updated ISA. Additionally, coordination with CMS throughout this process is critical.

The proposal appears focused on highly modular standards/specifications such as FHIR®. We would like to find a similar "streamlined" process for standards which do not have components updated independently, e.g., NCPDP SCRIPT Standard, ASC X12N transactions.

Section VIII - C - 2 - a

ONC:

"Health Care Providers - We are considering adjusting the information blocking definition of "health care provider" to cover all individuals and entities covered by the HIPAA "health care provider" definition. We seek comment on whether this approach would be justified, and commenters are encouraged to specify reasons why doing so might be necessary to ensure that the information blocking provision applies to all health care providers that might engage in information blocking."

NCPDP Comments:

NCPDP requests a proposed definition from ONC before commenting.

Section VIII - C - 3

ONC:

"ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information. Given that price information impacts the ability of patients to shop for and make decisions about their care, we seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking."

NCPDP Comments:

To allow providers to obtain real time prescription benefit information for the patient, NCPDP recommends pricing information should not be blocked.

Section X - Patient Matching Request for Information

ONC:

"There are a number of emerging private-sector led approaches in patient matching that may prove to be effective, and we seek input on these approaches, in general. A number of matching

services that leverage referential matching technology have emerged in the market recently, yet evaluations of this type of approach has either not been conducted or has not been made public. Other innovative technical approaches such as biometrics, machine learning and artificial intelligence, or locally developed unique identifier efforts, when used in combination with non-technical approaches such as patient engagement, supportive policies, data governance, and ongoing data quality improvement efforts may enhance capacity for matching.”

NCPDP Comments:

NCPDP encourages ONC to explore implementation of a patient matching solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries. NCPDP recommends ONC support industry-led efforts to have reliable identity matching. NCPDP’s UPI could be used for this purpose.

NCPDP has developed a solution, in partnership with Experian Health, to manage patient identities through a referential matching process. 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 assign a unique NCPDP UPI to each patient in the file. The NCPDP UPI can be used to exchange information amongst different healthcare entities. The joint offering addresses patient safety, financial and operational challenges across the U.S. healthcare ecosystem.

The following NCPDP Standards were identified as being applicable for communicating the UPI and were modified accordingly:

1. Post Adjudication Standard
2. Prescription Drug Monitoring Programs (PDMP) Reporting Standard
3. Prescription Transfer Standard
4. Prior Authorization Transfer Standard
5. SCRIPT Standard
6. Specialized Standard
7. Specialty Data Reporting Standard
8. Telecommunication Standard
9. Uniform Healthcare Payer Data Standard
10. Batch Standard Subrogation Standard

The Audit, Billing Unit, Formulary & Benefit, Product Identifiers, Retiree Drug Subsidy, UCF/Workers Comp Claim Form, Financial Information Reporting and Rebate Standards are the only standards that have been determined to not be applicable at this time. At such time these or any future standards are determined to be applicable, the UPI will be added to them.

Through its 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.

The UPI was developed by the industry, using the same consensus-building process that we use for federally mandated standards and industry guidance documents.

NCPDP's UPI is a pass-through number that is not known to the patient or the provider, thus addressing privacy protections.

- NCPDP's UPI does not collect or share any clinical claims or diagnostic information.
- The patient does not know that the UPI number is attached to his or her record.
- The UPI is not intended to be a patient-facing number in an effort to prevent misuse of the identifier or for data reselling purposes. The service provider controls the sharing of the patient information based on the consent that the patient signs to allow his or her information to be given to family members and the health plan.

Additionally, Experian has safeguards and protocols in place to handle billions of sensitive data records.

The NCPDP UPI is available to any healthcare organization that owns and exchanges patient data. It establishes the foundation for exchanging patient information across the healthcare ecosystem to:

- Reduce medical/medication errors and improve patient safety;
- Improve care coordination, population health management, prescription drug monitoring programs (PDMP); and
- Reduce human and financial resources needed to reconcile duplicate records and billing/claims errors.

NCPDP agrees with the ONC's comment that there are unique matching issues related to pediatrics. The NCPDP UPI leverages the Telecommunication Standard and the NCPDP SCRIPT Standard Version 2017071 and is propagated through the pharmacy system. This enables the NCPDP UPI to identify and further validate this segment of the population, as pediatric patients typically consume prescription drugs.

NCPDP's UPI combines referential matching methodologies with a unique patient identifier, that is only available within a healthcare system as a pass-through number. This unique combination increases match rates and addresses privacy concerns often associated with patient identifiers.

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.

Section XI Incorporation of Reference

ONC:

“National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017).”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071 Implementation Guide.

Section XI Incorporation of Reference

ONC:

“Summary: SCRIPT standards are developed for transmitting prescription information electronically.”

NCPDP Comments:

Change the above sentence to The NCPDP SCRIPT Standard Version 2017071 is developed for transmitting prescription information electronically.

Section XIV - C - 6 Executive Order 13771 Reducing Regulations and Controlling Regulatory Costs

ONC:

“(1) Standard. National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071.”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071 Implementation Guide.

Section XIV - C - 6 Executive Order 13771 Reducing Regulations and Controlling Regulatory Costs

ONC:

“(3) National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071.”

NCPDP Comments:

Update all references to: NCPDP SCRIPT Standard Version 2017071 Implementation Guide.

Section XIV - C - 6 Executive Order 13771 Reducing Regulations and Controlling Regulatory Costs

ONC:

“(ii) For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment.”

NCPDP Comments:

Change DRU Segment to DrugUseEvaluation group.

Section XIV - C - 6 Executive Order 13771 Reducing Regulations and Controlling Regulatory Costs

ONC:

“(iii) Optional. For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment.”

NCPDP Comments:

In the NCPDP SCRIPT Standard Version 2017071, the SIG Segment is mandatory and within the SIG Segment, the SigText field (instructions for using the prescription) is the only mandatory data element.

In conclusion, NCPDP and its members would like to thank HHS for the opportunity to provide written comments on the *ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*. In the future when issuing a large number of NPRMs of this magnitude, we request longer comment periods to provide adequate time for proper consideration and comments.

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


Paul Wilson

Technical Analyst, Standards Development

NCPDP

E: pwilson@ncdp.org

Sincerely,



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

lstember@ncdp.org

cc: NCPDP Board of Trustees