March 16, 2018

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Food and Drug Administration
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RE: Docket No. FDA– 2017–N–6502 for ‘‘Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation; Public Hearing; Request for Comments.”

Dear Ms. Davies:

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 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 40 years NCPDP has developed and promoted industry standards and business solutions that improve patient safety and health outcomes, while also decreasing costs. 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 used in electronic prescribing as named in MMA. NCPDP standards are named in HITECH and Meaningful Use (MU) as well.

NCPDP appreciates this opportunity to provide the following comments to the “*Opioid Policy Steering Committee: Prescribing Intervention—Exploring a Strategy for Implementation; Public Hearing; Request for Comments*.”

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 system today. This model is detailed in the white paper, entitled, *NCPDP’s Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances*. 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.

1. If a REMS were to specify threshold drug amounts for opioid analgesic prescriptions above which prescribers would be required to provide additional documentation of medical necessity, what should

the amounts be and how should they be determined for various clinical indications? What data are there to support such amounts? What additional data would be useful?

NCPDP Comment: Today, many states have enacted their own legislation placing limits on the number of days and/or the morphine milligram equivalent (MME) dose for a new prescription for an opioid medication. In addition, many states have created specific and variable exemptions to override the prescribing requirements. NCPDP created a fact sheet as a resource for states to consider when creating regulations which indicates the variances across the nation.

NCPDP recommends the Opioid Policy Steering Committee develop a national standard for both initial days supply and MME dose and that it be based on guidelines published by the Centers for Disease Control and Prevention (CDC) on opioid prescribing for acute and chronic pain. In addition, NCPDP recommends using the diagnosis code (ICD-10) and/or the SNOMED CT® indication code to document the need for a greater days supply and/or MME dose and whether the patient's diagnosis is for acute or chronic pain.

2. If such measures were required, how should prescribers be made aware of them? Within the Agency's statutory REMS authority, how should the Agency require sponsors to ensure compliance with them? How should the Agency require sponsors to assess their effect in reducing misuse, abuse, and new addictions?

NCPDP Comment: NCPDP created the following electronic Risk Evaluation and Mitigation Strategies (REMS) transactions. More information about these transactions is available in the NCPDP SCRIPT Implementation Guide Version 2017071.

- **REMSInitiationRequest** - This transaction is a request to the REMS administrator for the information required to submit a REMSRequest. It is a request for the information required to submit a REMS request for a specified patient and drug.
- **REMSInitiationResponse** - This transaction is a response from the REMS administrator with the information required to submit a REMSRequest. It is a response with the information required to submit a REMS request for a specified patient and drug.
- **REMSRequest** - This transaction is a request to the REMS administrator with information (answers to question set; clinical documents) to make a REMS determination (approved, denied, pended, etc.).
- **REMSResponse** - This transaction is a response from the REMS administrator to a REMSRequest.

To ensure compliance with the REMS, requiring the above electronic REMS transactions would allow the REMS administrator to approve or reject the requested dispensing amounts and MME dosing at point of prescribing based on the information contained in the transmission. If additional information is needed to authorize the prescribing of the REMS product, the REMSRequest allows the REMS administrator(s) to send a set of questions to the prescriber. The NCPDP Telecommunication Standard also allows the pharmacy to submit dispensing information to the REMS administrator(s) ensuring REMS requirements are met.

3. The Steering Committee requests input from the public on whether, in addition to, or in conjunction with the above described prescriber intervention, and to the extent consistent with its statutory authority, the Agency should consider requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioid analgesics.

NCPDP Comment: NCPDP supports the use of a nationwide prescription history database to facilitate safe use of opioid analgesics, as outlined in our white paper referenced in our opening comments. 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 is a proactive, sustainable, interoperable solution that:

- Shares complete and accurate real-time information at the point of care anywhere in the country through the use of 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 Prescription Drug Monitoring Program (PDMP) data shows that a patient exhibits patterns indicative of opioid misuse.
- Allows prescribers and pharmacists to make clinical decisions prior to prescribing or dispensing an opioid.
- Ensures access for patients with valid medical needs.

NCPDP's model effectively addresses deficiencies in current industry PDMPs and provides an onramp for existing PDMPs to optimize the value of the programs at both the state and national levels through the use of existing standards.

NCPDP's model utilizes existing infrastructure and connects prescribers and pharmacists to a national facilitator via two real-time, bidirectional, HIPAA-compliant standards as a means of providing those entrusted with the care of patients with complete, timely, and accurate information on which to base their clinical decisions.

4. If this approach were adopted, how should the Agency require sponsors to assess the impact of such requirements?

NCPDP Comment: The use of the NCPDP REMS and Medication History messages would minimize the impact on the industry because these standards are already widely implemented within provider workflows. The CMS-4182-P Proposed Rule includes a provision to move the NCPDP SCRIPT Standard to version 2017071, which includes the use of the REMS transactions. Additionally, the Office of the National Coordinator (ONC), through their S&I Framework PDMP Initiative project, named the NCPDP Medication History messages for use in the healthcare industry to allow for the querying of PDMP databases for abuse potential. Beyond the numerous functional benefits, the use of a National Facilitator enables the FDA to measure success of opioid REMS programs.

NCPDP has no comments on questions 5-8.

NCPDP looks forward to working with the Opioid Policy Steering Committee to enhance and improve efficiency of the electronic exchange of REMS information between healthcare providers and REMS administrators.

Thank you for your consideration of our input.

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

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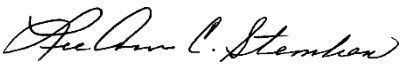
Sincerely,



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Appendix A: NCPDP Recommendations for Standardized Communications to Address the Opioid Epidemic

State Adoption of Opioid Prescription Dosage and Quantity Limits

Since 2015, 23 states have enacted legislation that imposes some type of prescribing limits, guidance or requirements on the maximum dose, quantity and/or days supply that prescribers can authorize on opioid prescriptions.

As states enact their own unique legislation and regulations, the differences in the specific rules create challenges for the interoperable exchange of information. This is further complicated when dealing with prescriptions that cross state lines (i.e., the prescriber is in one state and the pharmacy dispensing the prescription is in another state). The lack of standardization impedes health IT interoperability and efficiencies across all stakeholders (e.g., prescribers, pharmacies, payers) necessary to ensure compliance and patient safety.

Challenges with Implementing Laws Requiring Opioid Dosage and Quantity Limits

States recognize that prescribers may occasionally need to exceed the imposed prescribing limits and will allow exceptions to these limits. The list of exceptions can vary from state to state. While most states allow exceptions for a terminal illness or hospice care, exemptions for cancer diagnoses, traumatic injury, or surgery vary widely.

In addition, how these exemptions are identified as they are communicated through the healthcare system can differ between states. For example, State 1 might require exemption code values of 'A' for bone cancer, 'B' for pancreatic cancer and 'C' for colon cancer, while State 2 requires exemption code values of 'Q', 'Y' and 'Z', respectively. Allowing entities to exchange information using localized or proprietary code values hinders efficient, accurate healthcare communications and patient care delivery. Alternatively, this information could be exchanged using the existing standardized diagnosis code set (ICD-10)*.

*Some states are currently requiring diagnosis codes to convey the exemption.

NCPDP Recommendations to Standardize Communications in Addressing the Opioid Epidemic

As states and the industry continue their efforts to address the opioid crisis, NCPDP offers the following for consideration:

- States should support the creation of a list of standardized Opioid Exemption Code values
- States should work with NCPDP to create a list of standardized Opioid Exemption Code values
- All states should support the use of standardized language when referencing conditions or indications that are exempt from opioid restrictions
- States should utilize NCPDP and industry stakeholders as a resource as they consider the implementation of Opioid Exemption Code values

NCPDP welcomes the opportunity to work with states as they tackle this healthcare crisis. We stand ready to assist by providing guidance that can be considered and used when developing opioid prescribing and dispensing legislation and regulations.

Questions about this recommendation document can be sent to info@ncpdp.org.