



December 15, 2020

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Prescription Drug Monitoring Program  
ND State Board of Pharmacy  
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Kathy,

The PMIX Executive Committee would like to thank you for your feedback regarding the newly proposed schemas posted in September 2020. Below we have provided some feedback on the questions and concerns that you expressed. We hope that this information will aid you in understanding the new proposals, their foundation in the existing standards and the intent for the changes. The information outlined includes your comments in blue and the Committee's feedback in red.

- Can you outline the suggested changes from our existing PMIX Architecture schemas to the new schemas and the reasoning behind making these changes? This will help us better understand why any changes are needed and how they would benefit the greater goal of PDMP information sharing. The current data exchange standards in use by PDMPs are based on the National Information Exchange Model (NIEM) and the ASAP standard used in data collection. NIEM is simply a set of definitions for data elements. The current standards were based on these definitions when developed in 2010/2011 timeframe. Use of NIEM simplified the development of our standards. The changes proposed were brought forth because ASAP has had several revisions in recent years. The new ASAP data elements or changes to the use of data elements were not available in the current schemas. Since the additional elements added to ASAP were based on requirements that the PDMP community requested of ASAP, the committee felt it would be beneficial to have those elements available in case the PDMP community wanted to exchange them. While updating to the latest ASAP, the committee simply updated to the latest data definitions from NIEM where applicable. Finally, multiple states expressed interest in the ability to share alerts with their integration partners or other states. Since PMIX is used for the PDMP side of integration data exchanges, data elements would be needed to allow the exchange of alerts. The exchange of alerts is optional, the new schema simply provides a place for the information to be exchanged if desired.
- PMIX is a standards organization sponsored by BJA and its purpose is to support the sharing of Prescription Drug Monitoring Program data among PDMP organizations. ONC publishes the Interoperability Standards Advisory (ISA) as a way of recognizing interoperability standards and

implementation specifications for industry use to fulfill specific clinical health IT interoperability needs. I wasn't able to find the SOAP standards on the HealthIT.gov site. Other standards it mentioned were C-CDA, Direct, FHIR, HL7, and IHE to name a few. Was there any consideration into using a more widely used standard going forward that could potentially better support other healthcare entities data? The use of the PMIX standard does not preclude the use of other standards with your integrated data sharing partners. In fact, the Standards and Interoperability framework sponsored by ONC contains crosswalks from many healthcare standards to the PMIX. PMIX is simply the format for the PDMP side of the exchange. PMIX will continue to support this important work by ONC. PMIX does not require SOAP, we don't require any particular technology at all and have not required it since the new Security Standard went into effect several years ago. The new standard can be found on the PMIX website. It is a subset of NIST standard for information security used for HIPAA and other major information security initiatives. The NIST security catalogue is the same standards supported for HIPAA information security.

- What will the cost be to North Dakota or our vendor Appriss to accept these changes? Will our vendor be forced to comply with these changes even if they aren't in our states best interest? I'm concerned about costs to our state and an inflation of service costs to cover this in the future. PMIX Standards compliance is voluntary. In addition, the Standards Compliance process for the PMIX National Architecture is a tiered process. Each standard has a minimum level of compliance as well as higher levels. This process is designed to allow a baseline to exist without causing compliant states or vendors to choose to comply with other components of the standards. Some of the standards also have exemptions and plan for changes processes. These allow a request for exemption to be process or to be compliant while still adopting some of the standards. Costs would have to be discussed with each states' vendors.
- 4. This brings me to the last question which is how will these changes affect my current connections established with NDHIE, Gateway, and PMPi? Will we continue business as normal or will this affect how we currently exchange data with established connections to healthcare entities? Most healthcare entities do not use PMIX for their connections to PDMPs. Therefore, it should not impact them unless they are using PMIX for data exchange. If they are using PMIX for data exchange, they can voluntarily opt for standards certification when they are ready. With growth of PMPi and Gateway our state has built the infrastructure desired to extend out PDMP information to our health entities. Disruption to this growth is a real concern. The lengthy adoption timeframe in the standards proposal was provided to avoid disruption for any organization in moving to the new standards.

Please let us know if you have any additional questions. We look forward to your joining the Executive Committee in January.

Sincerely,

Jean Hall, Chair

Chad Garner, Vice Chair

Stan Murzynski, Secretary