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October 3, 2024

Office of the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, S.W.
Washington, D.C. 20201

RE: Docket HHS-ONC-2024-0010 – RIN 0955-AA06 – Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability

Submitted electronically via regulations.gov

Dear Assistant Secretary Tripathi:

Thank you for the opportunity to comment on ASTP's proposed rule: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability. The comments herein are made on behalf of the National Association of Boards of Pharmacy (NABP) **PMP InterConnect® Steering Committee** and the National Association of Controlled Substances Authorities (NASCSA) **PMP Committee**.

NABP is a 501(c)(3) nonprofit association that, for over 115 years, has protected public health by assisting its member boards of pharmacy and offering programs that promote safe pharmacy practices for the benefit of consumers. NABP PMP InterConnect® facilitates the transfer of prescription drug monitoring program (PDMP)[1] data across state lines. PMP InterConnect is governed by the PMP InterConnect Steering Committee, which is composed exclusively of representatives of the PDMPs that participate in the system. The Steering Committee serves as the governing and advisory body as it relates to the administration and function of PMP InterConnect. Currently, the PMP InterConnect Steering Committee is comprised of 53 PDMP Administrators from 53 states and territories.

The National Association of State Controlled Substances Authorities (NASCSA) was established in 1984 and is a 501 (C)(3) non-profit educational organization and is comprised of state agencies and others involved with controlled substances issues. NASCSA was established to provide a forum for the discussion and exchange of information and ideas, and to develop, implement, and monitor ongoing strategies to curtail the abuse, misuse, and diversion of controlled substances, including PDMPs. In 2015, recognizing the importance of PDMPs,

[1]Use of the term prescription drug monitoring program (PDMP) versus prescription monitoring program (PMP) varies state to state. For consistency, utilizing "PDMP" throughout this document except when referring to PMP InterConnect®.

NASCSA established a PDMP Committee comprised solely of state PDMP administrators that provides guidance and recommendations to the organization on policies, positions as well as content for our annual conference and webinars held throughout the year.

We are writing to share significant concerns with new requirements in the proposed rule relating to the exchange of prescription drug monitoring program (PDMP) data. The new requirements were written based on an outdated understanding of the current PDMP ecosystem and would significantly disrupt the progress that state PDMPs have made under the current ecosystem. We are also concerned that the new requirements would have a number of intended and unintended consequences, including conflicts with existing state law in most states. We appreciate the opportunity to work with ONC to achieve its goals of data interoperability and public health data sharing, without disrupting the ability of PDMPs to serve their important public health function. **Given the concerns and unintended consequences outlined in this letter, we respectfully recommend that ASTP remove sections § 170.315(f)(9) and § 170.315(f)(29) of this proposed rule.**

I. PDMP Origin and State Governance

As you know, prescription drug monitoring programs (PDMPs) have been around for decades and have been a joint federal-state effort. Each state and territory operate and governs their own PDMP in accordance with federal, state and jurisdictional laws. Some states receive federal funding for PDMP operations, which includes expanding PDMP access through established integration mechanisms. The Department of Justice (DOJ) initiated the Harold Rogers Prescription Drug Monitoring Grant Program in 2003, which was the first and primary federal funding source for establishing state-operated PDMPs. In addition, the DOJ Bureau of Justice Assistance (BJA) began the "Prescription Monitoring Information Exchange" (PMIX) project in 2005, which resulted in the PMIX requirements we have today. By 2010, most states were operating a PDMP. At that time, state PDMP administrators realized the need to be able to share PDMP data across state lines. As such, the DOJ Bureau of Justice Assistance (BJA) funded a system for interstate data sharing known as RxCheck and NABP created PMP InterConnect® both based on the work of the PMIX project.

State Governance

For a PDMP, the state law is the policy. Decisions about PDMP data sharing and access are not made at the administrative policy level by a corporation, not-for-profit, or state governmental department. Rather, PDMPs are governed by state law as dictated by their state legislatures. States determine who is authorized to access PDMP data for what purpose and when. Many states require prescribers and dispensers to access PDMP records before prescribing or dispensing an opioid or other controlled substance. State professional licensing boards have an obligation to ensure their licensees abide by mandatory use laws– requiring providers to utilize the PDMPs. PDMP access roles are clearly defined in each state and states agree with one another about access roles prior to interstate data sharing.

II. Current PDMP Ecosystem

The data source cited for PDMP knowledge in the rule is ONC's *Leveraging Prescription Drug Monitoring Programs and Health Information Technology for Addressing Substance Use Disorder and Opioid Use Disorder (LPASO)*[2] report published in March 2023. However, the report is not a comprehensive or up-to-date picture of the current PDMP landscape. Many components of the report are citing data from 2017 obtained from various public sources or surveys, which cannot be corroborated. Neither method of data collection is reliable enough to draw solid conclusions. The authors themselves indicate that a lack of publicly available secondary data sources

[2] LPASO_Landscape_Assessment_508.pdf (healthit.gov)

is a limitation to conducting landscape assessments. The document admits that this project had limited resources and used mainly secondary resources. Most of the documents referenced had limited state participation. This document does not reflect all states, nor does it include current data and cannot be used as an authoritative resource with such limited representation on a subject that has 55 states, territories, and jurisdictions with active PDMP programs. In this section, we provide more up-to-date and accurate data regarding multiple facets of the current PDMP ecosystem.

Current Interstate Data Sharing

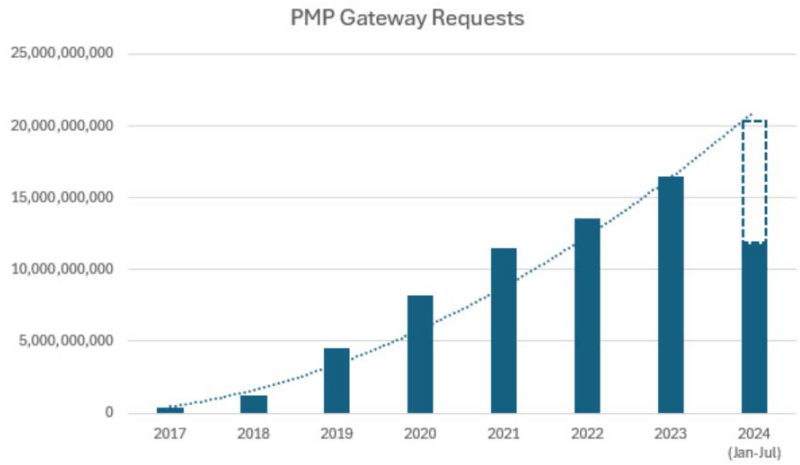
Today, nearly every state is connected to both interstate data sharing systems and is sharing data seamlessly across state lines, while maintaining control of state data in accordance with state laws. States share data through one of two hubs-RxCheck and PMP InterConnect. In the first quarter of 2024, these two hubs facilitated more than 927,000 and 330 million interstate data queries, respectively. Currently, 52 state, territory, and jurisdictional PDMPs share data through PMP Interconnect. Healthcare provider roles are standard across all interstate data sharing, allowing relevant providers universal access to all 52 PDMPs for clinical decision making.

Current PDMP-EHR Integration

The requirements related to PDMPs in the rule are based on a significantly outdated understanding of the current PDMP ecosystem, most notably, the current status of PDMP integration into electronic health records (EHRs) and the ability of PDMPs to perform public health functions necessary in today's environment. The understanding of PDMPs in the rule is based on data in the LPASO report cited above. While the report was published relatively recently, the hospital integration data cited was from 2017.

Using 2017 data to reflect the 2024 ecosystem is a critical flaw – 2017 and 2018 were the years that PDMP integration with hospitals skyrocketed, so using data from 2017 or before to establish the need for additional rules to promote PDMP integration is fallible. In 2017, mandatory use laws had just been put into effect in most states and PDMP programs were considering ways to ease the burden on providers who were now required to check the PDMP prior to prescribing or dispensing an opioid or a controlled substance. States began funding statewide integration programs, making integration penetration numbers grow exponentially. Additionally, the source for the integration numbers cited in the LPASO report was a survey conducted by the American Hospital Association (AHA) in 2017.

The LPASO report cited several states' integration data from 2017. Wyoming, New Mexico, Indiana, and Iowa had the lowest percentage of queries performed through integration, 0%, 7.8%, 8.5%, and 10.1%, respectively. In 2024, the percentage of prescribers querying the PDMP in those states through integration are 67%, 80%, 94%, and 79%, respectively. State mandatory use laws propelled state PDMPs to find solutions for providers' cumbersome access to PDMP data. Funding statewide integration has had a marked improvement on providers' access to PDMP data integrated through EHRs. PDMP records can be obtained within milliseconds of a single click within an EHR when PDMP data is integrated, compared to 4.22 minutes when obtaining the data through a PDMP web portal. In 2017, 387 million integrated PDMP searches were conducted nationwide. In 2024, absent any requirements for PDMP integration, state PDMPs are projected to process 20 billion integrated searches. The following graph illustrates the exponential growth of PDMP integrated searches since 2017.



Standards in Use in Current Ecosystem

As stated above, nearly every PDMP is connected to both interstate data sharing hubs for sharing data across state lines. Both data sharing hubs are built on the open, consensus base standard known as the Prescription Monitoring Information eXchange (PMIX) national framework. This framework is built on the National Information Exchange model and includes a common vocabulary, a common set of defined user roles, a security standard based on FIPS and a common set of data elements to be included in meta data. All but one PDMP jurisdiction utilizes the PMIX framework.

Additionally, PMP Gateway, which provides the integration of PDMP data into clinical workflow, supports data delivery via ASAP and NCPDP SCRIPT standards, where permitted by state policy. PMP Gateway is currently available in 44 states, used by tens of thousands of health systems, and services billions of PDMP integration transactions per year.

Thus, nearly all PDMPs are already adhering to consistent standards for different functions, and there is not a demonstrated need to move the whole system to new standards.

Current Interaction with Public Health Data

As discussed, unlike many other data sources, PDMPs are governed and operate according to prescriptive state law. Those state laws hold the PDMP responsible for adhering to the law and the responsibility cannot be passed to other entities such as health IT systems. Thus, PDMPs do not share their data with a wide variety of stakeholders, like health IT systems, unless explicitly directed by state law. This is done to protect sensitive data regarding dispensation of controlled substances, such as medications to treat substance use disorders (SUD) and mental health conditions. As you know, SUD and mental health data is often held to a higher privacy standard by both state and federal law than other types of health care data, due to the sensitivity of the information. At the federal level, SAMHSA's 42 CFR Part 2 rules are more stringent than the Health Insurance Portability and Accountability Act (HIPAA) that generally governs health care data. State law often further governs the privacy of SUD data and can be more stringent than federal law. Health IT interoperability policies that require PDMP data to flow freely and without the ability to monitor access would therefore be in direct violation of most states' laws.

Since 2020, more clinical decision support (CDS) tools and other non-dispensation data sets have been included into the PDMP including overdose data, vital statistic data, criminal data, and opioid treatment program (OTP) data. However, OTP data is not widely available in PDMPs because federal law around sensitive SUD (42 CFR Part 2) prohibited this data from being displayed in PDMP reports until recently. Even with federal updates to 42 CFR

Part 2 regulations, it is very difficult to meet all requirements to display this data.

In fact, in a recent update to federal privacy rules around SUD data, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) amended a proposed requirement to search PDMPs because SAMHSA and state treatment facility databases contain a broader range of providers and are more readily available for investigative agencies[3][4]. PDMPs primarily serve as a clinical decision support tool for providers to determine whether therapy with a controlled substance is appropriate. While criminal and administrative law enforcement may have access to PDMP data, that access is typically highly restricted and only provided through subpoena or court order. Eliminating these barriers places states at risk of violating privacy laws and may have a chilling effect on prescribers willing to treat patients with controlled substances, which could cause patient access issues.

PDMP Efforts to Combat the Opioid Epidemic

Today, with interstate data sharing and EHR integration close to seamless in most states, states have been able to innovate and improve their data sources and processes to combat the opioid epidemic. This is demonstrated by the numbers: while the opioid epidemic persists in full force today, overdose deaths related to prescription drug overdoses has significantly decreased while the contribution of overdose deaths due to illicit substances has increased[5,6,7]. In 2017 when PDMP mandatory use laws began to go into effect, prescription drug overdose deaths started to decline. By definition, drugs obtained through illicit means and not via a prescription are outside the scope of a PDMP. The fact that prescription drug overdose deaths have so sharply declined is evidence that PDMPs are working. PDMPs need to be supported to continue to operate and maintain that progress, while also being supported to evolve to help address emerging needs such as illicit drug use and stimulant prescribing. Disrupting the current ecosystem is counter to those goals.

PDMPs are Collecting and Displaying Dispensation Data for Public Health Use Cases

States have leveraged their PDMPs in response to the opioid epidemic and have enhanced offerings to providers and dispensers beyond providing patient dispensation reports. Disruption to the current PDMP ecosystem places all these advancements at risk of being unnecessarily dismantled.

1. Prescriber Reports
    a. 34 states issue prescriber reports to equip providers with insights into their controlled substance prescribing habits as compared to their peers and practice specialty.
2. Clinical Alerts
    a. 32 states have implemented clinical alerts which are delivered to prescribers within the PDMP platform when certain criteria are met to ensure prescribers are made aware of concerning patient behaviors.
3. Data Analytics
    a. 26 states have enabled providers access to advanced PDMP analytics to assist with clinical decision-making at the point of care.
4. Mandatory Use Reports
    a. 13 States utilize mandatory use reports to ensure providers are in compliance with mandatory use laws.

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[3] https://www.ecfr.gov/current/title-42/section-2.36

[4] 89 FR 12472. Final rule "Confidentiality of Substance Use Disorder (SUD) Patient Records". 2/16/2024. https://www.federalregister.gov/d/2024-02544/p-266

[5] https://www.cdc.gov/nchs/data/databriefs/db491.pdf

[6] 5.23.2024 NDTA-updated.pdf (dea.gov)

[7] 2023-nsduh-annual-national.pdf (samhsa.gov)

5. Internal PDMP Communications
    a. 11 states have elected to participate in a communications module that facilitates provider-to-provider messaging, including attachments, which can aid in the treatment of shared patients.
6. Medical Marijuana
    a. 10 states incorporate medical marijuana dispensary data into the PDMP.
7. Prescriber Outliers
    a. Four states utilize a detailed analysis of PDMP data to identify providers whose prescribing habits could potentially have negative repercussions on patient care.

As a specific example for clinical alerts and data analytics, in 2021, the South Carolina PDMP began ingesting naloxone administration data for both fatal and non-fatal opioid overdoses from healthcare facilities and first responders across the state. This information is presented in the PDMP to healthcare providers across the state to assist in clinical decision making resulting in safer prescribing and dispensing practices. The naloxone administration data is displayed as a clinical alert in the patient's PDMP report. Additionally, the administration of naloxone is calculated into the patient's unintentional overdose risk score to alert providers that the patient may need additional safety measures for certain controlled substances, including the co-prescribing of naloxone.

States have worked tirelessly to ensure providers have timely and convenient access to PDMP data and have adapted their PDMP systems in response to the individual needs of their state. Has ASTP considered what impact reversing all of this work might have on public health, safety, and welfare?

III. Questions and Concerns about the Rule's Disruption of the PDMP Ecosystem

With the understanding of the PDMP ecosystem as described above, the challenges with implementing the PDMP data sharing requirements proposed become apparent. We have identified a few overarching issues that we will elaborate on below.

Requiring PDMPs to share discrete data with outside sources would be in violation of state law and would disrupt the current PDMP ecosystem. The proposed rules are attempting to solve problems that no longer exist, based on faulty and outdated data and a misunderstanding of the current ecosystem.

If federal funding for PDMPs were to be tied to the standards set forth in the rule, HHS places states in an untenable situation by both hamstringing the ability of states to adequately fund their programs and potentially placing those programs in direct conflict with state laws.

While we respect ASTP's mission and goal of ensuring more health care data interoperability for patient and public health use, we urge the agency to understand the unique nature of PDMP data and the necessity that it be treated differently than other kinds of health care data. If not, it is not likely that PDMPs will be able to continue to operate.

Discrete Data Requirement Conflicts with State Laws

In order to maintain state law mandated control of PDMP data including the ability to grant and audit access roles, PDMP data is typically displayed to a health care professional in a nondigestible image format (PDF or weblink) rather than a raw or discrete data format. In other words, PDMP data is intentionally human readable, but not machine readable.

Unlike other sources of health data, the PDMP is not a first-hand source. The PDMP staff have no direct ability to verify the accuracy of the information with the dispensing pharmacist, prescribing provider or the patient. As

such, PDMP data is often amended and/or corrected. Once incorrect or incomplete data is ingested by a health IT system, the PDMP would have no ability to correct it. Therefore, various conflicting copies of the patient's controlled substance history could exist in the health IT ecosystem. To further this, if PMP data was subpoenaed from the patient's medical record and used in a civil/criminal case, there could be significant problems if the information ingested contained errors.

Even in an EHR integration scenario, the EHR does not currently receive raw or discrete data. Instead, the ability to query a PDMP or multiple state PDMPs is integrated into the EHR – which, for the provider is now a seamless process that results in a report that may be reviewed. Requiring instead that PDMPs share discrete data either with health care systems via their EHR or with other health IT systems would be a fundamental change to the current process. Once discrete data is shared, PDMPs no longer have any control over how it is used and can therefore not control or audit who accesses it. This would result in a direct violation of state law.

In some states, it is a criminal offense to access PDMP data inappropriately. There would be no way for state regulators to track and enforce inappropriate access if discrete data was integrated into an EHR where an entire health system of clinicians, administrators, and business associates have access to that data. Further, states currently govern how and when PDMP data can be used in civil litigation and by state and federal investigators. Integrating raw or discrete PDMP data into the EHR or other health IT system would render it impossible to follow those laws.

In cases where PDMPs obtain data from other sources to enhance the PDMP utility, PDMPs often enter into agreements with those data sources that the data will not be further shared. Again, this would be impossible to prevent if discrete PDMP data were required to be provided to health IT systems. In that case, some states may have to disconnect from their other data sources causing prescribers to have less information to make a clinical decision.

Lastly, many states now have mandatory use laws which require certain clinicians to check the PDMP before prescribing or dispensing a controlled substance or opioid. PDMP Administrators can monitor adherence to said laws by checking whether providers checked the PDMP. If discrete data were shared with EHRs, it could be displayed in a different format or location, making it impossible for PDMP Administrators and the state health professional licensing boards responsible for regulating and enforcing PDMP mandatory use laws and rules to determine whether a licensee appropriately accessed PDMP data.

Questions for ASTP regarding the discrete data proposal:

- Has ONC considered adjustments to custody and audits, how they will be maintained, and who will maintain the PDMP data? Will this responsibility rest with the state PDMP programs, corporate entities and health systems, electronic health record and pharmacy dispensing system vendors, or individual practitioners?
- How would custody of the data be maintained? Who is responsible for maintaining custody of the data? Who will be held responsible when a data breach occurs?
- How would the data be audited in accordance with existing state laws? Would this remain the responsibility of the state PDMP or now the health care providers that have ingested the discrete data?
- In states with mandatory use laws, who will hold providers accountable if PDMPs no longer have control over PDMP data? Will states need to subpoena health system IT infrastructure to determine whether a provider checked a patient's PDMP record?
- Has ASTP considered the potential impact to prescribers and patients if health systems and EHRs analyze discrete PDMP data to identify outliers? These analyses could lead to termination of prescribers' employment or patients that the health system identifies as being a liability.

- Has ASTP considered how states would be able to comply with the requirements of the Substance Use Disorder Prevention that Promotes Opioid Recover and Treatment (SUPPORT) Act of 2018 to accurately report the percentage of prescribers and dispensers who query the PDMP?
- If discrete data is made available to health IT vendors, what prohibitions are in place to prevent a health IT vendor from charging its customers for access to PDMP data?

Bi-Directional Query of PDMP Conflicts with State Laws

By tying federal funding, specifically the query of PDMP measure and the definition of a qualified PDMP, to the standards set forth in the rule, HHS places states in an untenable situation by both hamstringing the ability of states to adequately fund their programs and potentially placing those programs in direct conflict with state laws. As discussed in depth, most states do share their data interstate with one another, but it is unclear whether that meets the definition of bi-directional required here.

Questions for ASTP regarding bi-directional query requirements:

- What is ASTP's definition of bi-directional query as it pertains to the rule? Which entities need to share bi-directionally? State to state or state to hub or another set of entities?

Change in Standards Should Only Be Implemented if Necessary

As mentioned above, PDMPs currently operate under PMIX standards. Due to the disruptive nature of changing entire systems, a comprehensive change in standards in long-used standards (rather than just a version upgrade) should only be implemented if absolutely necessary and is guaranteed to provide additional benefit. Given the evidence provided in this letter, changing standards as envisioned by this rule not only fails to meet that threshold but will create significant challenges for state PDMPs. Additionally, the target implementation date for this rule is 2028 and requiring a specific version of a standard in a future time period is likely to stifle innovation and may not account for the newest technology that may be available at the target date.

Table 54 in the rule contemplates the costs of implementing the rule. However, the cost only considers the development effort of a single vendor into account. Not included are the costs of negotiating legal agreements and/or licensing, the cost of technical support, the cost of maintaining an electronic system, etc.

Questions for ASTP regarding a required change in standards:

- Would the proposed rules displace ASAP as the standard for PDMP data collection that is utilized across all PDMPs today?
- Has ASTP conducted an analysis of the full cost that would be incurred to PDMP programs, pharmacies, pharmacy management systems, and prescribers to replace a standard that supports billions of annual transactions across the country?

Additionally, for the past year, NABP, Bamboo Health, and state PDMP administrators have provided input on an ASTP-funded effort to update the version 3 "PDMP on FHIR HL7 Implementation Guide (IG)" to a more updated version 4 – a voluntary guide for PDMPs to adopt HL7 FHIR standards. Based on the feedback of many state PDMPs regarding concerns around sharing of discrete data consistent with the concerns outlined above, the latest iteration of the IG allowed an option to share view only rather than discrete data. While requiring a switch from the current standards to HL7 FHIR would not be ideal, it would be possible under a non-discrete data option. However, this rule discards all progress made in those discussions by ignoring the outcome of the IG. We have significant concerns given that the outcomes of the IG were driven by a consensus-based process.

Questions for ASTP regarding HL7 FHIR IG:

- What is the role of the PDMP on FHIR Implementation Guide in this proposed rule? Does this rule disregard what was a significant stakeholder driven, consensus-based effort to drive alignment?

Solving an Integration Problem that Does Not Exist

As detailed above, PDMPs are far more integrated into EHRs today than they were in 2018. There is still some work to be done, but that work should build on existing efforts to close gaps, not completely reinvent the wheel. If we start over, we lose all progress made with current integration, including the strong upticks in clinician utilization of PDMPs. If we disrupt the current PDMP ecosystem, we also risk losing ground on the decreasing prescription opioid overdose deaths.

Overhauling the current system would come with significant financial and administrative burdens.

Questions for ASTP regarding cost to implement proposed changes:

- Do the project costs outlined in the rule account for IT costs borne by health systems, pharmacies, prescribers, and other intermediaries that would be necessitated by this rule? For example, this only accounts for build. What about migration, audit, staffing and personnel costs for state PDMP programs and necessary changes to the core PDMP technology that states use?
- Is there a cost-benefit analysis of the PDMP-specific provisions in the rule?

Thank you once again for the opportunity to provide feedback on this proposed rule. The PMP InterConnect Steering Committee and the NASCSA PMP Committee or any of their member PDMPs would be pleased to have the opportunity to share more qualitative and quantitative data around individual state activity and our perspective on the current PDMP infrastructure and ecosystem. ASTP's Health Information Technology Advisory Committee (HITAC) Pharmacy Interoperability and Emerging Therapeutics Task Force included in its 2023 recommendations that ONC work with NABP on pharmacy data interoperability, but to date, we have not engaged directly with ONC, despite multiple efforts at outreach. NABP represents all 50 state boards of pharmacy and 53 of the PDMP administrators (sometimes housed in the state boards, sometimes not) and would be an appropriate conduit to the majority of states in the PDMP ecosystem.

Again, given the concerns and unintended consequences outlined in this letter, we respectfully recommend that ASTP remove sections § 170.315(f)(9) and § 170.315(f)(29) of this proposed rule.

Sincerely,

Alexandra Blasi
Chair, PMP InterConnect Steering Committee
Executive Secretary, Kansas Board of Pharmacy

Kathy Keough
Executive Director, National Association of State Controlled Substance Authorities