SUMMARY OF REVISIONS TO NASCSA'S MODEL PMP ACT (2016)

PURPOSE OF SUMMARY

This Summary is intended to help explain updates that the PMP Task Force proposes to NASCSA's Model PMP Act (2016) (Model Act 2016). The Summary will discuss (1) key substantive language changes to Model Act 2016; (2) the purposes of the language changes; and (3) key federal and state laws and policies the PMP Task Force reviewed in determining beneficial language refinements. The combined changes support the following themes:

- Expanding the types of substances monitored by PMPs;
- Expanding the types of information relating to monitored substances that PMPs collect and maintain; and
- Identifying and clarifying reporting, access, use, and disclosure requirements for the information that PMPs collect and maintain.

COMPOSITION OF PMP TASK FORCE AND METHODOLOGY

PMP data and information are accessed and used by a number of diverse stakeholders for informed clinical care of patients, early intervention with patients at risk of substance abuse or addiction, public health surveillance, and prevention of diversion. NASCSA established a 10 person Task Force to objectively review Model Act 2016 in the context of broad stakeholder input that highlights the current and emerging needs of authorized PMP users and officials. Geographically diverse, the Task Force included members from the Northeast, South, Midwest and West. Task Force members brought to the review many years of experience as PMP Administrators, pharmacists, state health care professionals, controlled substances regulators, and law and policy specialists. To supplement the Task Force's collective expertise, NASCSA solicited input about Model Act 2016 from health care providers and their associations, health care licensing boards, state controlled substances agencies, law enforcement officials and agencies, and PMP officials and vendors.

PROPOSED REVISIONS TO MODEL ACT (2016)

A. Definitions – Section 4.

1. "Deliver"

Since 2016, mail order prescription deliveries have steadily increased.[i] PMP officials experience challenges with mail order pharmacies reporting dispensing data to multiple PMPs. To prevent such duplicative reporting, the Task Force recommends defining "deliver" to mean a sale or other actual physical transfer of a monitored drug. Dispensing will occur in a state where a monitored drug is sold or otherwise physically transferred from one individual or entity to another individual or entity. Dispensers will report data to the PMP in the state where the physical possession of a monitored drug is transferred from the dispenser to ultimate user, or the user's agent.

2. "Dispenser"

Federally assisted substance abuse programs subject to federal confidentiality law and regulations, 42 U.S. C. § 290dd-2, 42 C.F.R. Part 2 (Part 2), have traditionally been exempt from reporting dispensing information regarding substance use disorder patients to PMPs. On July 15, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Final Rule adding a new section regarding PMP reporting to the regulations governing the Confidentiality of Substance Use Disorder (SUD) Patient Records. The new section, § 2.36, was effective August 14, 2020. Section 2.36 permits programs covered by Part 2 or other lawful holders of SUD records to report dispensed data to their respective state PMPs if they (1) are required to do so by applicable state law, and (2) have obtained written patient consent to the disclosure of information to a PMP prior to reporting such information.[ii] PMPs who are lawful holders of Part 2 data must comply with Part 2 confidentiality and data security requirements. On April 9, 2021, SAMHSA announced that the agency will issue additional changes to the Part 2 Rule later in 2021 to implement confidentiality law modifications passed in the 2020 Coronavirus Aid, Relief, and Economic Security Act (CARES Act).[iii]

For PMPs that wish to begin collecting Part 2 data, the Task Force proposes optional language to the definition of "Dispenser" that requires programs subject to Part 2 to report data to a PMP. Because the Final Rule is new and will be further modified in 2021, PMPs lack sufficient implementation experience for the Task Force to recommend that all PMPs become lawful holders of Part 2 data.

3. "Drug of concern" and "Monitored drug"

In 2016, PMPs primarily monitored prescribed controlled substances, and non-scheduled substances for which there is an indication of abuse, such as carisoprodol. In 2021, some PMPs significantly expand the types of substances for which they collect data. Nebraska and the Northern Mariana Islands monitor all prescribed substances, controlled and non-controlled.[iv] Colorado is considering a similar scope of monitoring.[v] Fifteen PMPs collect medical marijuana dispensings.[vi] Public health surveillance initiatives in 30 jurisdictions rely on PMPs to collect information on naloxone administration or dispensing, or both.[vii]

To accommodate PMPs' increasing scope of monitoring, the Task Force provides two optional definitions of "Monitored drug". For each option, there is a corresponding definition of "Drug of concern" for substances that have a potential for abuse or diversion, or need monitoring for public health purposes. The table below summarizes the two optional definitions:

	Primary category of substances monitored	Drug of concern
Option 1	Prescribed controlled substances in Schedules II-V (e.g., opioid, benzodiazepine)	1. Unscheduled substance (e.g., gabapentin, naloxone) 2. Non-prescribed substance in Schedules I-V (e.g., marijuana)
Option 2	Prescribed substances, including controlled and non-controlled (e.g., opioid, gabapentin, naloxone)	Non-prescribed substance (e.g., marijuana)

4. “PMP-generated analytical data”, “Supplemental data”, and “PMP information”

Model Act 2016 primarily focused on reporting, accessing, using, and disclosing PMP dispensation data, defined as “PMP data”. Access and use requirements for information regarding requests for PMP dispensation data, defined as “audit trail information”, were also included.

The Task Force identified two additional types of specific data now found in some PMPs. Since 2016, some PMPs have become a repository of non-dispensation data that helps a practitioner understand a patient’s patterns of substance use and possible abuse. Such data includes fatal and non-fatal overdose information, convictions for violations of controlled substances and other drug laws, and pain management agreements. As important public health and clinical tools, PMPs often produce a variety of statistical or analytical results of dispensed prescription data, including patient alerts, drug trends, and peer prescribing comparison reports.

The Task Force recommends the following definitions to address the four types of specific data currently maintained, managed, and disclosed by PMPs:

- “Audit trail information”. This original term and definition in Model Act 2016 remains the same for the revised Model Act.
- “PMP dispensation data”. This term replaces the original Model Act 2016 term “PMP data”. The original definition of “PMP data” remains the same for “PMP dispensation data”.
- “PMP-generated analytical data”. This new term means the statistical or analytical results of dispensed prescription data generated or produced by a PMP.
- “Supplemental data”. This new term means non-PMP dispensation data that may include, but is not limited to, pain management agreements, laboratory results, and information related to fatal and nonfatal overdoses.

Throughout Model Act 2016, the Task Force identifies the legal requirements that apply to each type of specific data, and proposes insertion of the appropriate data term. Where legal requirements apply to all four types of specific data, the Task Force proposes use of the term “PMP information” rather than individually listing each type of data. In the definitions section, “PMP information” means audit trail information, PMP dispensation data, PMP-generated analytical data **and** supplemental data.

B. Confidentiality of PMP Information – Section 8.

The Task Force updates the confidentiality and public record protections to apply to all categories of data maintained, managed, and disclosed by PMPs.

C. Access to and Use of PMP Information – Section 9.

Model Act 2016 focused on access, use, and disclosure requirements for PMP dispensation data. Access to audit trail information was reserved for health licensing entities and law enforcement

officials conducting active investigations. The Task Force proposes broadening the scope of Section 9 to address all four types of data disclosed by PMPs.

Detailed requirements for PMP dispensation data are organized within subsection B. The original 17 categories of authorized users of PMP dispensation data remain. Out-of-state recipients are expanded to include PMPs administered by U.S. territories, districts or jurisdictions. Guam, Puerto Rico, the Northern Mariana Islands, and military jurisdictions will be able to participate in interjurisdictional data sharing.

The Task Force provides jurisdictions significant discretion in determining who should receive supplemental data and PMP-generated analytical data. Both data categories include a broad range of information that may be collected or generated. PMPs may vary widely regarding the types of such data they maintain and disclose to accomplish specific goals. In subsection C, the Task Force recommends that jurisdictions identify the users within subsection B that are authorized recipients of supplemental data and PMP-generated analytical data. Disclosure to those recipients will be in accordance with federal and state laws.

Subsection D captures the original audit trail access language for health licensing entities and law enforcement officials. The Task Force recommends two additional types of authorized users for audit trail information. The first type is an individual responsible for monitoring compliance with PMP requirements under applicable federal and state laws. The Medicaid PARTNERSHIP Act requires Medicaid providers, beginning October 1, 2021, to check PMPs for the prescription history of their Medicaid patients.[viii] Beginning 2023, each state must annually report to the Secretary of the U.S. Health and Human Services Department the percentage of Medicaid providers who did request PMP reports for their Medicaid patients.[ix] The Task Force recognizes that state officials may request audit trail information to assist with their annual reports.

A second type of new user for audit trail information is an individual who received dispensed monitored drugs or the individual's legal agent. The individual or agent may request audit trail information to help determine suspected inappropriate access or use of the individual's PMP dispensation data. Twenty jurisdictions have publicly identified their PMPs as HIPAA covered entities.[x] Under HIPAA, an individual has a right to an accounting of certain disclosures of his or her protected health information.[xi] Additionally, state momentum to introduce and adopt privacy protections for individuals is at an all-time high.[xii] These protections often allow individuals to know the third parties with whom their personal information is shared. The Task Force's recommendation aligns with federal and state efforts to increase individuals' ability to monitor and manage their health and other personal information.

In subsection H, the Task Force builds on the original authority for prescribers and pharmacists, and their delegates, to request PMP dispensation data via health or pharmacy technology. Two options provide storage and re-disclosure policies for data received through approved technology. Option 1 allows storage of PMP dispensation data in a patient's medical record, and re-disclosure of the stored data under the same terms and conditions as other patient data in the record. Option 2 prohibits storage of PMP dispensation data in a patient's medical record, and permits re-disclosure of the data only for providing, or evaluating the need to provide, medical or pharmaceutical care to the patient.

CONCLUSION

PMPs grow in significance as multidisciplinary public health and safety tools. Use of PMP information is intended to simultaneously help prevent misuse and diversion of substances while facilitating practitioners' ability to help patients with substance use disorders. Users of PMP information range from staff in health care practices to seasoned drug investigators. The Task Force's proposed updates to Model Act 2016 help PMPs continue to efficiently and effectively serve the emerging needs of PMP users and officials.

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[i] https://blog.edentalsolutions.com/mail-order-drugs-the-rise-of-pharmacy-delivery-services https://www.wsj.com/articles/mail-order-drug-delivery-rises-during-coronavirus-lockdowns-11589281203

[ii] 42 C.F.R. Part 2, § 2.36, https://www.federalregister.gov/d/2020-14675 and https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html. For general information about 42 C.F.R. Part 2 and its application, please see SAMHSA's guidance at https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf and https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf.

[iii] https://www.samhsa.gov/newsroom/statements/2021/42-cfr-part-2-amendments-process

[iv] https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf

[v] https://leg.colorado.gov/bills/hb21-1012

[vi] https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf

[vii] https://www.pdmpassist.org/pdf/PDMP%20Policies%20and%20Capabilities%202020%20Assessment%20Results_20210111.pdf; https://www.pdmpassist.org/Policies/Maps/PDMPPolicies

[viii] The Medicaid PARTNERSHIP Act, Substance Use-Disorder Prevention that Promotes Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. No. 115-271, § 5042 (Oct. 24, 2018). https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf

[ix] Ibid.

[x] https://www.pdmpassist.org/State

[xi] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164, § 164.528. https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf

[xii] https://iapp.org/resources/article/state-comparison-table/