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Prescription Drug Monitoring Programs: A Policy Review and Recommendations for States

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Prescription Drug Monitoring Programs: A Policy Review and Recommendations for States

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By

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ABSTRACT

BACKGROUND: Prescription drug abuse heavily hinders the United States' health care, criminal justice and social services systems.[1] Studies have shown that prescription drug monitoring programs (PDMPs), however, are effective in slowing down drug abuse and reducing diversion. Accordingly, forty-nine states have authorized or are in the process of authorizing PDMPs.[2] Still, the programs have not reached their full potential. Few states have established a comprehensive policy to maximize the program's intended benefit, allowing utilization to remain relatively low.[3] More policy reviews are needed to help guide states in maximizing function and utilization of PDMPs through well-written legislation.

OBJECTIVE: This study aims to review existing PDMP statutes, and to provide recommendations for good legislative drafting that will create effective statutory components that will enhance the function and increase the use of PDMPs.

METHODS: This policy review was conducted from July 2014 to December 2014, using articles from PubMed dated January 01, 2004 to July 01, 2014. All PubMed searches were artificially limited to peer reviewed articles that were available as "free full text." To ensure a comprehensive review of the policies, statutes from all fifty states were surveyed using the legal database, Westlaw Next. The searches used terms commonly associated with PDMPs, and each statute was reviewed by title and content to determine applicability to the study. The list of statutes compiled from Westlaw Next was compared with other, existing publications that survey PDMP statutes. Any outstanding statutes were reviewed for reviewed for relevancy using the same criteria from the initial Westlaw Next search. "Major components"—as used in the analysis of this study—are derived from reoccurring topical patterns among PDMP statutes. The recommendations are based on the investigator's experience and training in law and public health in consultation with a legislative expert, and supported by peer reviewed articles, as well as legislative drafting guides.

RESULTS: There are twelve main topical components that are addressed in existing state PDMP statutes. The policy brief's three principal recommendations are based on enhancing communication between stakeholders, imposing accountability and increasing utilization. Specifically, the policy brief recommends implementing an advisory committee with an outlined membership, imposing a duty for the committee to routinely review database

1 EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES (2010). Available at http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf

2 *Id.*

3 *Id.*

information and to report on the findings, mandating practitioners to consult the database prior to administering controlled substances, and enacting a PDMP educational and training component for practitioners. Appendix A of this policy review (attached) provides a full list of the recommendations for effective legislation on all twelve topical components.

Prescription Drug Monitoring Programs: A Policy Review

and Recommendations for States

By Christine S. Lee

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AUTHOR'S STATEMENT PAGE

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DEDICATION

This policy brief is dedicated to my family that has supported me throughout my educational endeavors, to my friends who have provided me with encouraging words and much-needed coffee, to my boyfriend who has been my sounding board, and finally, to all my graduate professors who believed I would make an impact in the world.

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TABLE OF CONTENTS

POLICY BRIEF

I. INTRODUCTION

A. *Background on Prescription Drug Abuse*

Epidemic. Epidemic is a word that most people associate with contagions like influenza or smallpox. Yet, the word is now associated with prescription drug abuse.[1] Prescription drug abuse has been creeping towards epidemic status in the United States over the last decade. In 2012, when prescription drug overdoses surpassed motor vehicle crashes as the leading cause of accidental death in the United States, the matter reached epidemic status.[2]

One factor that adds to the prevalence of this epidemic is the wide spectrum of communities and age groups it affects. Roughly 42% of the individuals who report a lifetime of non-medical use of prescription drugs began at the age of 13 years or younger.[3] From 2005 to 2011, Substance Abuse and Mental Health Services Administration (SAMHSA) observed prescription drug abuse in individuals of ages twelve years and older across various geographic regions. In metropolitan areas, 6.4% of the surveyed individuals admitted to misusing prescription drugs in the past year, and in urbanized non-metropolitan areas, the number was slightly higher with 6.6% of the surveyed individuals

1 EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES (2010). Available at http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf [hereinafter "EXECUTIVE REPORT"].

2 Michele M. Straus, Udi E. Ghitza & Betty Tai, *Preventing Deaths from Rising Opioid Overdose in the US - The Promise of Naloxone Antidote in Community-based Naloxone Take-home Programs*, SUBST. ABUSE REHABIL. (2013).

3 Sean E. McCabe et al., *Does Early Onset of Non-medical Use of Prescription Drugs Predict Subsequent Prescription Drug Abuse and Dependence?,* 102 ADDICT. ABINGDON ENGL. 1920, 1923 (2007).

misusing prescription drugs in the past year.[4] Even in rural areas where the numbers were believed to be lower, the numbers still reached 5.4%.[5]

With the spectrum of communities affected by prescription drug abuse, emergency departments are witnessing an increase in prescription drug overdose cases. From 2004 to 2010, emergency departments witnessed a 115% spike in emergency room visits for prescription drug overdose.[6] The spike in overdoses can be tied to the high number of people, 15.7 million, who have admitted to using prescription drugs for non-medical purposes in the past year.[7] Correspondingly, prescription drugs have been dubbed the second most abused substance behind marijuana.[8]

In addition to the detriment to individuals' health and wellbeing, this abuse and misuse has led to heavy financial drains for the United States. Prescription drug abusers create a societal burden, costing the nation nine times more than non-users [9]. In particular, abusers generate $53 to $73 billion worth of unnecessary costs affiliated with the criminal justice and health care systems.[10] Fraudulent and abusive purchases of controlled substances have burned a $63 million hole in the collective pockets of Medicaid programs across California, Illinois, New York, North Carolina and Texas.[11]

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4 Substance Abuse and Mental Health Services Administration, *NSDUH SERIES H-38A, HHS PUBLICATION NO. SMA 10-4586FINDINGS, 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings* (2009), available at http://www.samhsa.gov/data/2k9/2k9Resultsweb/web/2k9results.pdf.

5 *Id.*

6 *Id.*

7 *Id.*

8 *Id.*

9 Amy Zosel et al., *Characterization of adolescent prescription drug abuse and misuse using the Researched Abuse Diversion and Addiction-related Surveillance (RADARS(®))*, 52 SYSTEM, J. AM. ACAD. OF CHILD AND ADOLESCENT PSYCHIATRY 196, 203 (2013).

10 Andrew W. Roberts & Asheley C. Skinner, *Assessing the Present State and Potential of Medicaid Controlled Substance Lock-in Programs*, 20 J. MANAG. CARE PHARM. JMCP 439, 439 (2014).

11 U.S. Gov't Accountability Office, GAO—09-1004T, MEDICAID: FRAUD AND ABUSE RELATED TO CONTROLLED SUBSTANCES IDENTIFIED IN SELECT STATES (2009).

While the effects of the abuse are evident, many still question the source of the problem. One source of the problem is liberal prescribing practices, which are often associated with pain management clinics.[12] Some pharmacists are receiving "outlandish quantities" for prescriptions, ranging from 240 pills to 540 pills.[13]Another source of the problem is drug-seeking behavior. The Centers for Disease Control and Prevention estimates that 80% of controlled substances actually originate from a legitimate source, legal prescriptions.[14] Legal prescriptions frequently end up in the wrong hands, with over 70% of prescription drug abusers obtaining their drugs from friends or family.[15] Given the nature of the growing epidemic of prescription drug abuse, the United States needs a comprehensive solution.

B. *Part of the Solution: Prescription Drug Monitoring Programs*

One part of the solution to this epidemic is prescription drug monitoring programs (PDMPs). PDMPs are state-run programs with the primary purpose of providing prescribers and dispensers with real-time data to identify and reduce prescription drug abuse and/or diversion among patients. Dispensers are tasked with the duty to populate and update their respective state databases with patient prescription information every time a patient refills a prescription for a controlled substance. The result is an aggregated drug history of controlled substances on each patient. This information is accessible to

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12 Khary K. Rigg, Samantha J. March & James A. Inciardi, *Prescription Drug Abuse & Diversion: Role of the Pain Clinic*, 40 J. DRUG ISSUES 681–702 (2010).

13 Stephen Barlas, *DEA Proposal on Hydrocodone Combination Products Divides Pharmacists: The Impacts on Pharmacy Workload and Prescription Drug Abuse Are at Issue*, 39 P T PEER-REV. J. FORMUL. MANAG. 311 (2014).

14 Roberts & Skinner, *supra* note 10 at 439.

15 Substance Abuse and Mental Health Services Administration, *The NSDUH Report: Nonmedical Use of Prescription-Type Drugs, by County Type* (2013), http://www.samhsa.gov/data/2k13/NSDUH098/sr098-UrbanRuralRxMisuse.htm.

prescribing and dispensing practitioners, as well as other stakeholders through the respective state-run database.

PDMPs are an effective tool for identifying and reducing drug abuse and diversion. Prescribers and dispensers often battle fraudulent medical documents and persuasive performances put on by drug seekers and have no method to verify the patients' motives. With a PDMP database, however, they not only accurately capture patients' prescription history 90.4% of the time,[16] but also provide prescribers and dispensers a tool to check a patient's drug history for patterns of misuse or abuse before administering prescriptions for highly addictive and/or abused substances.[17] Researchers have found a correlation between PDMPs and allowed prescribers to reduce fraudulent prescription drug-seeking behavior, as well as reduce the non-medical use of opioids.[18] Thus, merely consulting the database before prescribing and/or dispensing can address a lot of the concerns surrounding prescribing controlled substances.

Unfortunately, while forty-nine states have authorized or are the process of authorizing PDMPs, states are failing to maximize the intended benefit of the programs. First, many prescribers do not independently access the databases prior to prescribing nor are they required to do so in many states. As a result, there is no accountability or motivation to act, creating low utilization, which undercuts the purpose of the program. Second, there is not enough communication among states and users. Since PDMPs are

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16 Elle M. Sowa et al., *Prevalence of Substance Misuse in New Patients in an Outpatient Psychiatry Clinic Using a Prescription Monitoring Program*, 16 PRIM. CARE COMPANION CNS DISORD. e1, e5 (2014). The study confirmed the accuracy of the databases' data through interviews and interactions with the patients.

17 This particularly useful considering that serious prescription drug abusers admit to falsifying MRI documents and faking symptoms commonly associated with prescribing. Rigg, et al., *supra* note 12. Symptoms commonly associated with prescribing controlled substances often include back pain, headaches and sleeping problems. *Id.* At times, abusers even go as far as using props to "play up" the ailments in efforts to obtain prescription drugs. *Id.*

18 Roberts & Skinner, *supra* note 10.

state-run, each program's structure varies. Accordingly, there is no uniformity between states, which makes sharing information difficult. Furthermore, many states do not provide for information sharing in their statutes, which hinders practitioners' ability to detect and reduce drug abuse and diversion with out-of-state patients.

Consequently, the Office of the President of the United States proposed a call to action in its 2011 publication entitled, "Epidemic: Responding to America's Prescription Drug Abuse Crisis". [19] The call to action articulated four action areas, with the need for enhanced function and increased utilization of prescription drug monitoring programs as the third area.[20] To maximize the benefit of PDMPs, legislators need to understand the existing policies, as well as what policies the research supports. As demonstrated, more policy reviews need to be conducted to provide recommendations on how to achieve these goals of enhancing function and increasing utilization. Currently, few of PDMPs investigate what statutory components can enhance and increase utilization of PDMPs while also ensuring good legislative drafting. In response to this need, this study aims to provide guidance on how states should draft legislation or amend PDMP statutes to maximize the use and function of PDMPs while ensuring clarity, consistency, accuracy and efficacy.

II. PURPOSE

The purpose of this study is to assess the landscape of PDMP policies across the United States, looking at topical components in existing state PDMP statutes, and to provide useful recommendations to enhance the function and increase utilization of PDMPs.

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19 EXECUTIVE REPORT, *supra* note 1.

20 The first area addresses educating the public and providers and dispensers on nonmedical use of prescription drugs. The second area addresses access to proper disposal of prescription drugs. The third area addresses the need for enhancement and increased utilization of prescription monitoring programs, otherwise known as prescription drug monitoring programs, and the fourth area addresses strict enforcement of illegal prescriptions.

Specifically, the study intends to: (1) describe the concern surrounding prescription drug abuse in the United States; (2) identify policies addressing prescription drug abuse through PDMP state statutes; (3) analyze the major components found in PDMP state statutes; (4) provide statutory examples for the major components; and (5) propose recommendations for drafting major components that have the potential to enhance and/or increase utilization of PDMPs while instilling good legislative drafting essentials.

III. METHODS

A. *Approaching the Background*

This policy brief provides a comprehensive foundation for the context surrounding prescription drug abuse. Accordingly, a PubMed search with the string, "Prescription Drug Abuse" was conducted, resulting in 285 total articles. This was artificially limited with the filters, "free full text", and a date range of January 01, 2004 to July 01, 2014 to accommodate financial constraints and the project deadline. These filters reduced the findings to 63 results. Of those results, the study only used articles from peer-reviewed journals and information pertinent to the scope of this study, focusing on the effects in the United States. The only non-peer reviewed information used in this portion is information pulled from government sources with a targeted Google search.

A similar approach was taken to provide public health information on PDMPs. The study includes a PubMed search using PDPM terms adopted by state statutes to conduct a search in PubMed. Specifically, the string search used the terms, "'Prescription Drug Monitoring Program' or 'Controlled Substances Prescription Database' or 'Prescription Monitoring Program.'" The search provided 88 results. The same filters, "free full text" and

a date range of January 01, 2004 to July 01, 2014 were applied to produce 82 results. Again, the investigator only used pertinent information pulled from peer-reviewed journals.

B. *Approaching the Policies*

In regards to identifying the state policies addressing PDMPs, the study incorporates a comprehensive search using the legal database, Westlaw Next. The searches used terms commonly associated with PDMPs, which was based on media coverage and the purpose of PDMPs. First, the search employed the terms, "'prescription drug monitoring program'", "'prescription drug' or 'controlled substance' and 'monitoring program'", "prescription and database or monitor", "monitor! and prescription or substance"; "'prescription monitor!' and substance or database", "'prescription drug' and monitor! and program or database % investigat! % schedule". The search was then applied to all states, and filtered the results by "statutes."

Next, each statute was reviewed by the title of the act, as well as the content, to determine applicability to the study. If the statute related to PDMPs, it was included in the study. The inclusion criteria focused on statutes:

- Addressing prescription drug monitoring through a database or organized program that allows prescribers and dispensers to access information prior to prescribing and dispensing,
- Including an agency that oversees the database,
- Requiring reporting,
- Gathering information on patients, and
- Dictating which individuals have access to the database information.

Statutes covering the broader maintenance of scheduled controlled substance—e.g. writing prescriptions or education of abuse, etc.—were considered outside the scope of this study. Nonetheless, the investigator included relevant controlled substance statutes if they

pertained to the implementation of a database such as authority, relevant committee, and requirements.

Statutes are typically organized topically and often cross-reference other statutes. Correspondingly, the table of contents of the associated chapter or title was reviewed for relevancy by heading and/or content. Similarly, if a statute from the search list cross-referenced another statute, the cross-referenced statute was reviewed for relevancy.

Finally, the list of statutes compiled from Westlaw Next was compared with other, existing publications surveying PDMPs statutes. Any outstanding statutes that were not originally detected or included in the search results were reviewed for relevancy using the inclusion criteria from the study's initial Westlaw Next search. Since not all statutes relating to PDMP include key terminology, the investigator discovered approximately 64 additional statutes relating to PDMPs.

C. *Approaching the Analysis*

The scope of this study's analysis is limited to state statutes authorizing PDMPs. Thus, it does not take into consideration existing PDMP regulations, nor does it take into account rules implemented by various professional health boards that may alter or affect the program or the stakeholders' obligations or privileges. Instead, the discussion focuses on the components of the PDMP statutes.

"Major components" as used in this study are derived from examining common topical patterns among PDMP statutes. In determining which components should be considered major, the study reviewed the general organizational structure of all the available PDMP statutes. Existing publications surveying PDMP statutes were consulted to verify major components.

The analysis and recommendations from this study are based on three parts. The first part draws from the investigator's experience and training in law and public health.[21] The second part is based on the recommendations are supported by information pulled from the literature review on legislative drafting and the data from public health studies from peer-reviewed journals. The final part of the recommendations is based on consultations with a legislative expert.[22] The recommendations serve as general proposals. They should not be taken as legal advice. Drafters and policymakers would benefit from further research on the efficacy of the recommendations in conjunction with the other three action areas outlined by the Office of the President of the United States' four-part proposal.

III. MAJOR COMPONENTS IN PDMP STATE LEGISLATION

States vary in how they implement their PDMPs, but their statutes share common major components. Each component serves a different purpose in supporting the implementation and operation of the state PDMP. This study provides illustrations of the different approaches states have taken with various components. Where relevant, the study points to key considerations for selecting an approach. The major substantive components addressed in this study are:

A. Defining Major Terms
B. Delegating Authority
C. Advisory Committee to Help Establish, Maintain and Operate the PDMP

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21 The investigator has three years of legal training from an ABA accredited law school and five years of part-time experience in the legal field. During her legal studies, she has taken two courses with components addressing legislative drafting. She has also had the opportunity to draft—in part—a senate bill for Georgia's 2013 legislative session. The investigator also draws upon her experience in policy development from her term with the CDC's Public Health Law Program, as well as from her training as a public health student with a concentration in health management and policy.

22 Professor Sylvia Caley is a law professor at GSU College of Law, specializing in health law and policy, as well as public policy. She has a degree in nursing, business, and law. She has background working with advocacy groups, and has worked as a legislative monitor at the Georgia State Capitol for over 25 years.

D. Creating Accountability through the Department's Duty to Review & Report
E. Mandatory Reporting
F. Reportable Data Elements
G. Users with Access to Database Information
H. Duty to Consult the Database
I. Legal Protections
J. Enforcement
K. Funding
L. Interstate Sharing

A. *Defining Major Terms*

There is not a uniform term used to label PDMPs, so states have varied in what they call their programs. Some states have referred to PDMPs as "Prescription Drug Monitoring Program", "Controlled Substance Database," "Prescription Monitoring System," or "Prescription Monitoring Program," while others have called the programs, "Prescription Tracking Program" or "Electronic Prescription Drug Monitoring Program." Nonetheless, the overarching concept behind the program remains, more or less, the same.

Similarly, PDMP statutes have varied in the major terms they use. Even when they have used the same term, they may differ in definition. For example, Connecticut defines a dispenser simply as "a practitioner that dispenses."[23] Meanwhile, the District of Columbia defines a dispenser as:

> "(8) 'Dispenser' means a practitioner who dispenses a covered substance to the ultimate user, or his or her agent, but shall not include:
>
> > (A) A licensed hospital or institutional facility pharmacy that distributes covered substances for the purpose of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility;
> >
> > (B) A practitioner or other authorized person who administers a covered substance;
> >
> > (C) A wholesale distributor of a covered substance; or

[23] Conn. Gen. Stat. Ann. § 21a-254(j)(3) (West, Westlaw through 2014).

> (D) A clinical researcher providing a covered substance to research subjects as part of a research study approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protections programs."[24]

When a major term is ambiguous or vague, providing the possibility for multiple interpretations as in the case with the term "dispenser," states frequently include a separate statute—called the interpretation statute—or a paragraph to define these terms.[25] This definition section may address the broader chapter, or it may be specific to and self-contained within PDMP statutes. If the meaning of a major term is plain, providing only one interpretation, however, then there is little need to look outside of the text to further define it. In the end, the terms used in a PDMP statute are to ensure clarity, in general, and uniformity among existing laws.

Recommendation A.1: *The PDMP statutes should include a definition section, describing ambiguous and vague terms that may differ from one context to another. The PDMP statutory language should use existing terms and similar language structure as used in the rest of the chapter code to ensure cohesion and uniformity among the laws within a state.*

B. *Delegating Authority*

i. Guiding the Governmental Body in its Powers and Duties

States have charged a range of administrative agencies and departments with oversight and implementation responsibilities. To do this, states have delegated authority to select governmental bodies by bestowing powers such as rulemaking abilities, as well as duties on them. Many states like Iowa have delegated the task to the Board of Pharmacy since its board already manages substance control and the scheduling of prescription

[24] D.C. Code § 48-853.01(8) (West, Westlaw through 2014).

[25] This is particularly important when which rights and responsibilities might affect addressing which individuals. The definition section, then, should include and define the individuals, as well as the rights and responsibilities.

drugs.[26] Other states have looked towards larger departments like the Department of Health[27] or Department of Public Health[28] or Safety[29] to take the lead.

All of the state that have adopted PMDPs have included language to promulgate regulations to properly delegate authority and bestow all the necessary powers. In delegating authority, states have primarily selected one of two approaches. With the first approach, the legislature expressly delegates authority to promulgate regulations in the statute. Meanwhile, the second approach legislature expressly delegates authority to promulgate regulations in the statute and provides specific regulatory topics to guide the administrator's rulemaking process.

Under these two approaches, the statute confers discretion to the governmental body and the regulatory process. The governmental body does not need to wait for the legislative session to change the laws, which allows for flexibility and efficiency. Flexibility is crucial when dealing with swiftly evolving matters reliant on scientific advances or social trends such as prescription drug abuse.

The two approaches differ, however, in the level of guidance provided. Under the first approach, a statute will use broad language to confer this discretion, providing minimal guidance but more discretion. Georgia's statute, for instance, says, "The agency shall establish rules and regulations to implement the requirements of this part."[30] ***Forty-***

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26 Iowa Code Ann. § 124.551 (West, Westlaw through 2014); Iowa Code Ann. § 124.101 (West, Westlaw through 2014).
27 *See, e.g.* Me. Rev. Stat. Ann. tit. 22 § 1-A(2) (West, Westlaw through 2014).
28 *See, e.g.* Mass. Gen. Laws Ann. Ch. 94C § 24A (West, Westlaw through 2014).
29 N.J. Stat. Ann. § 45:1-45 (West, Westlaw through 2014).
30 Ga. Code Ann. § 16-13-62 (West, Westlaw through 2014).

two states have adopted this method.[31] Under the second approach, a statute will take it one step further and prescribe regulatory topics. To illustrate, Indiana's PDMP statute says:

> "The board shall adopt rules . . . to implement this chapter, including the following:
>
> > (1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.
> >
> > (2) Design for the creation of the data base required under section 10.1 of this chapter.
> >
> > (3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.
> >
> > (4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.
> >
> > (5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program . . . ."[32]

thirty-two states have elected to follow the second approach.[33] By prescribing regulatory topics but using terms like "includes," the language allows for flexibility while drawing the administrators' attention to expected duties.[34]

Regardless of the approach adopted in conferring discretion to the governmental body, the goal should be to craft a clear and specific delegation of authority. It should explain precisely what powers are being granted, eliminating any ambiguity. This is

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31 *See* Table 1.

32 Ind. Code Ann.§ 35-48-7-12.1 (West, Westlaw through 2014).

33 *See* Table 1.

34 Lawrence E. Filson, LEGISLATIVE DRAFTER'S DESK REFERENCE 264 (1992). Normally, the terms "including" or "including, but not limited to," are misused. Drafters often use it when the language before it already captures the groupings following it, thereby making it unnecessary. It may be used, however, for purpose of drawing attention to certain concepts that may—intentionally or unintentionally—overlooked by the administrator.

especially true if the statute gives the governmental body the power to make substantive rules rather than just procedural rules.[35]

Recommendation B.1: *Before including an authority component, the first step should be to check if the enabling act, the act that creates the governmental body, already delegates the power to issue rules and regulations to avoid redundancy.[36] If one does not exist, language promulgating specific regulatory topics is preferable. The regulatory topics should include establishing and maintaining a process for reporting, as well as establishing and enforcing policies and procedures to guarantee the privacy and confidentiality of patients*

.

WHERE PDMP LAWS DERIVES AUTHORITY	NUMBER OF STATES
# States that Promulgate Regulations	42[37]
# States of those that Promulgate, and also Prescribe Specific Topics	32[38]

Table 1.

ii. Ability to Contract with External Entities

In carrying out its duty to implement a PDMP, the governmental body may need to consult external resources for expertise. Consequently, ***twenty-nine*** states include a provision that allows the governmental body to contract with outside entities to support the goals of the PDMP and increase efficacy.[39] For example, Kansas' statute permits, "[t]he

35 A substantive rule differs from a procedural rule. A substantive rule affects individuals' legal obligations, duties, and rights—i.e. a rule that sets out an obligation to check the database before prescribing controlled substances. A procedural rule is concerned with the mechanics of how to carry out the law—i.e. check the database for every new patient.

36 The enabling act is the act that breathes life into a particular agency and dictates the scope of the agency's powers and duties.

37 AL, AK, AZ, CA, CO, CT, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OR, RI, SC, SD, TN, TX, VT, VA, WA, WV, WI, WY. *See* Appendix B (listing out specific state statutes).

38 AL, AK, AZ, CA, CO, CT, DC, DE, FL, ID, IL, IN, IA, KS, MA, MD, MI, MT, NC, ND, NH, NY, OH, OR, SD, TN, TX, UT, VA, VT, WI, WV. *See* Appendix B (listing out specific state statutes).

39 Ala. Code § 20-2-212(3) (West, Westlaw through 2014); Alaska Stat. Ann. § 17.30.200(f) (West, Westlaw through 2014); Ariz. Rev. Stat. Ann. § 36-2602(B) (West, Westlaw through 2014); Ark. Code Ann. § 20-7-609 (West, Westlaw through 2014); Colo. Rev. Stat. Ann. § 12-42.5-403(4) (West, Westlaw through 2014); Del. Code Ann. tit. 16, § 4798(m) (West, Westlaw through 2014); D.C. Code § 48-853.02(b) (West, Westlaw through 2014); Ind. Code Ann. § 35-48-7-10.1(b) (West, Westlaw through 2014); Kan. Stat. Ann. § 65-1686

board . . . to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program."[40] If the PDMP statutes provide for the ability to contract, the component should include language that subjects those contractors to the same confidentiality and user liability standards to which PDMP permitted users are subject. Louisiana's statute does this by stating, "Any contractor shall be bound to comply with provisions regarding confidentiality of prescription information in R.S. 40:1007 and further shall be subject to the penalties specified in R.S. 40:1009 for unlawful acts."[41] This language holds contractors accountable for their actions while creating an environment that protects their actions if performed in good faith.

Recommendation B.2: *PDMPs can maximize the use of external resources by including a component that authorizes the government body to contract with third parties. This component should hold contractors up to the same legal standards as employees or any other users of the PDMP.*

(West, Westlaw through 2014); La. Rev. Stat. Ann. § 40:1012; 40:1004(b) (West, Westlaw through 2014); Me. Rev. Stat. Ann. tit. 22 § 7248(2) (West, Westlaw through 2014); Md. Ann. Code Health-Gen. § 21-2A-03(b)(2) (West, Westlaw through 2014); Mass. Gen. Laws Ann. ch. 94C, § 24A(i) (West, Westlaw through 2014); Mich. Comp. Laws Ann. § 333.733a(8) (West, Westlaw through 2014); Minn. Stat. Ann. § 152.126(2)(b) (West, Westlaw through 2014); Miss. Code Ann. § 152.126 (West, Westlaw through 2014); Mont. Code Ann. § 37-7-1509 (West, Westlaw through 2014); Nev. Rev. Stat. Ann. § 453.154(3) West, Westlaw through 2014); N.J. Stat. Ann. § 45:1-50 (West, Westlaw through 2014); N.D. Cent. Code Ann. § 19-03.5-04 (West, Westlaw through 2014); Okla. Stat. Ann. tit. 63 § 2-309F(B); (West, Westlaw through 2014); Or. Rev. Stat. Ann. § 431.962(1)(c) (West, Westlaw through 2014); S.C. Code Ann. § 44-53-1660 (West, Westlaw through 2014);; S.D. Codified Laws § 34-20E-10 (West, Westlaw through 2014); Tex. Health & Safety Code Ann. § 481.0761(f) (West, Westlaw through 2014); Utah Code Ann. § 58-37f-201(3); Va. Code Ann. § 54.1-2520(C) (West, Westlaw through 2014); Wash. Rev. Code Ann. § 700.225.050 (West, Westlaw through 2014).

40 Kan. Stat. Ann. § 65-1686 (West, Westlaw through 2014).

41 La. Rev. Stat. Ann. § 40:1012 (West, Westlaw through 2014).

C. *Advisory Committee to Help Establish, Maintain and Operate the PDMP*

Twenty-four states that have implemented PDMP laws have also elected to appoint an advisory committee to establish, maintain and operate the database program.[42] A PDMP advisory committee is usually comprised of representative experts and/or stakeholders from various health care professional licensure boards. It ensures the involvement, as well as the investment, of a diverse group of stakeholders. As a result, any recommendations set forth by the committee will more likely account for the burdens and motivations of all users involved. In turn, the laws can use those perspectives to create a more effective program.

Statutes addressing advisory committees may be broadly written to allow departments to select its members. Illinois' advisory committee component, for example, states, "The Secretary of the Department of Human Services must appoint an advisory committee to assist the Department in implementing the controlled substance prescription monitoring program . . . . The Advisory Committee consists of prescribers and dispensers."[43] Correspondingly, the Secretary is left to select how many members should be on the committee and who specifically should be on the committee.

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42 Ala. Code § 20-2-212(4) (West, Westlaw through 2014); Ariz. Rev. Stat. Ann. § 36-2603(A) (West, Westlaw through 2014); Ark. Code Ann.§ 20-7-605(a) (West, Westlaw through 2014); Colo. Rev. Stat. Ann. § 12-42.5-408.5 (West, Westlaw through 2014); Conn. Gen. Stat. Ann. § 21a-254a (West, Westlaw through 2014); D.C. Code § 48-853.02(c) (West, Westlaw through 2014); Fla. Stat. Ann.§ 893.055(11) (West, Westlaw through 2014); Ga. Code Ann. § 16-13-61(a) (West, Westlaw through 2014); 720 Ill. Comp. Stat. Ann. 570/320 (West, Westlaw through 2014); Iowa Code Ann.§ 124.555 (West, Westlaw through 2014); Kan. Stat. Ann. § 65-1689 (West, Westlaw through 2014); La. Rev. Stat. Ann. § 40:1005 (West, Westlaw through 2014); Md. Ann. Code Health-Gen. § 21-2A-05(a) (West, Westlaw through 2014); Mich. Comp. Laws Ann. § 333.7113 (West, Westlaw through 2014); Minn. Stat. Ann. § 152.126(3) (West, Westlaw through 2014); Mont. Code Ann. § 37-7-1510 (West, Westlaw through 2014); N.H. Rev. Stat. Ann. 318-B:38 (West, Westlaw through 2014); N.D. Cent. CodeAnn. § 19-03.5-07(West, Westlaw through 2014); Or. Rev. Stat. Ann. § 431.976 (West, Westlaw through 2014); S.D. Codified Laws § 34-20E-15 (West, Westlaw through 2014); Tenn. Code Ann. § 53-10-303 (West, Westlaw through 2014); Tex. Health & Safety Code Ann. § 481.351 (West, Westlaw through 2014); Va. Code Ann. § 54.1-2520(E) (West, Westlaw through 2014); W. Va. Code Ann. § 60A-9-5(a)(3) (West, Westlaw through 2014).

43 720 Ill. Comp. Stat. Ann. 570/320 (West, Westlaw through 2014).

Another option is to outline the advisory committee's membership, detailing which licensure boards must participate in the committee through a representative. Maryland takes this approach. Its statute requires:

> "(b) The Board shall consist of the following members:
> (1) The Secretary, or the Secretary's designee;
> (2) The President of the Maryland Board of Pharmacy, or the President's designee;
> (3) The Chair of the Maryland Board of Physicians, or the Chair's designee;
> (4) The President of the Maryland Board of Nursing, or the President's designee;
> (5) The Chairman of the Maryland Health Care Commission, or the Chairman's designee;
> (6) Four physicians and one nurse practitioner with expertise in clinical treatment using controlled dangerous substances, including pain management, substance abuse, and behavioral disorders, appointed by the Secretary after consultation with:
>
> (i) For the physician appointments, the Medical and Chirurgical Faculty of Maryland, the Maryland Physical Medicine and Rehabilitation Society, the Maryland Society of Anesthesiologists, the Maryland-D.C. Society of Clinical Oncology, the Hospice and Palliative Care Network of Maryland, and the Maryland Chapter of the American Academy of Pediatrics; and
>
> (ii) For the nurse practitioner appointment, the Maryland Nurses Association;
>
> (7) One pediatrician, appointed by the Secretary after consultation with the Maryland Chapter of the American Academy of Pediatrics;
> (8) Three pharmacists who represent the perspective of independent and chain pharmacies, appointed by the Secretary after consultation with the Maryland Pharmacists Association, the Maryland Association of Chain Drug Stores, and any other appropriate organization;
> (9) A local law enforcement official, appointed by the Secretary after consultation with the Maryland Chiefs of Police Association and the Maryland Sheriff's Association; and
> (10) Two Maryland residents who represent the perspective of patients, appointed by the Secretary."[44]

[44] Md. Ann. Code Health-Gen. § 21-2A-05(b) (West, Westlaw through 2014).

Recommendation C.1: *PDMP statutes should include an advisory committee component that outlines the membership of a diverse group of PDMP stakeholders.*

D. *Creating Accountability and Communication through the Department's Duty to Review & Report*

To establish accountability and better communication, a number of states have placed an affirmative duty on the governmental body or advisory committee to review PDMP data and to report on their findings. Review of the PDMP data comes in two forms. The first involves the review of specific patient information and practitioners' prescribing behavior. The second involves the evaluation of the program as a whole.

Under the first method, the governmental body or advisory committee inspect the PDMP data for indicators of illegal conduct and to report any suspect findings to a higher authority or prescriber. Currently, ***twenty-one*** states adopt this approach.[45] The illegal conduct may be high prescription abuse or diversion among patients, as well as prohibited acts conducted by prescribers, dispensers and others users with access to the database information. For illustration, Arizona's statute says:

> **"B.** The board or its designee shall review the prescription information collected pursuant to this article. If the board or its designee has reason to believe an act of

[45] Ariz. Rev. Stat. Ann. § 36-2604(B) (West, Westlaw through 2014); Fla. Stat. Ann.§ 893.055(8) (West, Westlaw through 2014); Ind. Code Ann. § 35-48-7-16(a)(2) (West, Westlaw through 2014); (West, Westlaw through 2014); Ky. Rev. Stat. Ann. § 218A.240(7)(a) (West, Westlaw through 2014); La. Rev. Stat. Ann. § 40:1008(C); (West, Westlaw through 2014); (West, Westlaw through 2014); (West, Westlaw through 2014); (West, Westlaw through 2014); Me. Rev. Stat. Ann. tit. 22 § 7250(2) (West, Westlaw through 2014); Md. Ann. Code Health-Gen. § 21-2A-04(b)(7) (West, Westlaw through 2014); Mass. Gen. Laws Ann. ch. 94C, § 24A(e) West, Westlaw through 2014); Mich. Comp. Laws Ann. § 333.7113(1) (West, Westlaw through 2014); Minn. Stat. Ann. § 152.126(6)(i) (West, Westlaw through 2014); Miss. Code Ann. § 73-21-127(c) (West, Westlaw through 2014); Nev. Rev. Stat. Ann. § 453.154(2) (West, Westlaw through 2014); N.H. Rev. Stat. Ann. 318-B:35(III) (West, Westlaw through 2014); N.Y. Pub. Health Law § 3343-a(7) (West, Westlaw through 2014); N.D. Cent. Code Ann. § 19-03.5-06 (West, Westlaw through 2014); Ohio Rev. Code Ann. §4729.81 (West, Westlaw through 2014); (West, Westlaw through 2014); S.D. Codified Laws § 34-20E-12 (West, Westlaw through 2014); Tenn. Code Ann. § 53-10-309 (West, Westlaw through 2014); Va. Code Ann. § 54.1-2523.1 (West,Westlaw through 2014); W. Va. Code Ann. § 60A-9-5(a)(2) (West, Westlaw through 2014); Wyo. Stat. Ann. § 35-7-1060(c)(ii) (West, Westlaw through 2014).

> unprofessional or illegal conduct has occurred, the board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation."[46]

Adding an affirmative duty to inspect the database information for illegal behavior is strongly recommended because research shows that it can have beneficial effects on physicians' prescribing behavior. In particular, it can reduce the quantity of controlled drugs physicians prescribe. In the Gershman, Gershman, Fass, and Popovici study, 93.6% of the surveyed physicians accessing the PDMPs noticed they were prescribing fewer controlled drugs after referring to the database or reducing the quantity.[47] Physicians attributed their changed prescribing behavior to the belief that their conduct is being more closely monitored; this finding is consistent with other studies.[48] Thus, a provision requiring the governmental body or advisory committee to review the information can contribute to accountability and, in response, thoughtful habits.

Under the second method for creating accountability, the department reviews the PDMP information to assess the program's efficacy as a whole. The goal, here, is to determine whether the program is achieving its intended goal. Further, the governmental body will relay its assessment to a higher authority and make recommendations. This method promotes continual communication, which allows for adjustments and encourages data analysis. It also efficiently delegates responsibilities and utilizes expertise.[49] For instance, Colorado's statute offers:

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46 Ariz. Rev. Stat. Ann. § 36-2604(B) (West, Westlaw through 2014).

47 Jennifer A. Gershman et al., *Evaluation of Florida Physicians' Knowledge and Attitudes Toward Accessing the State Prescription Drug Monitoring Program as a Prescribing Tool*, PAIN MED. MALDEN MASS 5 (2014).

48 Lance Feldman et al., *Awareness and Utilization of a Prescription Monitoring Program Among Physicians*, 25 J. PAIN PALLIAT. CARE PHARMACOTHER. 313, 316 (2011).

49 Often, administrators are already subject to periodic reporting of its functions and findings. Thus, the states should check relevant statutes to see if reporting duties already exist.

> "(1) The executive director of the department of regulatory agencies shall create a prescription drug monitoring program task force or consult with and request assistance from the Colorado team assembled by the governor's office to develop a strategic plan to reduce prescription drug abuse, or its successor group, in order to:
>
> > (a) Examine issues, opportunities, and weaknesses of the program, including how personal information is secured in the program and whether inclusion of personal identifying information in the program and access to that information is necessary; and
> >
> > (b) Make recommendations to the executive director on ways to make the program a more effective tool for practitioners and pharmacists in order to reduce prescription drug abuse in this state.
>
> (2) If the executive director convenes a task force or obtains assistance from the Colorado team, the applicable group shall submit annual reports to the executive director and the general assembly detailing its findings and recommendations. Notwithstanding section 24-1-136(11), C.R.S., the requirement in this section to report to the general assembly continues indefinitely."[50]

Recommendation D.1: *Either the advisory committee or governmental body should be tasked with the affirmative duty to inspect the database information for illegal behavior. The same entity should also have the duty to review the PDMP information to evaluate the effectiveness of the program as a whole, and make recommendations to the state legislature.*

E. *Mandatory Reporting*

i. Professional Groups Subject to Mandatory Reporting

All states that have a PDMP list out the professional groups who are subject to mandatory reporting. These groups are responsible for populating the database with the prescription information associated with each patient's initial prescription or subsequent refill. Pharmacists are usually the main professional group subject to reporting. Some states, however, extend the reporting obligation to include prescribing physicians and hospital facilities.

[50] Colo. Rev. Stat. Ann. § 12-42.5-408.5 (West, Westlaw through 2014).

Like with many other components, states have differed in the degree of detail when addressing the professional groups subject to mandatory reporting. Some states have elected to list out specific dispensers like dentists, veterinarians, prescribing physicians and/or pharmacists.

To provide an illustration of a list of specific dispensers, Alabama's statute provides:

> "(b) The following entities or practitioners are subject to the reporting requirements of subsection (a):
>
> (1) Licensed pharmacies, not including pharmacies of general and specialized hospitals, nursing homes, and any other healthcare facilities which provide inpatient care, so long as the controlled substance is administered and used by a patient on the premises of the facility.
>
> (2) Mail order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing controlled substances to residents of this state.
>
> (3) Licensed physicians, dentists, podiatrists, optometrists, or veterinarians who dispense Class II, Class III, Class IV, and Class V controlled substances directly to patients, or in the case of veterinarians, for administration to animals, but excluding sample medications. For the purposes of this article, sample medications are defined as those drugs labeled as a sample, not for resale under the laws and regulations of the Federal Food and Drug Administration. Controlled substances administered to patients by injection, topical application, suppository administration, or oral administration during the course of treatment are excluded from the reporting requirement."[51]

Meanwhile, other states chose to adopt broad terms like "dispenser". Broad terms by their very nature extend to include all the potential dispensers, and promote legislative efficiency in the amendment process. Legislators can consult and amend just one statute, the interpretive definition statute, rather than all the statutes corresponding to the different health professional groups.

Georgia's statute provides an example of states that use the broad term "dispenser" to capture the spectrum of professionals subject to reporting. Georgia's reporting

[51] Ala. Code §§ 20-2-213(b)(3) (West, Westlaw through 2014).

component requires that "each dispenser shall submit to the agency by electronic means information regarding each prescription dispensed for a Schedule II, III, IV, or V controlled substance."[52] States that elect to use a broad term like dispenser also define the term in the PDMP definition section or in the greater chapter, which ensures comprehension and clarity. To illustration, Georgia defines "dispenser" in the following manner:

> "(10) 'Dispenser' means a person licensed under the laws of this state, or any other state or territory of the United States to dispense or deliver a Schedule II, III, IV, or V controlled substance to the ultimate user in this state but shall not include:
>
> (A) A pharmacy licensed as a hospital pharmacy by the Georgia State Board of Pharmacy pursuant to Code Section 26-4-110;
>
> (B) An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides patient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility;
>
> I A practitioner or other authorized person who administers such a substance; or
>
> (D) A pharmacy operated by, on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution. This shall include correctional institutions operated by private entities in this state which house inmates under the Department of Corrections."[53]

When using broader terminology, the term should logically extend to these dispensing health professionals based on the common dictionary definition. Alternatively, the section defining terms should define the broad terms to include these individuals. For example, Georgia's component addressing mandatory reporting uses "practitioner" to define "dispenser" in part, and defines "practitioner" in the greater chapter as follows:

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52 Ga. Code Ann. § 16-13-59(a) (West, Westlaw through 2014).
53 Ga. Code Ann. § 16-13-21(10) (West, Westlaw through 2014).

(23) "Practitioner" means:

(A) A physician, dentist, pharmacist, podiatrist, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise authorized by law to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

I An advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25. For purposes of this chapter and Code Section 43-34-25, an advanced practice registered nurse is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities; or

(D) A physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician assistant is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities.[54]

Recommendation E.1: *In identifying professional groups subject to mandatory reporting, using broader terms like "dispenser" or "practitioner" is preferable.*

ii. Reporting Time

The reporting component of PDMP statutes also addresses when information must be transmitted to the governmental body from the time of dispensing, i.e. reporting time. The reporting time varies from state to state. Still, states have typically followed one of three trends. Under the first trend, states choose to remain silent in their PDMP statutes and presumably leave the decision up to the regulatory process. Under the second and third trend, the states specify the reporting time but differ in specificity and flexibility. Presently, [#] states dictate frequency of reporting in their statute.

54 Ga. Code Ann. § 16-13-21(23) (West, Westlaw through 2014).

Under the second trend, states will set a particular reporting time that cannot be altered by the governmental body. The District of Columbia and South Carolina, for example, require reporting within 24 hours of the dispensing.[55] Louisiana requires the next business day.[56]

Under the third trend, states provide a reporting time with flexibility. For example, Massachusetts requires reporting "at least every 7 days."[57] California and Florida encourage early reporting by using, "as soon as reasonably possible" but then, cap the reporting period to no more than seven days from issuance.[58] This, in effect, is not different than setting a seven-day period, but all three of these states allow for early reporting.

Illinois takes, yet, another approach by dictating the reporting time but leaving discretion to the governmental body to adjust the turnaround time. Illinois' statute reads, "must be transmitted not more than 7 days after the date on which a controlled substance is dispensed, or at such other time as may be required by the Department by administrative rule."[59] The statue starts out by setting an expected reporting time, but it creates flexibility by delegating discretion to the department.

Based on Illinois' language, this approach has strengths but it also has the greatest potential for abuse. It provides the strongest approach because it specifies a time, but also understands that the reporting time—with newfound information—may be in a better position to set a reporting time. On the other hand, allowing the department to amend the turnaround time could potentially lead to be longer reporting time than the legislators

55 D.C. Code § 48-853.03(a)(1) (West, Westlaw through 2014); S.B. 840, 120 Leg., Reg. Sess. (SC 2014)
56 S.B. 556, Leg. Reg. Sess. (LA 2014).
57 720 Ill. Comp. Stat. Ann. 570/316(a)(2) (West, Westlaw through 2014).
58 Cal. Health & Safety Code §11165(d) (West, Westlaw through 2014); Fla. Stat. Ann. § 893.055(4) (West, Westlaw through 2014).
59 720 Ill. Comp. Stat. Ann. 570/316(a)(2) (West, Westlaw through 2014).

originally intended.

Recommendation E.1: *The reporting component of the statute should set an expected reporting time for reporting back to the governmental body, and allow for the governmental body to adjust the reporting time. Discretion to adjust the reporting time should only extend to only allow for shorter reporting times and not longer.*

F. *Reportable Data Elements*

Reportable data elements refer to the categories the dispensers must populate in the PDMP database. Reportable data elements typically incorporate, at the very least, the dispenser's DEA number, the type of controlled substance, the date the prescription was filled and written, the quantity, the prescriber's DEA number, and patient information. For illustration, Arkansas' statutes provides:

> "I Each dispenser required to report under subsection (b) of this section shall submit to the department by electronic means information that shall include without limitation:
>
> (1) The dispenser's identification number;
> (2) The date the prescription was filled;
> (3) The prescription number;
> (4) Whether the prescription is new or is a refill;
> (5) The National Drug Code number for the controlled substance that is dispensed;
> (6) The quantity of the controlled substance dispensed;
> (7) The number of days' supply dispensed;
> (8) The number of refills ordered;
> (9) (A) A patient identifier.
> (B) A patient identifier shall not be a social security number or a driver's license number;
> (10) The patient's name;
> (11) The patient's address;
> (12) The patient's date of birth;
> (13) The patient's gender;
> (14) The prescriber's identification number;
> (15) The date the prescription was issued by the prescriber; and
> (16) The source of the payment for the prescription."[60]

[60] Ark. Code. Ann. § 20-7-604 (West, Westlaw through 2014).

Requiring uniform reportable data elements serve three main purposes. One purpose of the data elements is to help dispensers, prescribers and advisory committees identify abuse and diversion. The information provides how many controlled substances the patient has been prescribed and by whom. Prescriptions from a handful of different physicians can suggest doctor shopping. The information also indicates how frequently a patient is refilling a prescription. Based how many pills a patient is supposed to take in a given day and how frequently the patient is attempting to or successfully refilling his/her prescription, dispensers, prescribers and advisory committees can determine if the patient is misusing or abusing the prescription.

Another purpose of the reportable data elements is to track prescribers and their prescribing behavior. A review of the data would reveal prescribers who frequently prescribe high quantities of controlled substance. The committees or departments may use this information to determine if any one prescriber practices dangerous and unethical prescribing habits.

The third purpose of the reportable data elements is to provide point of contact information. As previously noted in Section C, discussing the role of advisory committees, some statutes require committees or the governmental body to review the database information to identify patients who's prescription history suggests abuse or diversion. The committee or department must, then, point out the issue to the associated prescriber. Thus, the committee or department must know whom to contact in addition to how to contact the prescriber. The prescriber, in turn, must address the issue with the patient.

Recommendation F.1: *States should review their PDMP reportable data elements to ensure that the elements provided are sufficient to: (1) help dispensers, prescribers and advisory committees identify abuse and diversion; (2) identify and monitor prescribers and their prescribing behavior; and (3) provide a method of communication to reach the relevant practitioner.*

G. *Users with Access to Database Information*

All existing PDMP statutes include a provision defining a range of individuals who have access to the database information. Access is typically divided into three categories of stakeholders. The categories are differentiated by the scope of information and how readily available the information is to the individual.

i. First Category: Users with Direct Access to Unfiltered Information

Typically, the first category covers individuals who have direct access to the database information. Direct access means that there is no formalized application process to obtain the information each time. The users in this category merely register annually as a user, and then access the database as needed or required. Moreover, direct access allows these individuals to unfiltered information. Information is in its complete form with no redactions.

This category is comprised of individuals who benefit from information on patients' drug history to avoid exacerbating any patterns of diversion and abuse. Consequently, dispensers and prescribers are the primary users included in this category. Florida's statute provides:

> "A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the

> direction of the program manager or, in the absence of the program manager, as authorized."[61]

Like the Section D(i) discussing Professional Groups Subject to Mandatory Reporting, states should carefully consider what terms to use to best capture the intended individuals with direct access. Broad terms like "prescribers" or "practitioners" differ from specific terms like "physicians," thereby affecting the scope of who has access and who may have a mandatory duty to consult the database before prescribing. Arkansas, for example, uses the term "practitioner" as a group with direct access, and defines it in a PDMP definition statute as:

> "(A) A physician, dentist, veterinarian, advanced practice nurse, physician assistant, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and
>
> (B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state."[62]

As used in Arkansas' statute, the term, "practitioner" ensures that many individuals who may need direct access to the database are included. This is particularly important when considering dentists and veterinarians may be overlooked if the term "physician" is used, instead.

States may choose to extend direct access to include authorized agents or employees of dispensers and prescribers who have been delegated the task of consulting the database their superior's behalf. The ability for authorized agents to access the database should be considered because it eases the burden on dispensers and prescribers.

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61 Fla. Stat. Ann.§ 893.055(7)(b) (West, Westlaw through 2014).
62 Ark. Code Ann.§ 20-7-603(4) (West, Westlaw through 2014).

Some states choose also to include contractors and employees involved in the program, medical directors of the state health department, medical examiners, and other healthcare providers from other states.[63]

Recommendation G.1: *PDMP statutes should use the broader term "practitioner" when defining users who have direct access to unfiltered information, and extend the direct access to authorized agents of the practitioner.*

ii. Second Category: Users with Indirect Access to Unfiltered Information

The second category of permissible users is also privileged to database information with no redactions, but they do not share the same degree of access to the information as the first category. Individuals in this category have included law enforcement, patients and their parents, and government departments. The second category of users has limited access to select patients' information based on a demonstrated need. Users in this category must make a formal request to the overseeing committee or department and wait for the approval. Only with the approval of the overseeing committee or department can the second category receive a report with the database information.

Where individuals in the first category proactively use the database for prevention purposes, individuals in the second category reactively use the database for response purposes. Users in this category benefit from the information after diversion, abuse or fraud have occurred. For example, law enforcement may use PDMP data to investigate physicians who may be knowingly writing prescriptions to individuals involved in diversion or pharmacists who may be falsely filling in database information to sell more

63 Vt. Stat. Ann. tit. 18, § 4284(b)(1) (West, Westlaw through 2014).

prescriptions.[64] The database's content can often assist the respective interests of those included in this category by supplementing existing resources. Florida's statute includes:

> "I The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:
>
> 1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.
>
> 2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.
>
> 3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.
>
> 4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database."[65]

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64 *Prescription Drug Abuse*, U.S. CONGRESS (2014), available at http://www.nacds.org/ceo/2014/0529/CRS_Drug_Abuse_Report.pdf.

65 Fla. Stat. Ann.§ 893.055(7)(c) (West, Westlaw through 2014).

iii. Third Category: Users with Indirect Access to Filtered Information

The third group is usually comprised of the public, specifically individuals who seek the data for general educational or research purposes. For instance, Oregon's statute articulates:

> "(b) The authority may disclose information from the prescription monitoring program that does not identify a patient, practitioner or drug outlet:
>
> (A) For educational, research or public health purposes;
>
> (B) To a local public health authority, as defined in ORS 431.260; or
>
> I To officials of the authority who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 413.196 and rules adopted under ORS 431.110."[66]

In efforts to maintain the privacy and confidentiality of the patients, individuals in the third category are not privy to the same degree of access or scope of information as the other two categories. The third category of users must also make a formal request to the overseeing committee or department and wait for the approval. The reports provided to this category are filtered to ensure patient identifiers are removed.

As noted, there are three main categories of individuals who have access to database information. While drafting the access provision, legislators and policy makers should give due consideration to which stakeholders would benefit from access to the database information. Further, legislators and policy makers must carefully contemplate to what extent those stake holders should be granted access.

66 Or. Rev. Stat. Ann. § 431.966(2) (West, Westlaw through 2014).

H. *Duty to Consult the Database*

i. Imposing a Duty to Consult the Database

While all states with a PDMP impose a duty on dispensers to report and populate the database, they do not all impose a duty on prescribers to consult the database before prescribing. Currently, ***seven*** states require practitioners to access the database before administering controlled substances.[67] New York's statute, for illustration, requires consultation with the database for certain scheduled drugs:

> "Duty to consult prescription monitoring program registry; practitioners. (a) Every practitioner shall consult the prescription monitoring program registry prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV of section thirty-three hundred six of this article, for the purpose of reviewing a patient's controlled substance history as set forth in such registry; provided, however, that nothing in this section shall preclude an authorized practitioner, other than a veterinarian, from consulting the registry at his or her option prior to prescribing or dispensing any controlled substance."[68]

ii. Conditioning the Duty to Consult the Database

Alternatively, a state may wish only to require practitioners to access the database when certain conditions are triggered. Nevada's statute, for instance, requires:

> "A practitioner shall, before writing a prescription for a controlled substance listed in schedule II, III or IV for a patient, obtain a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Board and the Investigation Division of the Department of Public Safety pursuant to NRS 453.1545 if the practitioner has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:
>
> 1. The patient is a new patient of the practitioner; or

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67 This includes any state statute that requires either prescribers or prescribers and dispensers to check the database prior to prescribing or dispensing controlled substances, and this also includes consultations conditioned on certain events. Del. Code Ann. tit. 16, § 4798(e) & (f) (West, Westlaw through 2014); Ind. Code Ann. § 35-48-712.1(a)(5) (West, Westlaw through 2014); Ky. Rev. Stat. Ann. § 218A.172(1)(b) (West, Westlaw through 2014); Nev. Rev. Stat. Ann. § 639.23507 (West, Westlaw through 2014); N.Y. Pub. Health Law § 3343-a(2); Tenn. Code Ann. § 53-10-310(e) (West, Westlaw through 2014); W. Va. Code Ann. § 60A-9-5a(a) (West, Westlaw through 2014); W. Va. Code Ann. § 16-5H-4(7) (West, Westlaw through 2014).

68 N.Y. Pub. Health Law § 3343-a(2) (West, Westlaw through 2014).

> 2. The patient has not received any prescription for a controlled substance from the practitioner in the preceding 12 months.
>
> The practitioner shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary."[69]

A conditional approach using "reasonable belief" like Nevada's mandate, however, creates two complications. First, the conditional language may add to rather than lessen the burden on practitioners. Some practitioners may find that consulting the database every single time is cumbersome; therefore, consulting the database only when "a reasonable belief" is triggered presumably eases the perceived burden. A condition, though, requires the practitioners to learn and memorize precisely under what circumstances they need to obtain a report. As a result, this may add an unnecessary burden on the practitioners—beyond what would be required if consultation was applied uniformly to every situation.

Second, the conditional language with a discretionary element creates a major loophole in the mandate. The duty to consult the database is conditioned in part on whether the practitioner has a "reasonable belief." So while the events listed under "1" and "2," triggering a consultation are concrete, the language "reasonable belief"—despite the intention to be objective—leaves much room for interpretation. "Reasonable belief" delegates a level of discretion to the prescriber in deciding whether he/she should consult the database.

iii. No Duty to Consult the Database

Another option states have taken is to decline imposing a duty on practitioners to consult the database before prescribing. ***Thirteen*** states explicitly provide that there is no requirement or obligation for prescribers to check the database prior to writing

[69] Nev. Rev. Stat. Ann. § 639.23507 (West, Westlaw through 2014).

prescriptions for scheduled drugs.[70] Alabama, for instance, says, "Practitioners shall have no requirement or obligation, under this article, to access or check the information in the controlled substances database prior to prescribing, dispensing, or administering medications or as part of their professional practice."[71]

Nonetheless, states that choose not to impose a duty to consult the database may choose to include language in their statute that encourages consultation. The language may motivate the health professional boards to set requirements like Alabama's statue does or motivate health facilities to implement internal practices.[72] Alabama's statute includes, "However, the applicable licensing boards in their discretion, may impose such a requirement or obligation by regulations."[73]

Although certain practitioners may feel an added burden with an obligation to check the database before prescribing, peer reviewed research supports mandatory consultation with the database before prescribing controlled substances. In a study conducted by Gershman, Gershman, Fass, and Popovici, the participating physicians who frequently used the PDMP—conducting more than twenty-five searches—felt strongly about the usefulness of PDMP as a tool for monitoring patient's controlled substance history.[74] In another study conducted by Feldman et al., prescribers found that checking the database actually

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70 Ala. Code § 20-2-214(2) (West, Westlaw through 2014); Alaska Stat. Ann.§ 17.30.200(h) (West, Westlaw through 2014); Ind. Code Ann. § 35-48-7-11.1(k) (West, Westlaw through 2014); 720 Ill. Comp. Stat. Ann. 570/318(j)(7) (West, Westlaw through 2014); Iowa Code Ann.§ 124.553(6) (West, Westlaw through 2014); Kan. Stat. Ann. § 65-1688 (West, Westlaw through 2014); (West, Westlaw through 2014); Md. Ann. Code Health-Gen. § 21-2A-04(4) (West, Westlaw through 2014); Minn. Stat. Ann. § 152.126(9)(b) (West, Westlaw through 2014); N.D. Cent. Code Ann. § 19-03.5-05(West, Westlaw through 2014); H.B. 2665, 55th Leg.,2nd Reg. Sess. (OK 2014); Or. Rev. Stat. Ann. § 431.966(7); S.B. 840, 120 Leg., Reg. Sess. (SC 2014); W. Va. Code Ann. § 60A-9-5(i)(stating no duty to check each time except upon initial prescribing or dispensing)(West, Westlaw through 2014).

71 Ala. Code §§ 20-2-214(2) (West, Westlaw through 2014).

72 *Id.*

73 *Id.*

74 Gershman et al., *supra* note 47.

alleviated their concerns surrounding prescribing controlled substances.[75] Specifically, 30% of prescribers were less concerned after consulting the database, and 14% of prescribers actually increased the quantity prescribed because the patient's drug history report assuaged their existing concerns.

Furthermore, in a study assessing medical residents use of PDMPS, the findings demonstrated that if attendings physicians wanted residents of a particular hospital to use the database, then the hospital needed to impose a requirement mandating the residents to use the database.[76] Applying that same theory to the greater prescribing community, mandating all prescribers to consult the database would yield the highest level of compliance and result in a best practice in prescribing controlled substances. As such, states should mandate practitioners to consult the database before prescribing and dispensing controlled substances to reduce prescription drug abuse.

Recommendation H.1: *State should create a flat requirement for practitioners to access and consult the database prior to prescribing and dispensing controlled substances to maximize the utility of PDMPs.*

iv. Educating and Training the Practitioners on Consulting the Database

Regardless of whether practitioners are required to access the database prior to prescribing or dispensing, policymakers and legislators should consider adding an educational and training component to the PDMP laws for practitioners, at the very least. Currently, a great number of physicians fail to use the PDMPs. This has been largely attributed to a lack of knowledge on how to use the database, as well as on its very

75 Feldman et al., *supra* note 48.

76 Lance Feldman et al., *Influencing controlled substance prescribing: attending and resident physician use of a state prescription monitoring program*, 13 PAIN MED. MALDEN MASS 908, 914 (2012).

existance.[77] In a study measuring the knowledge on PDMPs, all of the physicians who were unaware of the program admitted that they would likely use the database had they known of its existence.[78]

Therefore, an educational component could raise awareness of the program, as well as train prescribers on how to use the system. In the states where consultation is mandatory, an educational component ensures that practioners are using the database correctly, maximizing utility and minimizing penalties to those attempting to use the database but using it improperly. In the states where consultation is not required, an educational component encourages the use by familiarizing practitioners to the process and making the experience more comfortable. In short, exposure and training is likely encourage and increase utiliziation of PDMPs.

Recommendation H.2: *In addition to mandatory consultation of the database prior to administering controlled substances, PDMP statutes should include a training component to familiarize practitioners with the database, as well as to educate them on proper usage.*

I. *Legal Protections*

State PDMP statutes often include legal protections concerning privacy, confidentiality, protection from discovery or subpoena, and immunity from liability. These sections should comply with existing federal and state laws protecting patient privacy. States have differed in whether to include all four elements, as well as how they group the legal protections. With the exception of two states, most states that set up their PDMPs through statute provide some kind of legal provision.[79] Maryland addresses confidentiality,

[77] Gershman et al., *supra* note 47.
[78] Feldman et al., *supra* note 48.
[79] MI, NE.

privacy and disclosure issues by stating:

> "(a) Prescription monitoring data:
>
> (1) Are confidential and privileged, and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation;
> (2) Are not public records; and
> (3) Except as provided in subsections (b) and (d) of this section or as otherwise provided by law, may not be disclosed to any person."[80]

Moreover, the policy makers and legislators should include an immunity component. Immunity components encourage stakeholders to utilize the database by protecting their actions so long as the actions are performed in good faith. Maryland addresses immunity in a separate provision from its privacy component. It specifies protected actions by stating:

> "Department agents and employees
>
> (a) With respect to the administration and operation of the Program, the Department and its agents and employees are not subject to liability arising from:
>
> (1) The inaccuracy of any information submitted to the Program in accordance with this subtitle; or
>
> (2) The unauthorized use or disclosure of prescription monitoring data by a person to whom the Program was authorized to provide the prescription monitoring data under this subtitle.
>
> Prescribers or dispensers
>
> (b) A prescriber or dispenser, acting in good faith, is not subject to liability or disciplinary action arising solely from:
>
> (1) Requesting or receiving, or failing to request or receive, prescription monitoring data from the Program; or
>
> (2) Acting, or failing to act, on the basis of prescription monitoring data provided by the Program."[81]

Recommendation I.1: *A legal protections component should always be included as part of a PDMP statute. PDMP statutes should have the governmental body establish and enforce*

80 Md. Ann. Code Health-Gen. § 21-2A-06(A)(1) (West, Westlaw through 2014).
81 Md. Ann. Code Health-Gen. § 21-2A-08 (West, Westlaw through 2014).

policies and procedures that, at minimum, cover privacy, confidentiality, disclosure and liability. The privacy, confidentiality and disclosure component must comply with existing state and federal health care laws, and should explicitly provide that the information generated for the purpose of the database, submitted to, maintained by, or stored as part of the PDMP is privileged and confidential, is not subject to public or open record laws, and is not subject to discovery or subpoena for civil proceedings. The governmental body should also be tasked with the duty to establish and maintain a process to verify credentials for the release of patient reports to authorized users.

To address liability, the state should include language that explicitly protects the actions of the governmental body and its employees, as well as the practitioners who are obligated to access and/or populate the database. The protection from liability should be conditioned on actions performed in good faith in an attempt to follow policy and procedures. This portion should list out specific actions are immune from liability.

J. *Enforcement*

An enforcement component addresses prohibited acts and the associated sanctions and penalties. The goal with an enforcement component is to identify prohibited acts and outline the penalties to provide fair notice to any individual who may be accused of a violation. Thus, language must be clear as to the standard of conduct. Additionally, the statute must describe the nature and cause of the violation.[82] In the absence of clarity established by a set standard, the provision may be rendered void because it is too vague and may be arbitrarily applied.[83]

i. Prohibited Acts

Prohibited Acts generally focus on acts that defeat the purpose of the program, or violate privacy and confidentiality. For example, prohibited acts that may defeat the purpose of the program include failure of practitioners to register for database access,

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82 GUIDE TO LEGISLATIVE RESEARCH AND DRAFTING 20 (American Bar Association 1978).

83 The U.S. Constitution's Due Process clause, as well as the Fifth and Fourteenth Amendment require that criminal laws explicitly define prohibited conduct. If a criminal fails to do so, it is considered void for vagueness. *Void for Vagueness Doctrine*, CORNELL UNIV. L. SCH., http://www.law.cornell.edu/wex/vagueness_doctrine (last accessed Nov. 16, 2014).

failure of dispensers to submit database information or submission of false information, and destruction of database information. Meanwhile, prohibited acts that violate privacy and confidentiality include unauthorized access, use or disclosure.

ii. Associated Sanctions and Penalties

In regards to sanctions, there are typically three forms—administrative, civil and criminal. The appropriate form of sanction should be shaped by the desired objective.[84] An administrative sanction explicitly authorizes an organized professional licensing board to administer disciplinary actions. For instance, Minnesota's statute provides:

> "Subd. 7. Disciplinary action. (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.
>
> (b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties."[85]

A civil sanction entails fines. The fines may set a cap for all prohibited actions like Colorado does. Colorado's statute states:

> "A person who knowingly releases, obtains, or attempts to obtain information from the program in violation of this part 4 shall be punished by a civil fine of not less than one thousand dollars and not more than ten thousand dollars for each violation. Fines paid shall be deposited in the general fund."[86]

Alternatively, fines may correspond with specific prohibited acts like Maryland's Fines and Penalties for Violation Provision. Maryland's statute includes the following:

> "Knowing failure to submit data
> (a) A dispenser who knowingly fails to submit prescription monitoring data to the Program as required under this subtitle shall be subject to a civil penalty not exceeding $500 for each failure to submit required information.

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84 GUIDE TO LEGISLATIVE RESEARCH AND DRAFTING, *supra* note 82.
85 Minn. Stat. Ann. § 152.126(7) (West, Westlaw through 2014).
86 Colo. Rev. Stat. Ann. § 12-42.5-406 (West, Westlaw through 2014).

> Knowing disclosure, use, or receipt of data by fraud or deceit
> (b)(1) A person who knowingly discloses, uses, obtains, or attempts to obtain by fraud or deceit, prescription monitoring data in violation of this subtitle shall be guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 1 year or a fine not exceeding $10,000 or both.
> (2) In addition to the penalties under paragraph (1) of this subsection, a prescriber or dispenser who knowingly discloses or uses prescription monitoring data in violation of this subtitle shall be subject to disciplinary action by the appropriate licensing entity.
> (3) The release of prescription monitoring data by a prescriber or dispenser to a licensed health care professional solely for treatment purposes in a manner otherwise consistent with State and federal law is not a violation of this subtitle."[87]

An effective and clear criminal penalty includes four main elements. The first element addresses the person subject to the provision. The second element addresses the prohibited action. The third element addresses the associated penalty while the fourth element addresses the requisite state of mind while committing the violation.[88]

The two elements that may pose difficulties for drafters are elements one and four. In regards to the first element, the language does not need to name a specific group. It can be as generic as "any individual who . . . ."

When addressing the fourth element, the requisite state of mind, three variations are used. The first variation does not require the actor to have a criminal intent, which would incriminate more individuals. Arizona's statute, for example, simply states, "[a] person who is subject to this article and who fails to report required information pursuant to § 36-2608 is guilty of a class 2 misdemeanor."[89]

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87 Md. Ann. Code Health-Gen. § 21-2A-09(a) (West, Westlaw through 2014).
88 Filson, *supra* note 34 at 144.
89 Ariz. Rev. Stat. Ann. § 36-2606(A) (West, Westlaw through 2014).

The second variation requires a generalized criminal intent. This means an individual must willfully or knowingly perform the prohibited act. It does not mean the individual must have willfully or knowingly performed the prohibited act for the specific purpose of violating that law. Arizona also has a provision addressing this. It says, "[a] person who is subject to this article and who knowingly fails to report required information to the board in violation of § 36-2608 is guilty of a class 1 misdemeanor."[90] Here, the actor must have acted with purpose. Consequently, the corresponding penalty is usually harsher than the one associated with the first variation.

The third variation requires the actor to have acted with a specific criminal intent. Specific criminal intent requires the individual to perform a prohibited act with the specific purpose to violate the law.[91] While its language is not as precise, Arkansas' statute demonstrates the most difficult standard to prove:

> "(a)(1) It is unlawful for a dispenser to purposely fail to submit prescription monitoring information as required under this subchapter.
> (2) A violation of subdivision (a)(1) of this section is a Class B misdemeanor."[92]

To tighten up to writing and the effect of this particular statute, the language would preferably say, "A dispenser who purposely fails to submit prescription information as required under this subchapter is guilty of a Class B misdemeanor, or A dispenser shall not purposely fail to . . .or such person is guilty of a Class B misdemeanor." Further, the term "purposely fail" should be defined to create clear-cut standard with objective criteria.

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90 Ariz. Rev. Stat. Ann. § 36-2606(B) (West, Westlaw through 2014).

91 Acting with purpose differs from acting with knowledge. *Model Penal Code's Mens Rea*, NAT'L PARALEGAL COLL., http://nationalparalegal.edu/public_documents/courseware_asp_files/criminalLaw/basicElements/ModelPenalCodeMensRea.asp (last accessed Dec. 03, 2014). Acting with purpose means that the actor set out to the prohibited conduct. Acting with knowledge means that the actor was aware that the prohibited conduct was likely to occur, but it was not the end goal but rather a byproduct of another intent.

92 Ark. Code Ann. § 20-7-611 (West, Westlaw through 2014).

Explicit sanctions can promote compliance and provide of the expected standard of conduct.[93]

Recommendation J.1: *The enforcement component should clearly identify prohibited acts and outline the penalties to provide fair notice to any individual who may be accused of a violation.* Thus, language must be clear as to the standard of conduct, describing the nature and cause of the violation.

K. *Funding*

Most statutes have a financial component that discusses how the program will be funded and/or what expenses are covered by the PDMP funds, as well as what happens to the funds at the end of each year. Funding may come from a variety of sources. Some common sources are donations, grants and gifts, as well as registration or licensure fees. New Hampshire's statute, for example, includes:

> "II. All costs incurred by the board for the implementation and operation of the program shall be supported through grants, gifts, or user contributions. The board may charge a fee to individuals who request their own prescription information. The amount charged for an individual's request for his or her prescription information shall not exceed the actual cost of providing that information."[94]

As of July 2014, ***twenty states*** fund their PDMPs through licensure or registration fees.[95] In particular, ***eight states*** fund their PMPs through controlled substances registration fees—in part or whole.[96] Another ten states rely in whole or part on unspecified licensure fees that may include controlled substance registration fees.[97]

Well-drafted funding components also included prohibited sources of funding. ***Ten states*** explicitly prohibit funding from certain activities like fees associated with licensing

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93 FILSON, *supra* note 34 at 144.
94 N.H. Rev. Stat. Ann. 318-B:32(II) (West, Westlaw through 2014).
95 National Alliance for Model State Drug Laws, *Prescription Drug Abuse, Addiction and Diversion: Overview of State Legislative and Policy Initiatives Part 1*, (2014) [HEREINAFTER "NAMSDL PART 1"].
96 *Id.* AL, CA, HI, IN, MT, NC, OR, SC.
97 *Id.* AZ, IA, MI, MN, MS, NE, NJ, ND, UT, WV.

or requests for patient reports to support PDMP activities.[98] Listing licensure or registration fees as a prohibited source of funding can prevent practitioners from building resistance towards the use of PDMPs, which can occur if practitioners are expected to fund the programs with money from their own pockets. Accordingly, New York's financial component expresses the following in its funding component:

> "8. Funding the prescription monitoring program registry. (a) The commissioner shall make reasonable efforts to apply for monies available from the federal government and other institutions, to the extent deemed appropriate by the commissioner, and use any monies so obtained to supplement any other monies made available for the purposes of this title.
> (b) Operation of the registry established by this section shall not be funded, in whole or in part, by fees imposed specifically for such purposes upon practitioners, pharmacists, designees or patients subject to this section."

Prohibited sources of funding may also include general state funds. For instance, New Hampshire's statute says, "There shall be no state general funds appropriated for the implementation or operation of the program."[99] Instead, it relies entirely on gifts, grants, and user contributions and fees.[100] Nonetheless, by listing prohibited sources of funding, the state may be severely limiting the chance of the PDMP's survival or for a robust PDMP by cutting funding opportunities.

In addition to discussing sources of funding, some states address reimbursements in the financial component. This language is used to ensure that participants will not incur any costs that may deter them from using or promoting the use of the PDMP. Explicitly, Alabama reimburses pharmacists for any costs they incur for their use of the database.[101] Maryland, on the other hand, reimburses the board of pharmacy for expenses they may

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98 *Id.* AR, FL, KS, KY, MD, NE, NH, NY, OH, WA.
99 N.H. Rev. Stat. Ann. 318-B:32(III) (West, Westlaw through 2014).
100 N.H. Rev. Stat. Ann. 318-B:32(II) (West, Westlaw through 2014).
101 Ala. Code § 20-2-218 (West, Westlaw through 2014).

have sustained.[102]

Recommendation K.1: *PDMP statutes should include a financial component that lists out sources of funding to include state appropriations, as well as donations, gifts, fees and grants. The financial component should also explicitly state any prohibited sources of funding. Furthermore, this section should address whether funds allocated to the PDMP should revert back to the state general fund at the end of a state fiscal year; ideally, funds would remain in the PDMP fund.*

L. *Interstate Sharing*

Interstate sharing is when a state PDMP allows other state PDMPs to access its patient data. A PDMP is only effective if it fully captures the patient's history. Unfortunately, patients do not always confine their doctor visits or prescription refills to a single state. In fact, many individuals who are doctor shopping or stockpiling pills for diversion travel across state lines after already collecting prescriptions from within their own state.

Interstate sharing creates a more comprehensive approach to discourage doctor shopping. It allows practitioners to check the drug history of patients who are from out-of-state, or who may live in the state but frequent doctors out-of-state. Accordingly, ***thirty*** states provide for interstate sharing in their PDMP statutes.[103] The language may be as simple as Virginia's, which states:

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102 Md. Ann. Code Health-Gen. § 21-2A-05(e)(2) (West, Westlaw through 2014).

103 Ala. Code § 20-2-214(9) (West, Westlaw through 2014); Ark. Code Ann. § 20-7-608 (West, Westlaw through 2014); Colo. Rev. Stat. Ann. § 12-42.5-404(6) (West, Westlaw through 2014); Del. Code Ann. tit. 16, § 4798(p) (West, Westlaw through 2014); D.C. Code § 48-853.06(a) (West, Westlaw through 2014); Haw. Rev. Stat. § 329-104(c)(4) (West, Westlaw through 2014); 720 Ill. Comp. Stat. Ann. 570/11.1(d)(5) (West, Westlaw through 2014); Ind. Code Ann. § 35-48-7-11.1(d)(5) (West, Westlaw through 2014); Iowa Code Ann. § 124.553(8) (West, Westlaw through 2014); Ky. Rev. Stat. Ann. § 218A.245 (West, Westlaw through 2014); La. Rev. Stat. Ann. § 40:1007 (West, Westlaw through 2014); Me. Rev. Stat. Ann. tit. 22 § 7250(4-A); Md. Ann. Code Health-Gen. § 21-2A-06(h)-(j) (West, Westlaw through 2014); Mass. Gen. Laws Ann. ch. 94C, § 24A(a)(2) (West, Westlaw through 2014); Minn. Stat. Ann. § 152.126(6)(g) (West, Westlaw through 2014); Miss. Code Ann. § 73-21-127(e)(i) (West, Westlaw through 2014); Mont. Code Ann. § 37-7-1506(1)(g) (West, Westlaw through 2014); Nev. Rev. Stat. Ann. § 453.1545(5) (West, Westlaw through 2014); N.H. Rev. Stat. Ann. 318-B:35(I)(b)(4) (West, Westlaw through 2014); N.J. Stat. Ann. § 45:1-46(d)(8) (West, Westlaw through 2014); N.Y. Pub. Health Law § 3343-a(1)(c) (West, Westlaw through 2014); N.C. Gen. Stat. Ann. § 90-113.74(c)(4) (West, Westlaw through 2014); N.D. Cent.

> "D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter."[104]

This language broadly allows for agreements between states. It provides no limitations. At the same time, though, it also provides no guidance.

Some state take it a step further, outlining elements that must be present if the state decides to enter into an interstate sharing agreement, which is preferable because it assists with consistency. Further, this approach ensures that the agency is thoughtful to whom it extends sensitive information. Tennessee's statute, for one, says:

> "Notwithstanding any other provision of this part to the contrary, the commissioner is authorized to enter into agreements with other states or other entities acting on behalf of a state for the purposes of sharing and dissemination of data and information in the database. Disclosure of such agreements shall be consistent with the provisions and limitations set forth in this part. All such agreements shall specifically provide which prescribers, dispensers, healthcare practitioner extenders or law enforcement personnel who are licensed, registered, or certified in other states shall have access to the database."[105]

Nonetheless, the very presence of any interstate sharing component is a step in the right direction. The current limitation of many PDMPs is the lack of shared patient data between states, as well as the failure to streamline the PDMP information with other existing electronic health record data to reduce repetition. [106],

<u>Recommendation L.1</u>: *Interstates sharing should be part of the PDMP statute. The language should authorize sharing of information with other established state databases and should*

Code Ann. § 19-03.5-08 (West, Westlaw through 2014); Ohio Rev. Code Ann. §4729.80(11) (West, Westlaw through 2014); H.B. 2665, 55th Leg.,2nd Reg. Sess. (OK 2014); (West, Westlaw through 2014); Or. Rev. Stat. Ann. § 431.966(2)(a)(F) (West, Westlaw through 2014); S.D. Codified Laws § 34-20E-14 (West, Westlaw through 2014); Tenn. Code Ann. § 53-10-311 (West, Westlaw through 2014); Vt. Stat. Ann. tit. 18, § 4284(b)(2)(F) (West, Westlaw through 2014); Va. Code Ann. § 54.1-2523(D) (West, Westlaw through 2014).

104 Va. Code Ann. § 54.1-2523(D) (West, Westlaw through 2014).

105 Tenn. Code Ann. § 53-10-311 (West, Westlaw through 2014).

106 Stephen Barlas, *Prescription drug abuse hits hospitals hard: tighter federal steps aim to deflate crisis*, 38 P T PEER-REV. J. FORMUL. MANAG. 531–534 (2013).

encourage future efforts to streamline PDMPs processes and content with other states, as well as with existing electronic health records to reduce duplication.

IV. CONLUSION

As the literature demonstrates, prescription drug abuse is a real concern for the United States. Prescription drug abuse costs the criminal justice and health care system $53 to $73 billion, and is an epidemic that the United States cannot afford to ignore.[107] Although studies have shown PDMPs to be effective and almost all of the states have responded by implementing PDMPs, database utilization is still relatively low. [108] Given that prescription drug abuse is the leading cause of accidental death[109] and pervades a wide spectrum of individuals from all communities, this epidemic must be addressed more aggressively.

In response to the need for enhanced PDMPs and increased PDMP utilization, states and stakeholders should review their PDMPs policies to determine what statutory components are lacking. There are numerous options discussed in this study on how to draft statutes to enhance PDPMs and increase utilization. These options aim to also promote clarity and efficiency in the law. Specifically, this study addresses how to increase accountability among stakeholders, as well as the greater need for better communication and awareness horizontally—between states and practitioners—and vertically—between the agency and the PDMP users.

Although this study aims to recommend effective statutory components that will enhance the function and increase the use of PDMPs, stakeholders must acknowledge that state PDMPs, alone, will not reduce prescription drug abuse. These efforts must accompany

107 Roberts & Skinner, *supra* note 10.
108 Straus, *supra* note 2.
109 *Id.*

the remaining three major action areas—educating the public and practitioners on nonmedical use of prescription drugs, access to proper disposal of prescription drugs, and strict enforcement of illegal prescriptions. Furthermore, certain improvements may beyond the states' immediate influence. The federal government may need to step in to orchestrate or even mandate a uniform database system and incorporation of PDMP into electronic health records. After all, the scope and complexity of prescription drug abuse is expansive and requires all stakeholders to play a role; no single actor or policy can change the entire field. Nevertheless, the collective states are in a powerful position to reduce prescription drug abuse across the United States through their PDMP laws.

APPENDIX A

Recommendations for Effective PDMP Legislation

A. Defining Major Terms

Recommendation A.1: *The PDMP statutes should include a definition section, describing ambiguous and vague terms that may differ from one context to another. The PDMP statutory language should use existing terms and similar language structure as used in the rest of the chapter code to ensure cohesion and uniformity among the laws within a state.*

B. Delegating Authority

Recommendation B.1: *Before including an authority component, the first step should be to check if the enabling act, the act that creates the governmental body, already delegates the power to issue rules and regulations to avoid redundancy.*[113] *If one does not exist, language promulgating specific regulatory topics is preferable. The regulatory topics should include establishing and maintaining a process for reporting, as well as establishing and enforcing policies and procedures to guarantee the privacy and confidentiality of patients*

Recommendation B.2: *PDMPs can maximize the use of external resources by including a component that authorizes the government body to contract with third parties. This component should hold contractors up to the same legal standards as employees or any other users of the PDMP.*

C. Advisory Committee to Help Establish, Maintain and Operate the PDMP

Recommendation C.1: *PDMP statutes should include an advisory committee component that outlines the membership of a diverse group of PDMP stakeholders.*

D. Creating Accountability through the Department's Duty to Review & Report

Recommendation D.1: *Either the advisory committee or governmental body should be tasked with the affirmative duty to inspect the database information for illegal behavior. The same entity should also have the duty to review the PDMP information to evaluate the effectiveness of the program as a whole, and make recommendations to the state legislature.*

E. Mandatory Reporting

Recommendation E.1: *The reporting component of the statute should set an expected*

[113] The enabling act is the act that breathes life into a particular agency and dictates the scope of the agency's powers and duties.

reporting time for reporting back to the governmental body, and allow for the governmental body to adjust the reporting time. Discretion to adjust the reporting time should only extend to only allow for shorter reporting times and not longer.

F. Reportable Data Elements

Recommendation F.1: *States should review their PDMP reportable data elements to ensure that the elements provided are sufficient to: (1) help dispensers, prescribers and advisory committees identify abuse and diversion; (2) identify and monitor prescribers and their prescribing behavior; and (3) provide a method of communication to reach the relevant practitioner.*

G. Users with Access to Database Information

Recommendation G.1: *PDMP statutes should use the broader term "practitioner" when defining users who have direct access to unfiltered information, and extend the direct access to authorized agents of the practitioner.*

H. Duty to Consult the Database

Recommendation H.1: *State should create a flat requirement for practitioners to access and consult the database prior to prescribing and dispensing controlled substances to maximize the utility of PDMPs.*

Recommendation H.2: *In addition to mandatory consultation of the database prior to administering controlled substances, PDMP statutes should include a training component to familiarize practitioners with the database, as well as to educate them on proper usage.*

I. Legal Protections

Recommendation I.1: *A legal protections component should always be included as part of a PDMP statute. PDMP statutes should have the governmental body establish and enforce policies and procedures that, at minimum, cover privacy, confidentiality, disclosure and liability. The privacy, confidentiality and disclosure component must comply with existing state and federal health care laws, and should explicitly provide that the information generated for the purpose of the database, submitted to, maintained by, or stored as part of the PDMP is privileged and confidential, is not subject to public or open record laws, and is not subject to discovery or subpoena for civil proceedings. The governmental body should also be tasked with the duty to establish and maintain a process to verify credentials for the release of patient reports to authorized users.*

To address liability, the state should include language that explicitly protects the actions of the governmental body and its employees, as well as the practitioners who are obligated to access and/or populate the database. The protection from liability should be conditioned on

actions performed in good faith in an attempt to follow policy and procedures. This portion should list out specific actions are immune from liability.

J. Enforcement

Recommendation J.1: *The enforcement component should clearly identify prohibited acts and outline the penalties to provide fair notice to any individual who may be accused of a violation.* Thus, language must be clear as to the standard of conduct, describing the nature and cause of the violation.

K. Funding

Recommendation K.1: *PDMP statutes should include a financial component that lists out sources of funding to include state appropriations, as well as donations, gifts, fees and grants. The financial component should also explicitly state any prohibited sources of funding. Furthermore, this section should address whether funds allocated to the PDMP should revert back to the state general fund at the end of a state fiscal year; ideally, funds would remain in the PDMP fund.*

L. Interstate Sharing

Recommendation L.1: *Interstates sharing should be part of the PDMP statute. The language should authorize sharing of information with other established state databases and should encourage future efforts to streamline PDMPs processes and content with other states, as well as with existing electronic health records to reduce duplication.*

APPENDIX B

Table 1

States that Promulgated Regulations:

Ala. Code § 20-2-212(1) (West, Westlaw through 2014);
Alaska Stat.§ 08.80.030(b)(4) (West, Westlaw through 2014);
Ariz. Rev. Stat. Ann. § 36-2602(A) (West, Westlaw through 2014);
Ariz. Rev. Stat. Ann. § 36-2602(A) (West, Westlaw through 2014);
Cal. Health & Safety Code §11165.2(b) (West, Westlaw through 2014);
Colo. Rev. Stat. Ann. § 12-42.5-404(2) (West, Westlaw through 2014);
Conn. Gen. Stat. Ann. § 21a-254a (West, Westlaw through 2014);
D.C. Code Ann. tit. 16 § 48-853.10 (West, Westlaw through 2014);
Fla. Stat. Ann. § 893.055(16) (West, Westlaw through 2014);
Ga. Code Ann. § 16-13-62 (West, Westlaw through 2014);
Haw. Rev. Stat. § 329-31 (West, Westlaw through 2014);
Idaho Code Ann. § 37-2726 (West, Westlaw through 2014);
720 Ill. Comp. Stat. Ann. 570/507.2 (West, Westlaw through 2014);
720 Ill. Comp. Stat. Ann. 720 570/319 (West, Westlaw through 2014);
Ind. Code Ann. § 35-48-7-12.1 (West, Westlaw through 2014);
Iowa Code Ann. § 124.554 (West, Westlaw through 2014);
Kan. Stat. Ann. § 65-1682 (West, Westlaw through 2014);
Kan. Stat. Ann. § 65-1683(b) (West, Westlaw through 2014);
Kan. Stat. Ann. § 65-1692 (West, Westlaw through 2014);
Ky. Rev. Stat. Ann. § 218A.172 (West, Westlaw through 2014);
La. Rev. Stat. Ann. § 40:1011 (West, Westlaw through 2014);
Me. Rev. Stat. Ann. tit. 22 § 7252 (West, Westlaw through 2014);
Md. Ann. Code Health-Gen. § 21-2A-04(a) (West, Westlaw through 2014);
Mass. Gen. Laws Ann. ch. 94C, § 24A (c) & (j) (West, Westlaw through 2014);
Mich. Comp. Laws Ann. § 333.733a(1) (West, Westlaw through 2014);
Miss. Code Ann. § 73-21-81 (West, Westlaw through 2014);
Mont. Code Ann. § 37-7-1512 (West, Westlaw through 2014);
N.C. Gen. Stat. Ann. § 90-113.73(b) (West, Westlaw through 2014);
N.D. Cent. Code Ann. § 19-03.5-02(2) (West, Westlaw through 2014);
N.D. Cent. Code Ann. § 19-03.5-09 (West, Westlaw through 2014);
Neb. Rev. Stat. Ann. § 71-2455 (West, Westlaw through 2014);
N.H. Rev. Stat. Ann. 318-B:37 (West, Westlaw through 2014);
N.J. Stat. Ann. § 45:1-51-52 (West, Westlaw through 2014);
N.Y. Pub. Health Law § 3343-a(9) (West, Westlaw through 2014);
Ohio Rev. Code Ann. §4729.84 (West, Westlaw through 2014);
Or. Rev. Stat. Ann. § 431.962(2) (West, Westlaw through 2014);
R.I. Gen. Laws. Ann. § 21-28-3.01 (West, Westlaw through 2014);
S.C. Code Ann. § 44-53-1670 (West, Westlaw through 2014);

S.D. Codified Laws § 34-20E-20 (West, Westlaw through 2014);
Tenn. Code Ann. § 53-10-303(f) (West, Westlaw through 2014);
Tex. Health & Safety Code Ann. § 481.076(c) (West, Westlaw through 2014);
Vt. Stat. Ann. tit. 18, § 4287 (West, Westlaw through 2014);
Vt. Stat. Ann. tit. 18, § 4289(e) (West, Westlaw through 2014);
Va. Code Ann. § 54.1-2520(B) (West, Westlaw through 2014);
Wash. Rev. Code Ann. § 700.225.025 (West, Westlaw through 2014);
W. Va. Code Ann. § 60A-9-6; Wis. Stat. Ann. § 450.19(2) (West, Westlaw through 2014);
Wyo. Stat. Ann. § 35-7- 1023 (West, Westlaw through 2014).

States that Promulgated Regulations and Also Prescribed Specific Topics:

Ala. Code § 20-2-212(1) (West, Westlaw through 2014);
Alaska Stat.§ 08.80.030(b)(4) (West, Westlaw through 2014);
Ariz. Rev. Stat. Ann. § 36-2602(A) (West, Westlaw through 2014);
Ariz. Rev. Stat. Ann. § 36-2602(A) (West, Westlaw through 2014);
Cal. Health & Safety Code §11165.2(b) (West, Westlaw through 2014);
Colo. Rev. Stat. Ann. § 12-42.5-404(2) (West, Westlaw through 2014);
Conn. Gen. Stat. Ann. § 21a-254a (West, Westlaw through 2014);
D.C. Code Ann. tit. 16 § 48-853.10 (West, Westlaw through 2014);
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Idaho Code Ann. § 37-2726 (West, Westlaw through 2014);
720 Ill. Comp. Stat. Ann. 570/507.2 (West, Westlaw through 2014);
720 Ill. Comp. Stat. Ann. 720 570/319 (West, Westlaw through 2014);
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Kan. Stat. Ann. § 65-1683(b) (West, Westlaw through 2014);
Kan. Stat. Ann. § 65-1692 (West, Westlaw through 2014);
Ky. Rev. Stat. Ann. § 218A.172 (West, Westlaw through 2014);
La. Rev. Stat. Ann. § 40:1011 (West, Westlaw through 2014);
Me. Rev. Stat. Ann. tit. 22 § 7252 (West, Westlaw through 2014);
Md. Ann. Code Health-Gen. § 21-2A-04(a) (West, Westlaw through 2014);
Mass. Gen. Laws Ann. ch. 94C, § 24A (c)&(j) (West, Westlaw through 2014);
Mich. Comp. Laws Ann. § 333.733a(1) (West, Westlaw through 2014);
Miss. Code Ann. § 73-21-81 (West, Westlaw through 2014);
Mont. Code Ann. § 37-7-1512 (West, Westlaw through 2014);
N.C. Gen. Stat. Ann. § 90-113.73(b) (West, Westlaw through 2014);
N.D. Cent. Code Ann. § 19-03.5-02(2) (West, Westlaw through 2014);
N.D. Cent. Code Ann. § 19-03.5-09 (West, Westlaw through 2014);
Neb. Rev. Stat. Ann. § 71-2455 (West, Westlaw through 2014);
N.H. Rev. Stat. Ann. 318-B:37 (West, Westlaw through 2014);

N.J. Stat. Ann. § 45:1-51-52 (West, Westlaw through 2014);
N.Y. Pub. Health Law § 3343-a(9) (West, Westlaw through 2014);
Ohio Rev. Code Ann. §4729.84 (West, Westlaw through 2014);
Or. Rev. Stat. Ann. § 431.962(2) (West, Westlaw through 2014);
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S.D. Codified Laws § 34-20E-20 (West, Westlaw through 2014);
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Tex. Health & Safety Code Ann. § 481.076(c) (West, Westlaw through 2014);
Vt. Stat. Ann. tit. 18, § 4287 (West, Westlaw through 2014);
Vt. Stat. Ann. tit. 18, § 4289(e) (West, Westlaw through 2014);
Va. Code Ann. § 54.1-2520(B) (West, Westlaw through 2014);
Wash. Rev. Code Ann. § 700.225.025 (West, Westlaw through 2014);
W. Va. Code Ann. § 60A-9-6;
Wis. Stat. Ann. § 450.19(2) (West, Westlaw through 2014);
Wyo. Stat. Ann. § 35-7- 1023 (West, Westlaw through 2014).

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