MARYLAND ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING

OCTOBER 11, 2012
4:00PM TO 6:00 PM
ALCOHOL AND DRUG ABUSE ADMINISTRATION
55 WADE AVENUE
CATONSVILLE, MD 21228

Attendees

Advisory Board
Captain Daniel D. Alioto, Appointee
Janet M. Beebe, CRNP, Appointee
Shirley Devaris, designee of the President, Board of Nursing
J. Ramsay Farah, MD, MPH, Appointee
Vinu Ganti, MD, Appointee
Janet Getzey Hart, Appointee
Laura Herrera, MD, MPH, Designee of the Secretary of DHMH & Advisory Board Chair
Gail Amalia B. Katz, MPH, Appointee
Sharon Krumm, PhD, RN, designee of the Chair, Maryland Health Care Commission
Andrea Mathias, MD, Chair, Board of Physicians
Orlee Panitch, MD, Appointee
Howard R. Schiff, Appointee
Faryal Quereshi, PharmD, Appointee
Thelma B. Wright, MD, Appointee

Advisory Board Not Present
Hoover Adger, Jr., MD, MPH, MBA
Michael Souranis, President, Board of Pharmacy

Board Adjunct: Linda Bethman, JD, MA, Office of the Attorney General, DHMH

PDMP Staff
Michael Baier, PDMP Coordinator, ADAA
Tryphena Barnes, PDMP Secretary, ADAA

Public Attendees:
Dan Shattuck, Executive Director, Maryland Society of Anesthesiologist-
Nicole Ledbetter, US Health Group
Brian Rosen, Purdue Pharma
John Eadie, Brandeis University, Heller School/ Social Policy & Management
Michael Isaeff, Pharmacy Compliance Specialist-
Ken Fasulo, Delhaize America Shared Services Group, LLC
Krystal McBride

MINUTES

I. Roll Call, Agenda Review and Approval of Minutes: Meeting opened with roll call and agenda review by Michael Baier. There were no comments or changes to the minutes from the previous meeting requested. Michael stated that he would allow Board members more time to review minutes and send out a notification allowing for any comments or suggested changes.

II. Updates on Recent Activity: Michael Baier provided updates on recent PDMP implementation activity, including:

PDMP IT Procurement: DHMH continues to pursue a partnership with Chesapeake Regional Information System for our Patients (CRISP) to implement the PDMP. CRISP's role vis-à-vis that Department has evolved since its initial designation as the statewide health information exchange by the Maryland Health Care Commission. There are a number of other statewide agencies that want to work with CRISP for data collection and analysis purposes. . DHMH has been working with CRISP to put a new contractual framework in place which will affect us and any other entity that want to partner with CRISP in the future. CRISP has provided an initial budget proposal for PDMP implementation which is currently being reviewed.

2012 Harold Rogers PDMP Grant: ADAA was recently notified that its 2012 HRPDMP grant application to US Dept. of Justice had been awarded. The Grant was $400,000 dollars and budgeted as follows: $290,000 for the IT component of program, $100,000 for program evaluation and related cost and $10,000 dollars for travel and to support presentations and educational initiatives.

PDMP Presentations: Since the last meeting Michael has given PDMP presentations to the National Association of Drug Diversion Investigators, Calvert County Rx Abuse Abatement Council, Wicomico County Rx Abuse Task Force, and the Board of Dental Examiners.

Dr. Farah asked what role the local councils will play in PDMP implementation. Michael noted that DHMH is putting together an overdose prevention plan that will rely heavily on local collaborations to develop prevention and intervention strategies. Increase access to and use of the PDMP will be one aspect of the state's strategy.

Prescription Drug Disposal: ADAA will work with the Governor's Office of Crime Control & Prevention to track fixed controlled substance drop-off locations around the state and make this information available to the general public. ADAA has been receiving information on drop-off locations from jurisdictional prevention coordinators, but this often does not include sites that were established by law enforcement without the involvement of local health department prevention staff.

Captain Alioto stated that St. Mary's has had a box set up in their lobby for approximately one year and have already collected 131,000 pills. DEA have been taking up their collections and have been very accommodating in getting their collected pills to various disposal sites.

Linda Bethman noted that DEA is revising regulations to allow entities other than law enforcement, including healthcare facilities, pharmacies and nursing homes, to receive CDS for disposal.

PDMP Advisory Board Annual Report: The Board is required to submit an annual report to the General Assembly on the impact of the PDMP on patient access to pharmaceutical care and curbing prescription drug abuse, including any recommendations for modification or continuation of the program. The law also requires that the Board submit a report by December 1st on PDMP funding status, feedback from program stakeholders, recommendations for program improvements and whether a safe harbor provision is necessary to address patient access problems. As the program is not yet operational, DHMH would like to submit a letter to the General Assembly providing an update on implementation since the Interim Report from the Board rather than submit a new report. The Board approved of this approach.

III. Review of Comments on PDMP Proposed Regulations and DHMH Draft Responses: Michael Baier led a review of the public comments that were received on the proposed regulations for the PDMP and DHMH's draft responses to the comments (attached). The Board approved all draft responses. Dr. Herrera noted that the comments and responses will be published with the regulations.

IV. Educational Initiatives Planning: Michael Baier opened the meeting up to discussion of possible educational initiatives to coincide with PDMP roll out. Michael noted that the development of user manuals for the PDMP will have to await identification of all IT specifications for the system.

Dr. Wright asked whether she could give a presentation to the Maryland Society of Anesthesiology and/or MedChi about PDMP and its potential use in pain management. Dan Shattuck responded that he would be willing to have Dr. Wright present to MSA.

Dr. Herrera suggested querying other states' PDMPs to see what educational initiatives they had implemented. John Eadie noted that the PMP Training and Technical Assistance Center has materials to aid prescriber training that have been recently developed.

Nicole Ledbetter noted that she often provides physicians with information about their state's PDMP when meeting with them to discuss medication monitoring solutions that her company provides. She suggested that the PDMP's webpage have more information that was appropriate for prescriber education. Dr. Herrera noted that DHMH could work with MedChi and other professional societies to create a link between their webpages and an expanded PDMP site.

Dr. Mathias noted that the Board of Physicians would be willing to provide such a link and also suggested that ADAA do more to communicate to physicians the fact that the PDMP will be a reactive system rather than an active prescribing surveillance system.

V. Administrative Issues: Michael Baier noted that Technical Advisory Committee appointments will be a next step. Also, the next meeting will likely be the end of January or early February.

PDMP Regulations Comments & Proposed Responses
10/4/12

DEFINITIONS

Comment	Clarify exemption of drug administration from reporting requirement
Maryland Society of Anesthesiologists (Shattuck)	**.02 Definitions** There is a concern about the clarity of the proposed regulations as it impacts anesthesiologists who administer monitored prescription drugs during the course of a procedure or treatment in a hospital, office based setting and/or during an inpatient stay. While the definition of "Dispense" in this section excludes "(a) directly administering a monitored prescription drug to a patient; or... " nowhere else in the regulations do we see any explicit language that exempts or excludes reporting of monitored prescription drugs administered in the situation we describe above. Our goal is to ensure that there is enough clarity to avoid confusion on the roles and responsibilities of physician prescribers involved in direct patient care through the administration of monitored drugs.
RESPONSE	It is the Department's position that the purpose of excluding "directly administering a monitored prescription drug to a patient" from the definition of "dispense" was to exempt all instances of direct drug administration from the PDMP reporting requirement, including when anesthesiologists are administering monitored prescription drugs "during the course of a procedure or treatment in a hospital, office based setting and/or during an inpatient stay." Although the PDMP law did not include a definition of "administer," the Department will make the following non-substantive addition to the proposed regulations at 10.47.07.02(3) in order to clarify the exemption: "(a) directly administering a monitored prescription drug to a patient *in accordance with Health Occupations Article, §12-102(e), Annotated Code of Maryland*; or..." This citation includes a paragraph that defines "administering" as "the direct introduction of a single dosage of a drug or device at a given time, whether by injection or other means, and whether in liquid, tablet, capsule, or other form."

Comment	Exempt drug delivery within clinical trials from PDMP reporting
Maryland Society of Physical Medicine and Rehabilitation (Brokaw)	**Section .02 Definitions, B.,(3) Dispense (a), (b)** In addition to the definition of dispense we suggest adding letter (c) which would also exclude drugs administered and prescribed as a part of a clinical trial. The difficulty presented in reporting such drugs is that as the dispenser, especially in a blind trial, we are not aware of the actual dose and/or whether the patient is receiving a drug or a placebo. Many of the medications dispensed do not have a trade name, are not available to the

	general public with a prescription and are likely unknown to the general Physician community. There are already rigorous oversight and accountability requirements built into clinical trials. Specifically we propose that the section read as follows: (c) DIRECTLY ADMINISTERING OR DISPENSING A PATIENT A PRESCRIPTION DRUG(S) THAT IS PART OF A CLINICAL TRIAL APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.
Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Suggested Edit 7**: Add F. (7) to read, "Dispensing to patients enrolled in a clinical research trial provided that the dispensing pharmacy or prescriber has applied for and been granted a waiver by the Department pursuant to §G of this regulation." *Rationale*: Participants in a study are assured additional confidentiality measures, and the personal information collected could pose a risk to the confidentiality of clinical research.
RESPONSE	The definition of "dispense" included in the proposed regulations at 10.47.07.02(B)(3) is substantively identical to the definition found at Health General Article, § 21-2A-01(C), Annotated Code of Maryland. This was done to reiterate the General Assembly's determination regarding which types of monitored prescription drug delivery would qualify as "dispensing" under the PDMP law and therefore be required to be reported to the PDMP. The Secretary does not have the authority to add to or detract from the statutory definition of "dispense" in regulations. Inclusion of a blanket exemption from PDMP reporting for all monitored prescription drug delivery that takes place within clinical trials would therefore require a change to statute. However, the Department has determined that the majority, if not all, of the drug delivery that takes place within clinical trials would already be exempt from PDMP reporting under the current statutory definition of "dispense." Health General Article, § 21-2A-01(C)(1) cites the definition of "dispense" in § 12-101 of the Health Occupations Article," which includes the requirement that "dispensing" involve "(i)nterpretation of an authorized prescriber's prescription for a drug or device…" Given that drug delivery does not take place within clinical trials pursuant to a practitioner's prescription, but rather under an approved set of clinical protocols, this type of drug delivery would not qualify as "dispensing" under the PDMP law.

Comment	**Exempt dispensing to home infusion patients from the reporting requirement**
Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Suggested Edit 6**: Add F. (6) to read, "Dispensing to home infusion patients provided that the dispensing pharmacy has applied for and been granted a waiver by the Department pursuant to §G of this regulation." *Rationale*: The home infusion practice setting is in a controlled setting similar to hospital inpatient setting and is considered an extension of the hospital because these patients are discharged home to complete the infusion therapy. This controlled environment poses minimal risk for controlled substance misuse

RESPONSE	The reporting exemptions listed in the proposed regulations at 10.47.07.03(F) reiterate the exemptions created by the definition of "dispenser" in the PDMP law, Health General Article, § 21-2A-01(D), Annotated Code of Maryland. In this definition, the General Assembly created a reporting waiver that is available only to pharmacies dispensing to inpatient hospices and applicable only to their dispensing to hospice inpatients. The Secretary does not have the authority to create another waiver for dispensing to home infusion patients in regulations that does not exist in the statute. A specific exemption from reporting dispensing to home infusion patients would therefore require a change to statute.

Comment	**Exempt dispensing of a supply for a certain number of hours/days from reporting requirement**
Johns Hopkins Hospital (Holt) & Maryland Society of Health System Pharmacists (Davlin Swarthout)	Suggested Edit #2: Insert the following new statement between sections (i) and (ii) to read, "„Dispenser‟ does not include: (ii) a licensed hospital pharmacy or prescriber dispensing a monitored prescription drug to treat a patient for 48 hours or less." For consistency, this new statement would be inserted into section .03 Dispenser Reporting (page 4) F (2) as well. Rationale: A 48 hour starter supply that is dispensed after a professional evaluation poses minimal risk for controlled substance misuse. This proposed exemption is modeled after Michigan regulations (see attachment "Michigan Regulations R 338.3162e „Exemption from reporting requirements‟").
Sheppard Pratt (Walters)	Many of us fill "bridge" Rx's to carry a discharging pt over to their next outpatient appointment/prescription- especially when we are not going to be the care providers for that patient in the future. I suggest that any Rx intended for use less than "x # of days" (say, 5 or 7) be exempt from this regulation.
RESPONSE	The definitions of "dispense" and "dispenser" included in the proposed regulations at 10.47.07.02(B)(3) & (4) are substantively identical to the definitions found at Health General Article, § 21-2A-01(C) & (D), Annotated Code of Maryland. This was done to reiterate the General Assembly's determination regarding which types of monitored prescription drug delivery would qualify as "dispensing" under the PDMP law and therefore be required to be reported to the PDMP. The Secretary does not have the authority to add to or detract from the statutory definition of "dispense" in regulations. Inclusion of a specific exemption from PDMP reporting for dispensing of a certain amount of a monitored prescription drug would therefore require a change to statute. However, in accordance with the statutory definition, the definition of "dispense" in the proposed regulations excludes "Giving a patient prescription drug samples in accordance with Health Occupations Article, §12-102(d), Annotated Code of Maryland." The purpose of this exclusion was to alleviate the reporting requirement in situations where a dispenser was only providing a small amount of a drug to a patient. To qualify as a "sample" under this definition, the drug must be labeled in compliance

	with Health Occupations Article, § 12-505, provided to the patient at no charge and the prescriber must enter an appropriate record in the patient's chart.

Comment	Exempt all dispensing from hospital pharmacies from reporting requirement
MedStar Health (Townsend)	Section .02 B (4)(b)(i) specifies that the term "dispenser" does not include a licensed hospital pharmacy that only dispenses a monitored prescription drug for direct administration to an inpatient of the hospital. This exception should be broadened to include the emergency department, observation areas, operating rooms, procedural areas and hospital-based clinics. This change would reflect the fact that licensed hospital pharmacies dispense drugs in many different settings within the 4-walls of the hospital. The exclusion of licensed hospital pharmacies in the legislation was to reflect the fact that hospital pharmacies are distinctly different from the traditional retail pharmacy selling. They typically dispense medications by single dosage and are subject to very different requirements and oversight. Limiting the exemption to "inpatients at the hospital" would require hospital pharmacies to institute two separate systems and would negate the intent to recognize the unique nature of a hospital pharmacy. The dispenser is in fact the same entity within the hospital and the patients are patients of the hospital.
Johns Hopkins Hospital (Holt) & Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Section .02 Definitions (page 2) B. (4) (b) (i) – "„Dispenser‟ does not include: (i) a licensed hospital pharmacy that only dispenses a monitored prescription drug for direct administration to an inpatient of the hospital;"** Suggested Edit #1: Modify the definition of dispenser to, "(4b) „Dispenser‟ does not include: (i) a licensed hospital pharmacy that dispenses a monitored prescription drug for direct administration in the hospital including to the emergency department, observational areas, operating rooms, procedural areas, and hospital clinics." For consistency, this modified statement would replace section .03 Dispenser Reporting (page 4) F (1) as well. Rationale: This change also exempts an inpatient institutional pharmacy from reporting monitored medications that are directly administered within the facility to patients not admitted such as in the emergency department, observational areas, operating rooms, procedural areas, and hospital clinics. Without this exception, a high volume of hospital data would be temporary acute treatment administered onsite in outpatient areas (ED, OR etc.) It is unlikely that a patient could misuse controlled substances while controlled and directly administered by a licensed professional. This extra data detracts from the valuable surveillance of inappropriate use in the community.
RESPONSE	The definition of "dispenser" included in the proposed regulations at 10.47.07.02(B)(4) is substantively identical to the definition found in Health General Article, § 21-2A-01(D), Annotated Code of Maryland. This was done to reiterate the General Assembly's determination regarding which types of dispensers would receive blanket exemptions from reporting to the PDMP. Only hospital pharmacies that dispense monitored

	prescription drugs to hospital inpatients exclusively were given a blanket reporting exemption. The General Assembly did not intend to exempt outpatient dispensing by hospital pharmacies, as the risk of drug diversion from hospital-based outpatient pharmacies is similar to that of community pharmacies. The Secretary does not have the authority to add to or detract from the statutory definition of "dispenser" in regulations. Inclusion of a blanket exemption from PDMP reporting for hospital pharmacies would therefore require a change to statute. To the extent that monitored prescription drugs are administered directly to a patient in the emergency department, observational areas, hospital clinics, etc., such drug delivery will not be required to be reported pursuant to the exclusion of direct administration from the definition of "dispense." However, a drug dispensed from a hospital-based pharmacy to a patient who has not been admitted as an inpatient of the hospital or has been discharged will be required to be reported.

Comment	**Remove reporting exemption of pharmacies that serve long term care facilities**
Kimberly France	I simply want to register my objection to the exclusion of long-term care pharmacies from the reporting requirement. I recognize by virtue of their waiver status that they serve patients whose home and institution are the same. In this environment the patients are not the likely culprits in doctor shopping or prescription drug abuse, instead it is the staff. Those that have access to the drugs, orders etc. without the physician's knowledge. The pharmacies in my opinion and my personal experience could do more to secure the dispensing/distribution in this setting, given that almost half of the prescriptions dispensed are controlled substances.
RESPONSE	The definition of "dispenser" included in the proposed regulations at 10.47.07.02(B)(4) is substantively identical to the definition found in Health General Article, § 21-2A-01(D), Annotated Code of Maryland. This was done to reiterate the General Assembly's determination regarding which types of dispensers would receive blanket exemptions from reporting to the PDMP. The Secretary cannot add to or detract from these exemptions in regulations.

Comment	**Extend the reporting exemption for dispensing to hospice inpatients (upon issuance of a waiver from the Department) to include dispensing to home hospice patients**
Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Section .03 Dispenser Reporting (page 4) F. – Reporting Exemptions Suggested Edit 5**: Change the statement under Section .03 F (5) to read "Dispensing to hospice inpatients and home hospice patients provided that the dispensing pharmacy has applied for and been granted a waiver by the Department pursuant to §G of this regulation." *Rationale*: Hospice patients may be inpatients at a hospice facility or home hospice patients. The language change clarifies that both settings are included.
RESPONSE	Health General Article, § 21-2A-01(F)(1), Annotated Code of Maryland,

	states that, provided certain conditions are met, the Secretary "shall grant a waiver to a pharmacy that dispenses medications to an inpatient hospice from reporting to the Program prescription monitoring data for hospice inpatients…" By indicating that only pharmacies that dispense to "an inpatient hospice" may apply for the reporting waiver, and by specifying that the reporting waiver would only apply to dispensing to "hospice inpatients," the General Assembly made the reporting exemption applicable only to those patients admitted as inpatients to a hospice facility. As the scope of this exemption does not include dispensing to home hospice patients, the Secretary cannot expand the scope in regulations to include this class. A change to the PDMP law would be required for this purpose.

Comment	**Questioning the appropriateness of reporting exemption for opioid maintenance programs**
Maryland Society of Physical Medicine and Rehabilitation (Brokaw)	**Section .02 Definitions, B., (8) Opioid Maintenance Program** We recognize the intent to differentiate opioid maintenance programs; however we feel this is an area that needs to be closely watched upon implementation and may need to be revisited, While these programs are unique, it is unclear what the benefits are in excluding reporting. This is an area that needs ongoing discussion with stakeholders and the PDMP Advisory Board.
Kimberly France	I assume here is a methadone clinic or a facility that treats addiction/dependence. Pursuant to the approval of buprenorphine, many prescriptions to treat addiction/dependence are now dispensed in retail pharmacies. Is the purpose to exclude those prescriptions? When a prescriber is treating addiction/dependence he/she is supposed to have unique credentials to do so and should use those credentials when prescribing those drugs. Both methadone and buprenorphine are also prescribed frequently to treat pain. In those instances, the prescriber need only the state license, CDS license and DEA registration.
RESPONSE	In order to ensure that opioid maintenance programs maintain compliance with federal law and regulation, the federal Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration (SAMHSA) has advised that these programs not report patient-identifying information to state PDMPs. Recognizing the supremacy of federal law on this question, the General Assembly included a blanket exemption from the reporting requirement for these programs in Maryland's PDMP law. In September, 2011, SAMHSA provided a detailed explanation of the rationale for this exemption in a guidance document entitled "OTPs, PDMPs and Confidentiality Issues." The relevant section states: "State PDMPs collect and retain prescription drug information and disclose such information to legally authorized users. Most PDMP state laws

	require that providers who dispense more than a 48 hour supply of a schedule II-V controlled substance must report that transaction, including patient health information, to the State PDMP. Opioid Treatment Programs (OTP) and Drug Addiction Treatment Act of 2000 (DATA 2000)-Waived physicians are substance abuse treatment programs under the Federal confidentiality rules; therefore, disclosures of patient-identifying information by such programs to State PDMPs are not permitted unless an exception applies consistent with the federal confidentiality regulations. The legal framework established in the Public Health Service Act (42 U.S.C. 290dd-2) and Federal confidentiality regulations (42 CFR Part 2) protect records relating to a patient received or acquired by a federally-assisted substance abuse program, and include any information that could reasonably be used to identify an individual. Patient records may not be disclosed by federally-assisted substance abuse programs without patient consent, unless an exception specified in the regulations applies. State laws require PDMPs to establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information is protected and not disclosed to anyone who is not authorized to access this information…" **"May an OTP provide patient-identifying information to a PDMP under federal confidentiality rules?"** Disclosures of patient-identifying information by federally-assisted programs (including OTPs and DATA-waived physicians) are permitted with written patient consent under 42 CFR Part 2. However, redisclosures of such information is prohibited. Since one of the goals of PDMPs is to make information available to authorized users, currently it would not be feasible to ensure that the information will not be redisclosed. Therefore, OTPs and DATA-waived physicians should not disclose patient-identifying information to PDMPs. The question of disclosures of information to PDMPs with patient consent may be considered further by SAMHSA." It is important to note, however, that pharmacies are not covered under the definition of "treatment provider" in 42 CFR Part 2. Therefore, the State-law requirement that pharmacies report dispensing of buprenorphine prescriptions to the PDMP is still in effect, regardless of whether the prescription was written for the treatment of opioid dependence or any other condition.

DISPENSER REPORTING

Means of Reporting

Comment	Mandate the use of the American Society for Automation in Pharmacy (ASAP) PMP data standard for dispenser reporting
National Association of Chain Drug Stores (McCormack)	It is not clear to us if the Board intends to follow the ASAP standards. Various parts of the regulation do not follow the ASAP standards in regards to information that would be submitted. Our members have used significant resources to develop and format their systems to comply with the ASAP standards that is in use in all other states for their prescription monitoring programs. It would be quite difficult and costly for pharmacies to have to use non-ASAP standards. We ask that the rules be amended as needed to follow ASAP standards in accord with the process in other states.
RESPONSE	The Department is aware that most, if not all, currently operational state PDMPs that allow for electronic dispenser reporting require that data be reported in the American Society for Automation in Pharmacy (ASAP) PMP data standard. In developing the proposed regulations, the Advisory Board discussed the appropriateness of mandating use of the ASAP standard as other states have done in law or regulation. Given the rapidly changing nature of health information technology, it was determined that a regulatory mandate for a specific data standard would unduly limit the Department's ability to utilize the most efficient, accurate and novel means of data collection. Therefore, section 10.47.07.03(D) of the proposed regulations allows the Secretary to retain discretion over decisions regarding the details of the reporting process by stating that prescription monitoring data shall be transmitted to the Department "In a format or utilizing a data standard approved by the Department." Importantly, this does not prevent the Department from mandating use of the ASAP standard in Program guidelines, if appropriate. The Department is committed to developing a PDMP the employs standardized data exchange between dispensers, the Department and/or its agent and other stakeholders that will process or be given electronic access to prescription monitoring data. However, the specific standard that will be used will not be determined until the Department has identified the appropriate information technology to support PDMP data exchange in Maryland.

Data Elements

Comment	Simply/reduce the numbers of data elements required to be reported to the PDMP
Kaiser Permanente (Saha)	The proposed language includes a quite cumbersome list of detailed data elements that must be reported to the PDMP for each monitored prescription drug that is dispensed. These data elements are much greater in quantity and much more onerous than the reporting requirements of our neighboring

	jurisdictions. As mentioned previously, variations in reporting requirements between jurisdictions creates an undue financial burden on organizations who must invest in timely and costly programming changes to their computer and data systems to accommodate the differing reporting requirements in each jurisdiction. Standardizing the data elements that must be reported to a PDMP streamlines reporting, increases the ease of interoperability with neighboring jurisdictions, and alleviates any undue financial burden on organizations to come into compliance with the requirements of the PDMP. Therefore, Kaiser Permanente suggests the Alcohol and Drug Abuse Administration align the required data elements for reporting to the PDMP with those of neighboring jurisdictions. Specifically, Kaiser Permanente suggests the Alcohol and Drug Abuse Administration strike the language in 10.47.07.03(A) in its entirety in favor of the following: *"For each monitored prescription drug dispensed, the dispenser shall report the following prescription monitoring data to the Department:* *(1) The recipient's name and address;* *(2) The recipient's date of birth;* *(3) The covered substance that was dispensed to the recipient;* *(4) The quantity of the covered substance that was dispensed;* *(5) The date of the dispensing;* *(6) The prescriber's identifier number;* *(7) The dispenser's identifier number; and* *(8) The method of payment for the prescription.*
Sheppard Pratt (Walters)	Section.03 "Dispenser Reporting"- requires very specific info some of which is NOT part of our existing databases, so it would require additional technological support for pharmacists/pharmacies to be able to comply w/ this, OR if the state intends to supply an electronic reporting program, then Dispensers would have to install and maintain it, to insure system compatibility and data security. This potentially presents some financial and technical obstacles which need to be addressed.
RESPONSE	Almost all of the data elements listed in 10.47.07.03(A) of the proposed regulations were taken from those recommended by the Alliance of States with Prescription Monitoring Programs in its Model Act of 2010. The purpose of the Model Act is to provide states with a template PDMP legal framework that incorporates national best practices, including a list of required data elements that balance the current data collection and reporting capabilities of dispensers with the requirement that PDMPs provide useful information to authorized data recipients. The only data element mandated by the proposed regulations that is not included in the Model Act is the prescriber's last name; the Department has received feedback from pharmacy representatives that requiring reporting of this data element will not impose any significant marginal costs on dispensers. There is broad consensus among PDMP administrators and stakeholders across the country that increasing the quantity and quality of prescription monitoring data improves the ability of PDMPs to accurately identify unique patients in the database, therefore increasing the utility of the

	system for all authorized data recipients. The most recent version of the ASAP PMP data standard, used by most if not all PDMPs, allows for the reporting of all data elements in the proposed regulations. Similarly, many of the data elements that are included in the proposed regulations but not in the list provided (including National Drug Code, number of refills ordered, whether the prescription is new or a refill, number of refills ordered and prescription date) are required for state eligibility to receive grants under the DHHS, SAMHSA National All-Schedule Prescription Electronic Report (NASPER) program. The list above appears to have been taken from Virginia's PMP law (Chapter 25.2 of Title § 54.1-2521); it is important to note that this statute also mandates the reporting of "Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds." Virginia has recently augmented its list of required data elements (in regulations) in order to come into compliance with NASPER requirements. Delaware's recently established PDMP also requires a list of required data elements that is nearly identical to those in the proposed regulations.

Comment	**Remove "residential telephone number" from the list of possible patient identification numbers to be reported to the PDMP**
MedStar Health (Townsend), Johns Hopkins Hospital (Holt) & Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Section .03 Dispenser Reporting (page 4) A. (2) (f) – "A patient identification number, which may include: (ii) a residential telephone number"** Suggested Edit: Omit a residential telephone number from the patient identification number options. Rationale: A residential telephone number may not be unique and may refer to two or more patients in one household.
RESPONSE	10.47.07.03(A)(2)(f) of the proposed regulations includes a list of patient identification number types that dispensers may report to the PDMP to fulfill the required that some form of patient identification number be reported. It is important to note that the proposed regulations do not mandate that dispensers report any particular type of number, or even that they report a type that is included in the list. The Department will issue guidance for dispensers that conforms with best practice in the reporting of patient identification numbers. The purpose of requiring reporting of a patient identification number is to increase the amount of patient information available for analysis by the PDMP so that unique individuals can be accurately identified within the database. A particular patient identification number does not need to be unique to an individual (as is the case with a residential telephone number) in order to be useful for this purpose. Unique patient identification will be

	conducted by analyzing multiple pieces of patient information simultaneously, not by matching any one particular piece of information across multiple dispensing records. It is the Department's intention for the PDMP to utilize sophisticated data analysis technology that allows for matching of patient records with a high degree of accuracy. In situations where dispensers are not able to record an identification number that is unique to the patient, allowing for the reporting of identification numbers that, while not being wholly unique to a person, accurately identify an individual within a particular context (as with a number assigned to a patient by the dispenser's records management system) will greatly improve the accuracy of PDMP reports.

Comment	**Make the dispenser identification number type variable**
Kimberly France	0.03 Dispenser Reporting For #4 I recommend adding examples, Maryland CDS # or state license # rather than just repeating the DEA registration as in #3.
RESPONSE	Almost all of the data elements listed in 10.47.07.03(A) of the proposed regulations were taken from those recommended by the Alliance of States with Prescription Monitoring Programs in its Model Act of 2010, including the dispenser's DEA registration number. The Department is not aware of any state PDMP that does not require that dispensers report their DEA as a unique identifier. Also, the Department has received feedback from pharmacy stakeholders that the DEA number is a unique dispenser identification number that can easily be reported from dispenser systems. This may not be the case with the Maryland CDS permit number or pharmacy license number. For this reason, the Department chose to make DEA registration number the only mandatory dispenser identification number for reporting. However, the information technology employed to facilitate dispenser reporting may allow for the submission of other identification numbers in addition to DEA registration.

Reporting Deadlines

Comment	**Reduce the frequency of dispenser reporting by increasing the reporting timeframe from "3 business days" to 7 days.**
National Association of Chain Drug Stores (McCormack)	As written, the regulations call for reporting within 3 business days. We are asking the Board to change this to within 7 days. Most states have reporting within 7 days. Pharmacies could report earlier, but setting the required deadline at 7 days would aid pharmacies by maintaining consistency. It would also allow the Maryland program time to handle issues that may arise relative to reporting.
Kaiser Permanente (Saha)	The proposed language requires dispensers to report required information to the PDMP within three business days. A three business day reporting timeframe is not aligned with neighboring jurisdictions, such as Virginia, which currently require reporting within seven days of dispensing. For large pharmacy organizations whose networks expand across multiple

	jurisdictions, any variation in reporting timeframe requires resource allocation and costly programming changes to pharmacy software to accommodate these differences. While Kaiser Permanente understands the intent to require reporting to the PDMP as soon as possible, we also recognize that moving towards shorter reporting timeframes, and possible real time reporting, is a congregated effort amongst PDMPs across the nation. Due to national efforts to decrease reporting timeframes as technology advances, perhaps it is best for Maryland to align its reporting timeframe with that of neighboring jurisdictions at this time. As the national effort to decrease reporting timeframes comes to fruition, Maryland can decrease its reporting timeframe at that time to align itself with the other PDMPs across the nation. Therefore, to align the Maryland PDMP with neighboring jurisdictions, Kaiser Permanente would like to suggest that the Alcohol and Drug Abuse Administration consider striking the provision requiring reporting of PDMP data within three business days in favor of language that requires reporting to the PDMP within seven business days of dispensing a monitored prescription drug. Specifically, Kaiser Permanente suggests the Alcohol and Drug Abuse Administration consider the following language in 10.47.07.03(B)(1): "*A dispenser shall report prescription monitoring data to the Department no later than ~~3~~* **seven (7)** *business days after dispensing a monitored prescription drug."*
National Association of Chain Drug Stores (McCormack)	*Reporting Incomplete or Inaccurate Data* As written, the regulations would require pharmacies to correct and resubmit incomplete or inaccurate data within 3 business days after being notified by the Department. Due to the large volume of data submitted, the 3 day time period is problematic as it will likely take pharmacies longer to research and resubmit the data. Accordingly, we ask that the Board change this to 7 days.
Sheppard Pratt (Walters)	Although I understand the desire to be able to track usage quickly, it seems that this requirement would result in an enormous volume of data for the State to review and publish quickly. Since I have not seen the electronic program proposed to do this, I am at a disadvantage in trying to evaluate it. But if other states have such a monitoring system, I believe that it should be checked out to gauge its success, before Maryland initiates such a program. On the other hand, if other states have successfully implemented similar monitoring, then perhaps we should follow their model.
RESPONSE	The Department and the PDMP Advisory Board believe that a 3 business day reporting deadline represents a workable balance between the legislative mandate to limit the resource burden on dispensers and the Department's responsibility to provide timely, accurate prescription information to PDMP stakeholders. By requiring the same deadline for both initial dispenser reporting and reporting of corrected or updated dispensing information, the regulations will achieve consistency and reduce any incentive to achieve a longer reporting deadline through initial

	reporting of inaccurate information. If the dispenser is experiencing a technical or operational problem that prevents the resubmission of prescription monitoring data within the 3 business day deadline, 10.47.07.03(C) allows for the dispenser to request a waiver from the deadline. The Department and the Advisory Board recognize that 3 business day initial reporting deadline is shorter than what is currently required by most states. However, the national trend in prescription monitoring is clearly in the direction of increasing the timeliness of prescription monitoring data. States with newly operational PDMPs have required shorter deadlines than 3 business days, including Delaware which requires daily reporting. New York recently passed legislation that requires that state's PDMP to institute real time dispenser reporting in 2013. In its recent "white paper" on best practices in prescription monitoring, the PMP Center of Excellence at Brandeis University notes the importance of increasing the timeliness of data collection: "Ideally, PDMP data would be collected in real time, within a few minutes of a drug being dispensed. PDMPs across the country report increased demands from prescribers, particularly emergency department physicians, for prescription histories of their patients that are complete at the time of seeing a patient… Meanwhile, states can take incremental steps to reduce their data collection intervals from monthly to biweekly, weekly, or daily." The Department believes that the provision of timely prescription information (as close to real time as technology will allow) is essential to increasing the clinical utility of the PDMP, the primary public health goal of the program. Given the advances toward more timely data collection will take place state by state, it would be unreasonable to expect states to reduce reporting deadlines in unison.

Comment	**Increase the deadline for dispenser notification to the PDMP of a technical failure from 24 hours to 3 business days**
Johns Hopkins Hospital (Holt) & Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Section .03 Dispenser Reporting (page 4) B. (2) (a) – "Notify the Department, by a communications method approved by the Department, within 24 hours of discovery of the technical failure…"** Suggested Edit: "Notify the Department…within three business days of discovery of the technical failure…" Rationale: A technical failure could occur during the weekend or holidays when the pharmacy is closed. With three business days to report, failures resolved within the business day would not require Department notification.
RESPONSE	Part 10.47.07.03(B)(2) of the proposed regulations specify that only technical failures that preclude a dispenser's ability to report must be reported to the PDMP within 24 hours of discovery of the technical failure. If a technical failure is resolved within the same day that it occurred, it is highly unlikely that this failure will prevent the dispenser from meeting a reporting deadline. Therefore, notifying the PDMP of the failure will not be

	necessary. Importantly, the 24 hour deadline for notification begins once a dispenser has discovered a technical failure, not from when the failure actually occurred. A failure that happens when a pharmacy is closed, and is therefore not discovered until the next business day, will not have to be reported until a minimum of 24 hours after business operations have resumed.

DATA DISCLOSURE

Comment	**Re-label data disclosure sections**
Kimberly France	0.04 Disclosure of Prescription Monitoring Data I recommend adding Registration and Review to the title of this section or rewording A. to Disclosure pursuant to registration and H. to Disclosure to Federal agencies and J. Disclosure pursuant to review so that they are consistent with the other "lettered" sections within 0.04
RESPONSE	The Department believes that the current wording of 10.47.07.04 of the proposed regulations accurately conveys the terms and conditions of PDMP data disclosure while, to the greatest extent possible, maintaining a commitment to the principle of parsimony.

Comment	**Add "pharmacy" and "hospital" to the list of individuals and entities whose identifying information will be redacted from disclosures of prescription monitoring data for research, analysis, education and public reporting purposes.**
Sheppard Pratt (Walters)	Section .04B "Disclosure…of data"…Section I.(1) Disclosure…for Research…(c)"After redaction…" COMMENT- Please add, after "any other individual" the words "or pharmacy or hospital" to help to insure patient confidentiality.
RESPONSE	The language that governs redaction of identifying information upon disclosure of prescription monitoring data for research, analysis, education and public reporting purposes, found at 10.47.07.04(I)(1)(c), is taken directly from Health General Article, § 21–2A–06(E)(1)(i), Annotated Code of Maryland. The Department believes the inclusion of "dispenser" among the individuals and entities listed is sufficient to ensure that identifying information about both pharmacies and hospitals will not be disclosed for these purposes. Identifying information about pharmacies and hospitals will only be stored in the PDMP database in connection to their role as dispensers of monitored prescription drugs.

Comment	**Add "pharmacy" and "hospital" to the list of individuals and entities whose identifying information will be redacted from disclosures of prescription monitoring data for research, analysis, education and public reporting purposes.**
Sheppard Pratt (Walters)	Section .04B "Disclosure…of data"…Section I.(1) Disclosure…for Research…(c)"After redaction…" COMMENT- Please add, after "any other individual" the words "or pharmacy or hospital" to help to insure patient confidentiality.
RESPONSE	The language that governs redaction of identifying information upon disclosure of prescription monitoring data for research, analysis, education and public reporting purposes, found at 10.47.07.04(I)(1)(c), is taken directly from Health General Article, § 21–2A–06(E)(1)(i), Annotated Code of Maryland. The Department believes the inclusion of "dispenser" among the individuals and entities listed is sufficient to ensure that identifying information about both pharmacies and hospitals will not be disclosed for these purposes. Identifying information about pharmacies and hospitals will only be stored in the PDMP database in connection to their role as dispensers of monitored prescription drugs.

Comment	**Specify the turnaround time for response to prescription monitoring data requests by prescribers, dispensers and licensed health care practitioners authorized by a prescriber or a dispenser**
Maryland Society of Health System Pharmacists (Davlin Swarthout)	**Section .04 Disclosure of Prescription Monitoring Data (page 5) B. Disclosure of Prescription Monitoring Data to a Prescriber, a Dispenser, or an Authorized Licensed Health Care Practitioner** **Suggested Edit 9**: Clarify in statements (1), (2), and (3) the turnaround time in which the requested data will be provided to the requestor. Maryland Society of Health System Pharmacists would ask that this turnaround time would be a reasonable turnaround time, such as 3 business days, to allow for timely use of this information by health care practitioners to prevent misuse of controlled substances.
RESPONSE	It is the Department's intention to implement a PDMP that provides real time, electronic access to patient-specific prescription monitoring data to prescribers, dispensers and licensed health care practitioners authorized by a prescriber or a dispenser to access the PDMP on their behalf. In practice, this will mean that patient prescription history information will be available within seconds of submission of a request. The precise turnaround time for electronic disclosure of information in most cases will not be known until the information technology infrastructure of the PDMP has been implemented and tested. Therefore, the Department does not believe it would be appropriate to specify a turnaround time in regulations.

TECHNICAL ADVISORY COMMITTEE

Comment	Extend the timeframe for Technical Advisory Committee review of prescription monitoring data disclosure requests
Maryland Society of Physical Medicine and Rehabilitation (Brokaw)	**Section .04. J. Technical Advisory Committee Review (b)** We are concerned with the 10 business day turnaround time for the Technical Advisory Committee (TAC) to review a request and submit in written form guidance and interpretation. 10 business days may not be enough time to thoroughly examine the request, especially given the uncertainty of the number of requests that may be submitted at one time to the TAC. There needs to be consideration for a prioritization of requests and additional time granted for a review of each request. We therefore suggest the following changes noted in boldface: *"J. Technical Advisory Committee Review.* *(1) Before the Program discloses prescription monitoring data under COMAR 10.47.07.04C—E, G and H, the Technical Advisory Committee shall:* **(A) UPON RECEIPT OF A SUBMISSION SCHEDULE A REVIEW OF THE REQUEST AND IN THE EVENT OF A HIGH VOLUME OF REQUESTS ESTABLISH GUIDELINES TO PRIORITIZE REVIEWS;** *~~(a)~~ **(b)** Review the request for disclosure; and* *~~(b)~~ **(c)** Within ~~10~~ **15** business days of submission **REVIEW** of the request ~~to~~ **BY** the Technical Advisory Committee ~~for review~~, submit to the Program, in written form, clinical guidance and interpretation of the prescription monitoring data requested to:* *(i) Assist the Secretary's decision on how to respond to a judicial subpoena, administrative subpoena, or other request; and* *(ii) Be made available for use by the recipient of prescription monitoring data should the request for disclosure be authorized.* *(2) If the Technical Advisory Committee has not provided clinical guidance and interpretation within ~~10~~ **15** business days of ~~submission~~ **REVIEW** of the request, the Department may:* **(A) GRANT AN EXTENSION TO THE TECHNICAL ADVISORY COMMITTEE BEFORE PROCEEDING** *as if the Technical Advisory Committee does not have clinical guidance or interpretation to provide regarding the request at issue; and* *(b) Respond to the original request for disclosure."*
Maryland Society of Anesthesiologists (Shattuck)	**.04, J. Technical Advisory Committee Review** Regarding the work of the Technical Advisory Committee the timeline specified in the regulations of 10 business days to review and report on requests for data could be problematic. The thoroughness of a review could be hindered especially if a number of requests are received by the Committee within a short period of time. The TAC needs to have the flexibility to establish a schedule of reviews and prioritize requests in the event of numerous requests. We suggest that the TAC have 15 days to review and report, and that the 15 days begin not upon submission of the request, but from the date the review is scheduled. Suggested Language:

	J. (1) INSERT a new letter (a) to read: **UPON RECEIPT OF A SUBMISSION SCHEDULE A REVIEW OF THE REQUEST AND IN THE EVENT OF A HIGH VOLUME OF REQUESTS ESTABLISH GUIDELINES TO PRIORITIZE REVIEWS;** STRIKE the original (a) and INSERT **(b)** original text unchanged STRIKE the original (b) and INSERT **(c)** *Within ~~10~~* **15** *business days of ~~submission~~* **REVIEW** *of the request ~~to~~* **BY** *the Technical Advisory Committee ~~for review~~, submit to the Program, in written form, clinical guidance and interpretation of the prescription monitoring data requested to:* We also suggest that in **J. (b) 2** that before the Department may take action in absence of a report by the TAC that an extension be granted first. The goal of the TAC will be to complete its work as expeditiously as possible, but flexibility should be built in to allow for handling multiple requests and for the thorough review of all requests. Suggested Language: REPLACE J. (2) with the following: (2) If the Technical Advisory Committee has not provided clinical guidance and interpretation within ~~10~~ **15** business days of ~~submission~~ **REVIEW** of the request, the Department may: **(A) GRANT AN EXTENSION TO THE TECHNICAL ADVISORY COMMITTEE BEFORE PROCEEDING** as if the Technical Advisory Committee does not have clinical guidance or interpretation to provide regarding the request at issue; and (b) text unchanged
RESPONSE	The Department recognizes the important role that the Technical Advisory Committee (TAC) will play in providing insight on the clinical context of controlled substance prescribing and dispensing for PDMP data recipients that may not possess relevant medical expertise. However, the value of the TAC's advice and interpretation must be balanced against the Department's responsibility to provide access to data in a timely and efficient manner and the General Assembly's determination that the PDMP should be a useful tool for entities authorized to conduct lawful investigations into controlled substance diversion and fraud. The proposed regulations at 10.47.07.04(J) governing TAC review were written to provide sufficient structure to the review process, setting a timeframe based on clearly identifiable triggers while also allowing the TAC a degree of flexibility to prioritize requests if necessary. The 10 business deadline, triggered by submission of the request to the TAC, was included to give the TAC ample time to review the request while also providing the requester with a clear expectation for when a determination would be made about whether data disclosure will be authorized. The Department has received feedback from law enforcement professionals and public health officials that a deadline longer than 10 business days will significantly reduce the utility of the PDMP for

	investigative purposes; investigators can often access the original pharmacy records (upon which dispenser reports to the PDMP are based) in significantly less time than 10 business days. Similarly, changing the trigger for the 10 business day deadline from submission of the request to the TAC to the beginning of review by the TAC will introduce a great degree of ambiguity into the review process. As the need to expedite disclosure in many cases would make it impractical for the TAC to formally meet to review every disclosure request, the need to determine precisely when review commenced on a case-by-case basis would pose an undue burden on PDMP administrative staff and the efficient operation of the Program. It is important to note that, compared to those of other states, Maryland's PDMP law imposes a high bar for access to data by investigative authorities. Many states allow law enforcement, licensing boards and public health officials direct, electronic access to prescription monitoring data with the only requirement that an investigation already exist before database query. In Maryland, law enforcement and the licensing boards will need a subpoena pursuant to an existing investigation; in the case of the licensing boards, that subpoena will need to be approved by a quorum of the board. The Department believes that these protections are sufficient to ensure that the vast majority of data requests from investigative authorities will have been properly vetted to be in compliance with applicable law and regulation. For the few requests where legitimacy is questionable, the Secretary has the authority to request that the Office of the Attorney General seek appropriate injunctive relief to prevent disclosure. The General Assembly did not create the TAC to impose an additional barrier to access by investigative authorities, but rather to improve the quality of legitimate investigations duly authorized to receive prescription monitoring data. Finally, the Department does not believe that it is necessary to include any provision for the granting of an extension for TAC review. The proposed regulations preserve the Secretary's discretion to respond as he or she sees fit following expiration of the 10 business day deadline, including whether to allow the TAC more time to review the request.

INTEROPERABILITY

Comment	**Allow agreements with third party interstate data hub operators in addition to other state's PDMPs**
Kaiser Permanente (Saha)	The proposed language incorporates the ability of the Program to enter into agreements with other states' PDMPs for the purpose of interoperability. Kaiser Permanente views this as an essential element to further deter prescription drug abuse, especially since we are in the midst of a transient community. As the country moves towards developing and implementing a national PDMP database, however, it may be cumbersome to enter into individual agreements with forty-nine other states and the District of

	Columbia. Therefore, Kaiser Permanente would like to suggest the Alcohol and Drug Abuse Administration consider adding language to allow the Program to enter into agreements with third parties who operate interstate PDMP exchanges to minimize the need for individual agreements and to allow for efficient incorporation into a national database. Specifically, Kaiser Permanente suggests the Alcohol and Drug Abuse Administration consider amending the language in 10.47.07.04(G)(2) as follows: *"The Program may **enter into written agreements with other states' prescription drug monitoring programs or third parties who operate interstate prescription drug monitoring exchanges for the purpose of interoperability** ~~develop and implement interoperability with another state's prescription drug monitoring program~~ to facilitate the automated exchange of prescription monitoring data provided that a written agreement has been established with the other state's program **or third party operator** specifying that the information technology employed will:* *(a) Only disclose prescription monitoring data to registered users of the other state's **or third party operator's** program in a manner consistent with the provisions of Health-General Article, §21-2A-06, Annotated Code of Maryland, and this regulation; and* *(b) Operate in accordance with all other State and federal laws and regulations governing the security and confidentiality of protected health information and personal medical records."*
RESPONSE	Discussions with other states' PDMP administrators and interstate data sharing hub operators indicates that states that wish to develop interoperable/automated interstate data sharing will typically enter into an MOU with the entity that controls a particular hub. These MOUs govern the specific circumstances under which the hub entity will disclose a state's PDMP data pursuant to a request from another state's program. In this sense, the hub entity acts as the agent of a state's PDMP in relation to other states' programs. The Department believes that the current language in proposed regulations is sufficient to allow the Department to establish an agreement directly with another states' program or a hub entity operating as the agent of that state's PDMP for the purpose of interoperability.

CONFIDENTIALITY

Comment	**Can the Department conduct reviews of PDMP data to identify patterns of drug abuse?**
Kimberly France	0.06 Confidentiality I noticed that this is the only place where audits are mentioned and it is for the purpose of ensuring confidentiality. Is that the intention? Is it not within

	the program's purview to conduct periodic audits/reviews to look for patterns of abuse? As I read them it appears that the program exists only to register, collect data and disclose upon request.
RESPONSE	The PDMP law does not allow for pro-active disclosure of PDMP data by the Department. The circumstances of allowable disclosure of personally identifying information are tightly restricted, and in all cases must be in reaction to an authorized/approved request. The law does not prevent the Department from analyzing PDMP to identify patterns of potential controlled substance abuse (including doctor and pharmacy shopping). Such analyses could be used be units of the Department and external persons (with DHMH IRB approval, under the proposed regulations) for research, public reporting and educational purposes. However, any data disclosed or published in this manner must not identify a patient, prescriber, dispenser or any other person.

PENALTIES AND SANCTIONS

Comment	**Add language from the PDMP law relevant to prescriber liability for redisclosure of data**
Maryland Society of Physical Medicine and Rehabilitation (Brokaw) & Maryland Society of Anesthesiologists (Shattuck)	**Section .07 Penalties and Sanctions, A., B., and C.** This section needs clarity as it is unclear in what circumstances information can be shared. In the law as passed there was language to clarify under what circumstances a prescriber or dispenser can share data. We suggest including that language as letter D. in this section. D. 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 HEALTH-GENERAL, ARTICLE, §21-2A, ANNOTATED CODE OF MARYLAND.
RESPONSE	The Department will include the language from Health General Article § 21-2A-09(B)(3) in the proposed regulations at 10.47.07.07(D) as requested.

NOTICE TO PATIENTS

Comment	**Notice to patients issue**
Sheppard Pratt (Walters)	Section .05 “Notice to Patients”- This applies to Dispensers or Prescribers- COMMENT: This says “In lieu of posting a sign” we “may provide such notice in written material to the patient”. The problem here is that we may not know at the time we provide the prescription and/or medication that we intend to investigate the patient’s background on a SUBSEQUENT visit,

	when we would NOT be providing a prescription or medication. Thus it seems we would not be able to meet this provision and so would be in violation of it.
RESPONSE	The "notice to patients" described at 10.47.07.05 of the proposed regulations is not mandatory for either prescribers or dispensers. The section provides guidance on possible notification procedures should a prescriber or dispenser choose to provide notice.

NOT DIRECTLY RELATED TO REGS

Comment	When will the PDMP be implemented?
MedStar Health (Townsend)	Given the state is providing the technology needed to implement dispenser reporting of monitored prescription drugs, what is the estimated timeframe for implementation?
Maryland Society of Health System Pharmacists (Davlin Swarthout)	In light of the state provided technology needed to implement dispenser reporting of monitored prescription drugs, what is the date that reporting is expected to be implemented? As noted in the proposal, some outpatient pharmacies will need time and resource to create the infrastructure for reporting. MARYLAND SOCIETY OF HEALTH SYSTEM PHARMACISTS asks that outpatient pharmacies are given sufficient time to implement these infrastructure reporting changes before the regulations are enacted. This planning period should be at least 6 months in length.
RESPONSE	The Department plans to have a fully operational PDMP by the summer of 2013. Implementation will likely begin at the end of 2012 or beginning of 2013. All dispensers that will be subject to the reporting requirement will be notified well before the requirement will go into effect and be provided with detailed instructions on how maintain compliance.

Comment	Exempt dispensing of Schedule V controlled substances from the reporting requirement
Sheppard Pratt (Walters)	This seems like an incredible amount of work for Schedule 5 Controlled Substances that are basically not being abused-so I suggest Schedule 5 Controlled Substances be exempt from this regulation. If there is a concern about any particular drug in the future, the Board of Pharmacy or DHMH could re-classify the drug in Maryland.
Pfizer, Inc. (Gill)	While we support the establishment of regulations that "monitor the prescribing and dispensing of controlled dangerous substances and make this information available to controlled substance prescribers and dispensers, law enforcement" etc., we are concerned that the monitoring requirements for controlled dangerous substances may reduce access to non-opioid products, non-narcotic treatments for pain. An exemption of Schedule V, or more specifically those Schedule V categories with no

	opioids from new requirements, would help ensure this regulation does not inadvertently reach into areas which are not the focus of abuse and would ensure that patients in need of those medicines are not impacted. Schedule V drugs are particularly important for patients with chronic painful conditions such as fibromyalgia, painful diabetic peripheral neuropathy, post-herpetic neuralgia, as well as life threatening diseases such as epilepsy. Restrictions for Schedule V substances, particularly those that do not contain narcotics, impose unnecessary restrictions on medications indicated for the treatment of life threatening or serious painful conditions. These restrictions may have the effect of diminishing the quality of care for these patients, and have little or no tangible benefits. Currently, the following 18 states exempt Schedule V from Prescription Drug Monitoring Programs: Arizona, California, Florida, Iowa, Kansas, Maine, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Vermont, Virginia, Wyoming.
RESPONSE	The definition of "monitored prescription drug" found in Health General Article § 21-2A-01(F) includes Schedule V controlled dangerous substances. The Secretary cannot remove the reporting requirement for Schedule V drugs in regulations.