January 6, 2020

The Honorable Larry Hogan  
Governor  
100 State Circle  
Annapolis, MD 21401-1925

The Honorable Bill Ferguson  
President of the Senate  
H-107 State House  
Annapolis, MD 21401-1991

The Honorable Adrienne A. Jones  
Speaker of the House  
H-101 State House  
Annapolis, MD 21401-1991

RE: Health-General § 21-2A-05(f)(3) – Annual Prescription Drug Monitoring Program Report

Dear Governor Hogan, President Ferguson, and Speaker Jones:

Pursuant to Health-General § 21-2A-05(f)(3), Annual Prescription Drug Monitoring Program Report, the Maryland Department of Health respectfully submits the attached report detailing the status of the Prescription Drug Monitoring Program on behalf of the Advisory Board on Prescription Drug Monitoring.

If you have any questions about this report, please contact me or my Chief of Staff Tom Andrews at 410-767-0136 or Thomas.andrews@maryland.gov.

Sincerely,

Robert R. Neall  
Secretary
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Introduction

Title 21, Subtitle 2A of the Health-General Article [enacted by Senate Bill (SB) 883, Chapter 166 of the Acts of 2011] requires that the Maryland Department of Health (Department) create a Prescription Drug Monitoring Program (PDMP or Program) to reduce the misuse, abuse, and diversion of prescription drugs throughout the State. The duties of the PDMP, as outlined in the PDMP law, include:

- Monitoring dispensed prescriptions that contain controlled dangerous substances (CDS);
- Maintaining an electronic database of CDS prescription information; and
- Making these data available to statutorily-defined groups of individuals and entities responsible for ensuring the health and welfare of patients and the lawful use of CDS.

In 2019, the Program expanded outreach to clinical users to support the implementation of the PDMP use mandate, supported integrating the PDMP into providers’ clinical workflow, and transitioned to a new vendor to host the PDMP. The Chesapeake Regional Information System for our Patients (CRISP), the State-designated health information exchange (HIE), and the Department’s PDMP information technology provider, issued a Request for Proposal (RFP) on August 31, 2018 to solicit a partner to provide PDMP technology solutions that have the capability to integrate with the CRISP HIE core infrastructure. Transitioning to a new innovative technology partner allows the Program to meet the evolving statutory requirements of the PDMP and keep up with national best practices.

On January 18, 2019, the contract was signed with NIC to use their platform, RxGov, for pharmacies and dispensing prescribers to upload CDS dispenses, investigative users to make requests, and Program staff to perform administrative reporting functions. The migration for dispensers and investigative users from the legacy product to NIC’s RxGov was finalized in June, 2019 and administrative reporting dashboards and functionality are still undergoing programing and testing. Clinical users continue to view PDMP data through CRISP. The transition has implications for pharmacists and dispensing prescribers who dispense in or into Maryland, investigative users, prescribers through the development of new clinical tools, and Program staff. The transition to the new vendor has resulted in an improved process for investigative requests and the development of new clinical tools to support prescribers in their CDS prescribing decisions.

Section 21-2A-05 of the Health-General Article provides for the creation of the Advisory Board on Prescription Drug Monitoring (Board). The Board is composed of a diverse array of stakeholders. The Board has met regularly since the membership was first appointed in autumn 2011, and has provided feedback and recommendations on several topics, including regulations,
information technology (IT), interstate data sharing and interoperability, program evaluation, funding, and educational initiatives. The current Board membership is listed in Attachment A.

Section 21-2A-05(f)(3) of the Health-General Article requires that the Board provide annually to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly a report that includes:

I. The number of prescribers and prescriber delegates registered with and using the Program
II. The number of pharmacists and pharmacist delegates registered with and using the Program
III. The number of disclosures made to federal law enforcement agencies or State or local law enforcement agencies
IV. An analysis of the impact on the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State; and
V. 1. The number of providers, by provider type, who received outreach and education from the Program
   2. The number of cases for which the providers received outreach and education from the Program
VI. 1. The number of cases that were identified for Technical Advisory Committee review before referral to the Office (Office of Controlled Substances Administration)
   2. The number of providers, by provider type, involved in the cases
VII. 1. The number of cases that were referred to the Office for further evaluation and the outcomes of the Office evaluations
   2. The number of providers, by provider type, involved in the cases
VIII. Any recommendation related to modification or continuation of the Program.

In addition to sections I-VIII listed in Section 21-2A-05(f)(3) of the Health-General Article, the 2019 Maryland PDMP Annual Report includes a new section on the PDMP’s Technical Advisory Committee. House Bill (HB) 466 (Chapter 364, 2019) requires the 2019 Annual Report to report on the Technical Advisory Committee, including:

1. The written protocols for Technical Advisory Committee meetings and the procedures for reviewing unsolicited reports and investigative data requests (Attachment B);
2. A summary of Technical Advisory Committee meetings since the implementation of Chapter 147 of the Acts of the General Assembly of 2016; and
3. Recommendations on any changes necessary for the Technical Advisory Committee to meet the needs of the Prescription Drug Monitoring Program.
HB 466 (Chapter 364, 2019) requires the 2020 Maryland PDMP Annual Report to report on the recommendations not enacted by HB 466 made by the Department of Legislative Services in the December 2018 publication “Sunset Review: Evaluation of the Prescription Drug Monitoring Program”.

Clinical User Registration and Access of PDMP Data

The first two requirements of the report rely on registration and user statistics as follow:

I. The number of prescribers and prescriber delegates registered with and using the Program
II. The number of pharmacists and pharmacist delegates registered with and using the Program

As the largest group of end users, Maryland clinicians are key PDMP stakeholders. CRISP provides registration and access services for healthcare providers to view PDMP data. Clinical users access PDMP data through CRISP’s clinical query portal in a view called ‘PDMP Search’, or, increasingly, through an integration within an electronic health record (EHR). Integrations can take multiple forms and may navigate a registered PDMP clinical user to the PDMP search view from their EHR or may display PDMP data in a view without any further clicks. In 2019, the Program continued to implement enhancements to clinical user access to PDMP data. The program enhancements, funded by a combination of Federal grants and State general funds, were necessary to support clinical user adoption of the use mandate, build clinical tools to support prescribing practices, and improve the quality and timeliness of PDMP data.

Under HB437 (Chapter 147, 2016), all CDS prescribers and pharmacists licensed to dispense CDS in Maryland must be registered with the PDMP by July 1, 2017. Effective February 15, 2018, a prescriber must be PDMP registered before being issued a new or renewal CDS Registration by the Office of Controlled Substances Administration (OCSA). Prescribers must renew their CDS Registration every three years. Delegates, for both prescribers and pharmacists, are not subject to a registration mandate. As of August 31, 2019, over 87% of the individuals (86.29% of prescribers and 90.85% of pharmacists) have registered as required by the mandate.

Table 1 shows the total number of registered accounts, by user type, including providers who may reside out of state but have a Maryland CDS registration. Table 2 shows the number of total registrants across all user categories as of August of 2018 and 2019. Table 3 shows the number of registered prescribers and pharmacists by jurisdiction of the registrant.

The use mandate, impacting both prescribers and pharmacists, went into effect July 1, 2018. Prescribers and pharmacists are required to query the PDMP in certain prescribing and dispensing situations. Delegates, for both prescribers and pharmacists, are not subject to the use mandate. Table 4 shows the monthly total clinical PDMP queries across all user categories between January and August of 2019.
Table 1. Registered Clinical PDMP Users.

<table>
<thead>
<tr>
<th>Type of User</th>
<th># of Registered Users*</th>
<th># Individuals subject to Registration Mandate</th>
<th>% of Individuals who are PDMP Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber</td>
<td>32,135</td>
<td>37,242</td>
<td>86.29%</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>11,125</td>
<td>12,246</td>
<td>90.85%</td>
</tr>
<tr>
<td>Total Subject to Mandate</td>
<td>43,260</td>
<td>49,488</td>
<td>87.42%</td>
</tr>
<tr>
<td>Prescriber Delegates</td>
<td>9,672</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pharmacist Delegates</td>
<td>1,154</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* Number of Registered Users is current as of August 31, 2019

Table 2. CRISP Number of Registrants by User Category as of August 2018 & 2019

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of Registered Users</th>
<th>Prescriber</th>
<th>Prescriber Delegate</th>
<th>Pharmacist</th>
<th>Pharmacist Delegate</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2018</td>
<td>65,221</td>
<td>44,968</td>
<td>8,007</td>
<td>11,223</td>
<td>1,023</td>
</tr>
<tr>
<td>August 2019</td>
<td>73,919</td>
<td>51,412</td>
<td>9,672</td>
<td>11,681</td>
<td>1,154</td>
</tr>
</tbody>
</table>

Table 3. Prescriber and Pharmacist Registration Rates by Local Jurisdiction

<table>
<thead>
<tr>
<th>Jurisdiction*</th>
<th>Prescriber Registration Rate (# registered active CDS prescribers / # active CDS prescribers)</th>
<th>Pharmacist Registration Rate (# registered licensed pharmacists / # licensed pharmacists)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statewide</td>
<td>86.32% (31,696 / 36,715)</td>
<td>89.49% (6,477 / 7,238)</td>
</tr>
<tr>
<td>Allegany</td>
<td>83.88% (406 / 484)</td>
<td>93.85% (61 / 65)</td>
</tr>
<tr>
<td>Anne Arundel</td>
<td>90.52% (2,625 / 2,900)</td>
<td>92.35% (543 / 588)</td>
</tr>
<tr>
<td>Baltimore</td>
<td>87.56% (4,814 / 5,498)</td>
<td>91.29% (1,006 / 1,102)</td>
</tr>
<tr>
<td>Baltimore City</td>
<td>82.63% (6,687 / 8,093)</td>
<td>81.32% (418 / 514)</td>
</tr>
<tr>
<td>Calvert</td>
<td>88.06% (273 / 310)</td>
<td>96.08% (49 / 51)</td>
</tr>
<tr>
<td>Caroline</td>
<td>86.36% (57 / 66)</td>
<td>100.00% (16 / 16)</td>
</tr>
<tr>
<td>Carroll</td>
<td>92.64% (579 / 625)</td>
<td>92.79% (193 / 208)</td>
</tr>
<tr>
<td>Cecil</td>
<td>80.73% (331 / 410)</td>
<td>100.00% (44 / 44)</td>
</tr>
<tr>
<td>Charles</td>
<td>79.77% (481 / 603)</td>
<td>91.67% (77 / 84)</td>
</tr>
<tr>
<td>Dorchester</td>
<td>91.09% (92 / 101)</td>
<td>100.00% (22 / 22)</td>
</tr>
<tr>
<td>Frederick</td>
<td>88.85% (1100 / 1238)</td>
<td>93.70% (253 / 270)</td>
</tr>
<tr>
<td>Garrett</td>
<td>70.63% (89 / 126)</td>
<td>95.83% (23 / 24)</td>
</tr>
<tr>
<td>Harford</td>
<td>90.92% (921 / 1013)</td>
<td>94.86% (314 / 331)</td>
</tr>
<tr>
<td>Howard</td>
<td>88.97% (1460 / 1641)</td>
<td>90.94% (994 / 1,093)</td>
</tr>
<tr>
<td>Kent</td>
<td>90.36% (75 / 83)</td>
<td>100.00% (10 / 10)</td>
</tr>
<tr>
<td>Montgomery</td>
<td>87.15% (6,450 / 7,401)</td>
<td>86.11% (1,358 / 1,577)</td>
</tr>
</tbody>
</table>
Prince George's 84.98% (2,919 / 3,435) 85.03% (670 / 788)
Queen Anne's 91.92% (91 / 99) 92.50% (37 / 40)
Saint Mary's 85.84% (291 / 339) 94.00% (47 / 50)
Somerset 91.80% (56 / 61) 100.00% (10 / 10)
Talbot 87.26% (315 / 361) 88.10% (37 / 42)
Washington 86.59% (736 / 850) 95.40% (83 / 87)
Wicomico 86.89% (643 / 740) 95.54% (150 / 157)
Worcester 86.13% (205 / 238) 95.38% (62 / 65)

* Registered prescriber jurisdiction is assigned based on the zip code of the address self-reported to the OCSA.

Table 4. Number of PDMP Queries in CRISP Across all User Categories by Month

<table>
<thead>
<tr>
<th>Month</th>
<th>InContext1</th>
<th>InContext (data returned)2</th>
<th>SSO to PDMP Search3</th>
<th>PDMP Search4 - Prescribers</th>
<th>PDMP Search - Prescriber Delegates</th>
<th>PDMP Search - Pharmacists</th>
<th>PDMP Search - Pharmacist Delegates</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>3,405,809</td>
<td>1,154,614</td>
<td>24,709</td>
<td>130,801</td>
<td>62,464</td>
<td>63,580</td>
<td>3,920</td>
</tr>
<tr>
<td>February</td>
<td>3,037,110</td>
<td>1,103,973</td>
<td>19,186</td>
<td>111,131</td>
<td>50,119</td>
<td>56,930</td>
<td>3,399</td>
</tr>
<tr>
<td>March</td>
<td>3,320,621</td>
<td>1,191,183</td>
<td>19,430</td>
<td>120,586</td>
<td>55,195</td>
<td>59,899</td>
<td>3,835</td>
</tr>
<tr>
<td>April</td>
<td>3,315,248</td>
<td>1,172,748</td>
<td>19,432</td>
<td>125,564</td>
<td>54,761</td>
<td>59,016</td>
<td>3,903</td>
</tr>
<tr>
<td>May</td>
<td>3,691,557</td>
<td>1,304,076</td>
<td>19,813</td>
<td>121,445</td>
<td>52,270</td>
<td>60,050</td>
<td>4,128</td>
</tr>
<tr>
<td>June</td>
<td>3,367,082</td>
<td>1,261,594</td>
<td>12,470</td>
<td>107,250</td>
<td>54,677</td>
<td>55,552</td>
<td>3,906</td>
</tr>
<tr>
<td>July</td>
<td>3,722,182</td>
<td>1,365,458</td>
<td>11,942</td>
<td>111,252</td>
<td>67,307</td>
<td>61,480</td>
<td>4,048</td>
</tr>
<tr>
<td>August</td>
<td>4,150,431</td>
<td>1,497,009</td>
<td>10,892</td>
<td>101,842</td>
<td>73,228</td>
<td>58,969</td>
<td>4,608</td>
</tr>
<tr>
<td>Total</td>
<td>28,010,040</td>
<td>10,050,655</td>
<td>137,874</td>
<td>929,871</td>
<td>470,021</td>
<td>475,476</td>
<td>31,747</td>
</tr>
</tbody>
</table>

1. ‘InContext’ total includes all calls for PDMP data from a ‘zero-click’ integration by a registered PDMP clinical user. **regardless** of whether PDMP data was returned and displayed.
2. ‘InContext (data returned)’ only includes calls for PDMP from an InContext integration by a registered PDMP clinical user and when PDMP data was available to return and display.
3. ‘SSO to PDMP Search’ includes all PDMP queries using a ‘one-click’ single-sign on from an EHR to the PDMP Search within the CRISP clinical query portal.
4. ‘PDMP Search’ totals include queries made by a user in the PDMP Search user interface hosted within the CRISP clinical query portal.

In 2019, the Program continued to expand the data and resources available for clinical users through CRISP. The program continues to work to expand interstate data sharing by partnering with a new data-sharing hub which will expand the options for sharing data with other states. In 2019, CRISP will complete programming to accommodate a state-by-state list,
allowing providers to select states’ prescription data they wish to view when querying a patient’s CDS prescription history.

**Analysis of Impact of the Program**

This section of the report addresses the following reporting requirements:

III. The number of disclosures made to federal law enforcement agencies or State or local law enforcement agencies

IV. An analysis of the impact on the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State; and

Key components of the Program include enabling end users to make better use of the PDMP data in decision-making or actions to combat the opioid crisis.

**INVESTIGATIVE USER REGISTRATION AND USE DATA**

Under the PDMP law, the Program may disclose PDMP data to local, State, or Federal law enforcement agencies, Maryland’s health professional licensing boards, and four agencies within the Department (the Office of the Inspector General, Office of Health Care Quality, Medicaid, and Office of Controlled Substances Administration), to further existing, bona fide, individual investigations. Under HB 466 (Chapter 364, 2019), the Office of the Chief Medical Examiner was removed from the list of agencies within the Department that could receive PDMP data to further an existing, bona fide, individual investigation and will be allowed to access prescription monitoring data in accordance with §5-309 of the Health General Article pending the promulgation of regulations.

PDMP data is also disclosed to fatality review teams to further existing case review. **Table 5** shows the breakdown of investigative user accounts and total number of valid investigative data requests by user type: Federal, State, or local law enforcement; licensing board; Department agency; or fatality review team. All individuals who receive prescription data on behalf of the aforementioned investigative entity are trained by the Program on the purposes and uses of the PDMP and how to submit investigative requests to the PDMP. This training is required prior to receiving a unique investigative user account. The Program offers the training as a pre-recorded webinar as of June 13, 2019 when the PDMP migrated to the new investigative user platform, created by RxGov. Before the migration, the training was offered monthly for new investigative users; by offering a pre-recorded webinar, the Program is able to more efficiently use time and resources.

Individuals who receive prescription monitoring data in support of Overdose Fatality
Review (OFR) access PDMP data through an OFR Dashboard. Access to the OFR Dashboard is limited to Local Health Department Overdose Fatality Review teams and Department of Health staff who offer program support and technical assistance. Figure 1 shows monthly requests by requestor type submitted to the Maryland PDMP from January 1, 2018 through August 31, 2019.

Table 5. Total Number of Cumulative Investigative User Accounts and Cumulative Requests Submitted to Maryland PDMP

<table>
<thead>
<tr>
<th>Investigative Agency Type</th>
<th># of Registered Users</th>
<th># of Requests Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current Credentialed Users Aug 2019</td>
<td>Entire Program Calendar Year 2019 thru August</td>
</tr>
<tr>
<td>Federal, State, Local Law Enforcement</td>
<td>43 150</td>
<td>808 3,061</td>
</tr>
<tr>
<td>Licensing Board</td>
<td>10 71</td>
<td>117 331</td>
</tr>
<tr>
<td>Department Agency</td>
<td>3 32</td>
<td>142 195</td>
</tr>
<tr>
<td>Fatality Review</td>
<td>44* 85</td>
<td>288* 923*</td>
</tr>
<tr>
<td>Total</td>
<td>100 338</td>
<td>1355 4510</td>
</tr>
</tbody>
</table>

*Before May 2019, Overdose Fatality Review requests were submitted in both RxSentry, the platform before RxGov, and the OFR Dashboard. OFR PDMP requests and users from both platforms have been combined for the total.

Figure 1. Monthly Investigative Data Requests by Investigative Agency
Tracking population-level changes in the volume of prescriptions dispensed in or into Maryland is important for assessing the impact of the Program. The number of all Schedule II – V CDS prescriptions dispensed in or into Maryland and reported to the PDMP in corresponding time periods of years 2014 - 2019 (January 1 – August 31 of each year) is shown in Table 6. Prescriptions reported to the PDMP were dispensed in or into Maryland to a recipient with a Maryland address linked to the prescription but could have been prescribed by a provider who practices outside of Maryland. Breakdowns of dispensed prescriptions by therapeutic classes of interest can be found in Tables 7 – 9.

On October 8, 2018, PDMP regulatory updates impacting reporting requirements of dispensers went into effect and a full communication plan was implemented April 10, 2019 to coincide with the migration to the new platform. Dispensers are now required to report at least every 24 hours, including a “zero” report or an indication that no controlled substance was dispensed during the previous 24 hours. The regulatory change from three days to every 24 hours ensures prescribers are viewing timely dispense history when they query a patient in the PDMP to better support their clinical decision making.

Table 6. Total Controlled Substance Prescriptions Dispensed to Maryland Recipients

<table>
<thead>
<tr>
<th>Year (Jan 1 – Aug 31)</th>
<th>Prescription Count</th>
<th>% Change (Year to Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>5,665,844</td>
<td>N/A</td>
</tr>
<tr>
<td>2015</td>
<td>5,962,081</td>
<td>5.23</td>
</tr>
<tr>
<td>2016</td>
<td>5,948,204</td>
<td>-0.23</td>
</tr>
<tr>
<td>2017</td>
<td>5,521,830</td>
<td>-7.17</td>
</tr>
<tr>
<td>2018</td>
<td>5,206,155</td>
<td>-5.72</td>
</tr>
<tr>
<td>2019</td>
<td>5,123,355</td>
<td>-1.59</td>
</tr>
</tbody>
</table>
Table 7. Total Opioid* Prescriptions Dispensed to Maryland Recipients

<table>
<thead>
<tr>
<th>Year (Jan 1 – Aug31)</th>
<th>Prescription Count</th>
<th>% Change (Year to Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>2,407,018</td>
<td>N/A</td>
</tr>
<tr>
<td>2015</td>
<td>2,700,342</td>
<td>+12.19**</td>
</tr>
<tr>
<td>2016</td>
<td>2,615,985</td>
<td>-3.12</td>
</tr>
<tr>
<td>2017</td>
<td>2,309,853</td>
<td>-11.7</td>
</tr>
<tr>
<td>2018</td>
<td>2,030,811</td>
<td>-12.08</td>
</tr>
<tr>
<td>2019</td>
<td>1,845,871</td>
<td>-9.12</td>
</tr>
</tbody>
</table>

*Total opioids include all prescriptions containing a medication in the opioid class of drugs, except medications containing buprenorphine in a formulation indicated for the treatment of opioid use disorder. Indication was determined based on FDA indication for approved use for treatment of opioid use disorder. Strict adherence to approved indications may not occur. Prescriptions were not compared with diagnoses for patients to whom they were prescribed as PDMP does not have this information, and thus this measurable proxy was used.

**Tramadol was scheduled at the end of August 2014 and subsequently became reportable to the PDMP; this could account for some of the increase in opioid dispensing between 2014 and 2015.

Table 8. Total Buprenorphine-containing Prescriptions Dispensed by Treatment Indication* to Maryland Recipients

<table>
<thead>
<tr>
<th>Year (Jan 1 – Aug31)</th>
<th>SUD Treatment</th>
<th>Pain Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prescription Count</td>
<td>% Change (Year to Year)</td>
</tr>
<tr>
<td>2014</td>
<td>166,900</td>
<td>N/A</td>
</tr>
<tr>
<td>2015</td>
<td>171,103</td>
<td>+2.52</td>
</tr>
<tr>
<td>2016</td>
<td>180,217</td>
<td>+5.33</td>
</tr>
<tr>
<td>2017</td>
<td>193,979</td>
<td>+7.64</td>
</tr>
<tr>
<td>2018</td>
<td>235,329</td>
<td>+21.32</td>
</tr>
<tr>
<td>2019</td>
<td>308,095</td>
<td>+30.92</td>
</tr>
</tbody>
</table>

*Buprenorphine is a medication within the opioid class of drugs, but which is prescribed in specific formulations for the treatment of pain as well as for the treatment of opioid use disorder (OUD). Indication was determined based on FDA indication for approved use for either the treatment of pain or treatment of OUDs. Strict adherence to approved indications may not occur. Prescriptions were not compared with diagnoses for patients to whom they were prescribed as PDMP does not have this information, and thus this measurable proxy was used.

Table 9. Total Benzodiazepine Prescriptions Dispensed to Maryland Recipients

<table>
<thead>
<tr>
<th>Year (Jan 1 – Aug31)</th>
<th>Prescription Count</th>
<th>% Change (Year to Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>1,214,653</td>
<td>N/A</td>
</tr>
<tr>
<td>2015</td>
<td>1,204,550</td>
<td>-0.83</td>
</tr>
<tr>
<td>2016</td>
<td>1,208,395</td>
<td>+0.32</td>
</tr>
<tr>
<td>2017</td>
<td>1,110,483</td>
<td>-8.1</td>
</tr>
<tr>
<td>2018</td>
<td>1,043,114</td>
<td>-6.07</td>
</tr>
<tr>
<td>2019</td>
<td>994,208</td>
<td>-4.69</td>
</tr>
</tbody>
</table>

There are some important considerations when reviewing PDMP data output.

- Most data are reported in total number of prescriptions, which should not serve as a
surrogate for number of patients. Additionally, changes from fewer prescriptions for large quantities of pills to more frequent small quantity prescriptions, as well as diagnosis or age-specific differences in prescribing trends, may skew reports based on total number of prescriptions. The PDMP will continue to work with State and national partners to apply best practices in reporting prescription data.

- Total opioid prescription counts also include tramadol, an opioid that was moved by DEA from being unscheduled to a Schedule IV prescription, effective August 18, 2014.\(^1\) Therefore, for most of the period of 2014 included in this report, tramadol prescriptions were not reported to the Maryland PDMP, while all tramadol prescriptions from 2015 onward were required to be reported to the PDMP.

- An analysis conducted comparing PDMP dispensing records against a national prescription comparator [IMS National Prescription Audit (NPA) aggregate prescription data for Maryland], showed congruency of IMS and PDMP data starting in August 2014, showing potential gaps in reporting data prior to this date. The gaps are likely due to bringing all dispensers into compliance with the requirement to report dispensed prescriptions to the PDMP starting August 2013. Therefore, all calendar year 2014 data could be subject to underreporting.

### Provider Education and Referral for Investigation

This section of the report is intended to address the following reporting requirements:

V.  
1. The number of providers, by provider type, who received outreach and education from the Program
2. The number of cases for which the providers received outreach and education from the Program

VI.  
1. The number of cases that were identified for Technical Advisory Committee review before referral to the Office (Office of Controlled Substances Administration)
2. The number of providers, by provider type, involved in the cases

VII.  
1. The number of cases that were referred to the Office for further evaluation and the outcomes of the Office evaluations
2. The number of providers, by provider type, involved in the cases

**HB 025 (Chapter 531, Prescription Drug Monitoring Program – Revisions, 2019)** expanded the scope and responsibilities of the Program and allows proactive data sharing with an investigative entity, OCSA. Under HB 025 (Chapter 531, 2019) reporting requirements V-

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VII were established. Unsolicited Reporting Notifications are a key component of the Program’s responsibilities and the primary method in which the Program offers education to providers. The Program and the Advisory Board is currently working on promulgating regulations to implement HB 025 (Chapter 531, 2019) as well as policies and procedures to implement the new referral to OCSA authority. Once the Advisory Board and the Technical Advisory Committee (TAC) review and approve the policies and procedures and regulations are promulgated, the Program will begin implementing proactive referrals to OCSA and provide information for reporting requirements VI and VII.

Unsolicited Reporting Notifications

Unsolicited reporting is considered a best practice by the Department of Justice Bureau of Justice Assistance’s Prescription Drug Monitoring Program Center of Excellence at Brandeis University, and has been or is currently being adopted by a majority of states. States vary on the types of PDMP users who may receive PDMP data or notifications and the types of questionable patterns identified by the Program that are used to generate notifications. Proactive reporting to prescribers and pharmacists allows the Program to further support clinical decision-making around prescribing CDS, improving legitimate patient access to pharmaceutical care, and assist prescribers and dispensers in identifying prescription drug diversion.

Chapter 651 (HB 1296, An Act concerning Prescription Drug Monitoring Program – Review and Reporting of Possible Misuse or Abuse of Monitored Prescription Drugs) was passed during the 2014 legislative session. The statute establishes the authority for the Program to review the PDMP for indications of possible misuse or abuse of a monitored prescription drug, and the Program may proactively report to the prescriber or dispenser of the prescription drug if the review indicates possible misuse or abuse. Under HB 025 (Chapter 531, 2019), the Program is required to review prescription monitoring data for indications of possible misuse or abuse of a monitored prescription drug; possible violations of law and possible breaches of professional standards by a prescriber or a dispenser. The PDMP’s TAC may review the prescription drug monitoring data prior to release of a notification to a prescriber or dispenser and may provide clinical guidance regarding the methods used to identify indications of possible misuse or abuse of a monitored prescription drug; possible violations of law and possible breaches of professional standards by a prescriber or a dispenser. Under HB 025 (Chapter 531, 2019), the Program is required to notify and provide education to providers who are identified during the data review process.

Unsolicited Reporting Notifications are the primary method in which the Program offers education to providers. The goal of the Unsolicited Reporting Notifications is to inform a provider about their prescribing practices, or patient specific activities that could be
addressed by a provider and offer resources to improve their CDS prescribing or dispensing
decisions. The intended outcomes of Unsolicited Reporting Notifications include increased
use of the PDMP, improved relationships between providers and patients, adoption of
improved CDS prescribing and dispensing behaviors, and implementation of overdose
prevention activities. Each Unsolicited Reporting Notification includes, but is not limited to,
the following educational resources: Centers for Disease Control and Prevention (CDC)
guidelines and resources for prescribing opioids, information on naloxone, information on the
PDMP, how to access the Maryland Addiction Consultation Services (MACS), how to
implement Screening, Brief Intervention, and Referral to Treatment (SBIRT), and Substance
Abuse and Mental Health Services Administration (SAMHSA) approved screening tools.

Implementation of this unsolicited reporting authority (under HB 1296 / Chapter 651,
2014 and expanded under HB 025/Chapter 531) occurred in 2016 and notifications are sent
monthly. The Program currently sends three types of Unsolicited Reporting Notifications to
providers: Multiple Provider Episode, Fatal Overdose Notifications, and High Amount of
Opioid Prescriptions. Table 10 shows a breakdown of the 902 Unsolicited Reporting
Notifications sent to date in 2019.

**Multiple Provider Episodes**

The Program is using a standard approach deployed by many states to identify patients
receiving prescriptions from the greatest number of prescribers and filled at the greatest
number of pharmacies over specified time periods. Providers identified as having prescribed a
controlled substance prescription to that patient during the specified period receive a
notification that the patient met or exceeded the set threshold. The threshold used for multiple
provider episodes is calculated by identifying unique individuals who have obtained CDS
prescriptions from at least a certain number prescribers and at least a certain number of
dispensers in a three (3)-month time period. This type of notification has been actively sent
since Summer 2016.

**Fatal Overdose Notifications**

In 2019, the Program began sending a new type of unsolicited reporting notification
when possible misuse or abuse of monitored prescription drugs is identified. The program
now informs providers about the death of a patient when the cause of death is opioid-related
when the provider prescribed an opioid or a benzodiazepine within three months of the death.
In February 2019, the Program presented a review of other states’ efforts to inform prescribers
of overdose deaths with PDMP data and the Advisory Board’s requested the creation of an ad
hoc subcommittee for Fatal Overdose Notifications. The subcommittee convened in February
and March and presented recommendations to the Advisory Board in April 2019. The
subcommittee advised the Program on the scenarios that would generate Fatal Overdose Notifications and provide input on the content of the notification. The TAC reviewed the methods that would generate Fatal Overdose Notifications and the content of the Notifications in April 2019.

In 2020, dispensers will begin receiving notifications. Through an agreement with the Maryland Office of the Chief Medical Examiner (OCME) and the Vital Statistics Administration, the Program partners with CRISP to match OCME data with PDMP data. The program will send notifications monthly and the notifications will be dependent on the new decedents provided monthly by OCME. Depending on the time needed for the Medical Examiner to complete the investigation and the required time to match the data, prescribers will receive a notification one to three months after the fatal overdose.

**High Amount of Opioid Prescriptions**

Effective October 1, 2016 (HB 437 (Chapter 147, 2016) and expanded under HB 025, (Chapter 531, 2019)), analysis of PDMP data for possible violations of law and possible breaches of professional standards by prescribers and pharmacists is used as the basis for proactive notification to prescribers and pharmacists for educational purposes. The PDMP’s TAC is required to review the prescription drug monitoring data prior to issuing a notification to the prescriber or dispenser of a CDS. During the November 2019 and 2020 TAC meetings, the TAC will advise on the methods the Program will use to identify prescribers and dispensers, allowing the program to expand the types of unsolicited reporting notifications sent to Maryland providers. An analytics project to identify ‘red flags’ that may indicate possible violations of law or possible breaches of professional standards was completed as of June 30, 2018. PDMP staff applied the results of this project and developed procedures, in consultation with the TAC, to begin notifying prescribers and pharmacists. In 2019, the Program began sending notifications to providers who were identified as writing a high amount of opioid prescriptions. The TAC identified 2,000 prescriptions within a three-month timeframe as an indicator of possible outlier prescribing practices.

**Table 10. Unsolicited Reporting Prescriber Notifications, through October 2019**

<table>
<thead>
<tr>
<th>Type of Unsolicited Reporting Notification</th>
<th>Number of Unsolicited Reporting Notifications Sent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Provider Episode</td>
<td>717</td>
</tr>
<tr>
<td>Fatal Overdose Notification</td>
<td>177</td>
</tr>
<tr>
<td>High Amount of Opioid Prescriptions</td>
<td>8</td>
</tr>
</tbody>
</table>
The Technical Advisory Committee (TAC) was established through Chapter 166 of the Acts of 2011, the PDMP’s original authorizing legislation. The TAC supports the PDMP’s quantitative data analysis and provides clinical expertise. According to Health General §21-2A-07, the TAC is responsible for the following activities:

- Providing clinical guidance and interpretation of PDMP data,
- Providing clinical guidance regarding methods used to identify possible violations of law or possible breaches of professional standards within PDMP data,
- Reviewing certain investigative requests for PDMP data, and
- Providing recommendations and clinical guidance regarding PDMP referrals of providers to the state controlled dangerous substances (CDS) permit authority for investigation.

The “Maryland Prescription Drug Monitoring Program Technical Advisory Committee Protocol and Procedures” document was developed by the Program and shared with the TAC during the September 12, 2019 meeting. The document includes a review of TAC roles and responsibilities, structure, appointments and terms, TAC member requirements, and procedures for reviewing unsolicited reports and investigative data requests. “The Maryland Prescription Drug Monitoring Program Technical Advisory Committee Protocol and Procedures” (last updated September 12, 2019) is included as Attachment B.

HB 437 (Chapter 147, 2016) expanded the membership of the TAC and altered its duties by authorizing rather than requiring TAC review of investigative data requests. In response, PDMP adopted a policy of requiring TAC review of investigative requests only when an investigative user requested TAC review. HB 437 (Chapter 147, 2016) also altered TAC’s role regarding unsolicited reports by authorizing review of unsolicited reports concerning possible violations of law or possible breaches of professional standards by prescribers and dispensers. HB 437 (Chapter 147, 2016) requires TAC’s review of unsolicited reports focusing on prescriber and dispenser behavior to include review of PDMP data and clinical guidance.

TAC review supplements quantitative data analysis tools and methods the Program uses to identify potentially illegal or inappropriate prescribing or dispensing. The Program considers TAC’s guidance when determining whether and how to engage a provider about practice issues. While the Program does not submit each unsolicited report regarding possible patient drug misuse or abuse to TAC for review, the TAC is consulted regarding the
methodology and criteria that is used to identify indicators of misuse or abuse in order to generate the unsolicited report, and once regulations are promulgated in support of HB 025 (Chapter 531, 2019), the TAC will be consulted regarding the methodology and criteria that is used to identify indicators of possible violations of law or possible breaches of professional standards by prescribers and dispensers. HB 437 (Chapter 147, 2016) changed the frequency and content of TAC meetings. Table 11 contains a summary of TAC meeting dates and agenda topics through September 2019.

Table 11. Summary of TAC Meetings

<table>
<thead>
<tr>
<th>TAC Meeting Date</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 30, 2016</td>
<td>Review of unsolicited reporting thresholds, time periods, patients, and prescriber data</td>
</tr>
<tr>
<td>March 23, 2017</td>
<td>TAC meeting</td>
</tr>
<tr>
<td>December 1, 2017</td>
<td>TAC meeting</td>
</tr>
<tr>
<td>January 16, 2018</td>
<td>Training slides; introduction of members; PDMP 101; TAC Role and Activities</td>
</tr>
<tr>
<td>April 23, 2018</td>
<td>Review of Red Flags Project; Clinical Questions for Red Flag Deliverables</td>
</tr>
<tr>
<td>June 25, 2018</td>
<td>Review of Red Flags Criteria</td>
</tr>
<tr>
<td>December 10, 2018</td>
<td>Mission Review; Priority Indicators for High Opioid Prescribing data review process flow and data reports presentation</td>
</tr>
<tr>
<td>March 25, 2019</td>
<td>High Opioid Prescribing Criterion Review; Sunset Evaluation Report; 2019 Legislation Impacting TAC; PDMP Educational Videos</td>
</tr>
<tr>
<td>June 10, 2019</td>
<td>High Opioid Prescribing Letter review; Fatal Overdose Notification Criteria review; Passed 2019 Legislation Impacting TAC</td>
</tr>
<tr>
<td>September 12, 2019</td>
<td>Regulations Impacting TAC, TAC Protocol and Procedures Review</td>
</tr>
</tbody>
</table>

During the September 12, 2019 TAC meeting, the Program solicited recommendations from the TAC of any changes necessary for TAC to meet the needs of the PDMP. The TAC recommends staggering membership terms. TAC members are appointed by the Maryland Department of Health Secretary for three-year terms. Currently all nine clinical members are serving the terms that have the same beginning and end date. Staggering membership terms will allow for improved peer to peer interactions and knowledge transfer between members.

The TAC recommends improvements to the data review process. Members recommended improvements to the file format in which the Program shares prescription monitoring data. Depending on the investigation or the type of unsolicited reporting notification, TAC members may need to review large data sets and the Program will work with the TAC to identify effective methods to share and display data to support the TAC’s review.
The TAC recommended improving communication between TAC members and the Program. TAC members expressed an interest in receiving a compiled report of feedback from all TAC members after each member conducts a review of a data set. TAC members review data independently and send feedback and responses directly to the Program (see Attachment B for additional details). The Program will work with the TAC members to increase communication and share a compiled report summarizing every TAC member’s response to review data for a specific investigation or unsolicited reporting notification. Finally, TAC members recommended the Program communicate to the TAC members how TAC interpretation of data is used.

The Program will review the recommendations developed by the TAC and update the “The Maryland Prescription Drug Monitoring Program Technical Advisory Committee Protocol and Procedures” as necessary.

**Recommendations on Modification or Continuation of the Program**

This section of the report is intended to address the following reporting requirement:

VIII. Any recommendation related to modification or continuation of the Program

The Board continues to recommend items that were included in the 2018 report such as increase in adoption of PDMP use by clinical users through expanding interstate data sharing to other priority states and improving the clinical user interface to display relevant alerts based on PDMP data. The Board continues to recommend the Program conduct analyses investigating the possible impact of PDMP on access to and utilization of substance use disorder treatment services. The Board also continues to recommend the Program assess national trends in incorporating veterinarian CDS dispensing data into state PDMPs and whether there is a use case for providing veterinarians access to PDMP data. In 2020, the Board anticipates engaging in policy conversations related to use cases that may add value to veterinarians and reducing CDS specific adverse events.

The Board also has new recommendations for the 2019 report; Board members support continuation of the Program and its activities, with several areas for possible focus in the future. Supporting clinical users remains a major focus of the Board. The Board recommends a focus on ensuring systems performance on all ends, including integrating PDMP data into hospital and ambulatory providers’ EHRs and other electronic provider tools such as alerts and summaries of a prescriber’s prescribing practices. Finally, the Board recommends expanding the PDMP specific clinical resources available to pharmacists through CRISP.
Conclusion

During the past year, the Department made substantial progress implementing new Program activities, transitioning to a new vendor to host the PDMP, increasing visibility and uptake of the Program, and continues to work with the Board to increase the Program’s ability to meet the evolving roles of the PDMP within the State’s opioid strategy. Therefore, the Board recommends that the Governor and General Assembly continue to support ongoing development of the PDMP. Over the next year, the Board will continue to support the Department by providing ongoing advice about emerging stakeholder PDMP needs, and issue guidance on key priority areas to improve health and safety outcomes related to CDS prescriptions in Maryland. These priorities include expansion of education and outreach to clinical users and other relevant stakeholders, implementing new referral for investigation protocols, and disseminating clinical tools to support healthcare providers.
Attachment A: Advisory Board on Prescription Drug Monitoring – Membership

Chair
Richard A. Debenedetto, PharmD, MS AAHIVP
Assistant Professor of Pharmacy Practice & Administration
University of Maryland Eastern Shore School of Pharmacy & Health Professions

Current Members (As of October 2019)
Daniel M. Ashby, M.S., FASHP
President's designee, Board of Pharmacy
Vice President and Chief Pharmacy Officer
The Johns Hopkins Health System

Amit Bhargava, MD, MS, RMSK, Medical Director
Advanced International Pain & Sports Medicine

Thomas C.C. Bond, III
Senior Director
Programs & Strategic Partnerships
Helping Up Mission

Lenna Israbian-Jamgochian, PharmD, RPh
District Pharmacy Manager, Albertsons Safeway Inc-Eastern Division

Arthur C. Jee, DMD
President's designee, Board of Dental Examiners
Oral Maxillofacial Surgery

Chris Jillson, MD
Emergency Medicine Physician, Alteon Health

Marcus Jones, Assistant Chief
Investigative Services Bureau
Montgomery County Police, MD

Bryan Marascalchi, MD
Anesthesiologist/Pain Management Specialist
The Johns Hopkins Hospital

Stephen A. Nichols, MD, FAAP, FAAPMR
Senior Attending Physician for Rehabilitation Services
Mt. Washington Pediatric Hospital

Bonnie C. Oettinger, RN, MGA
President's designee, Maryland Board of Nursing

**Mark D. Olszyk**, MD, MBA, CPE, FACEP, FACHE, FFSMB
Chief Medical Officer/Vice President Medical Affairs Carrol Hospital
Vice President Carroll County Health Group

**Orlee Panitch**, MD
Physician, Medical Emergency Professionals

**Derek Peck**, Captain
Secretary's designee, Maryland State Police
Criminal Enforcement Division

**Laurence Polsky**, MD, MPH
President's Designee, Maryland Association of County Health Officers
Health Officer, Calvert County

**Joseph Scalese III**, RPh
Pharmacist, Weis Pharmacy

**Amar Setty**, MD
Anesthesiologist and Pain Medicine
Immediate Past President Maryland Society of Anesthesiology

**David Sharp**, Ph.D.
Chairman's designee, Maryland Health Care Commission
Director, Center for Health Information Technology & Innovative Care Delivery

**Alexander Shekhdar**, JD, MHS
Senior Director, Medicaid Initiatives

**D. Gail Shorter**, DNP
Nurse Practitioner, University of Maryland Shore Medical Group

**Yvonne Umezurike**, DPM
Vice President, Board of Podiatric Examiners

**Michael Vaughn**
Law Enforcement Officer, Baltimore City
Attachment B: The Maryland Prescription Drug Monitoring Program Technical Advisory Committee Protocol and Procedures

See attached document.
Maryland Prescription Drug Monitoring Program
Technical Advisory Committee Protocol and Procedures

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Technical Advisory Committee Mission and Responsibilities

Maryland’s Prescription Drug Monitoring Program (PDMP) Technical Advisory Committee (TAC) was established through Chapter 166 of the Acts of 2011, the PDMP’s original authorizing legislation. The TAC supports the PDMP’s quantitative data analysis and provides clinical expertise. According to Health General §21-2A-07, the TAC is responsible for these activities:

- Providing clinical guidance and interpretation of PDMP data,
- Providing clinical guidance regarding methods used to identify possible violations of law or possible breaches of professional standards within PDMP data,
- Reviewing certain investigative requests for PDMP data, and
- Providing recommendations and clinical guidance regarding PDMP referrals of providers to the state controlled dangerous substances (CDS) permit authority for investigation.

TAC review supplements quantitative data analysis tools and methods that the PDMP employs to identify potentially illegal or inappropriate prescribing or dispensing. The TAC’s guidance is taken into consideration when the PDMP is determining whether and how to engage a provider on appropriate prescribing practices. The TAC plays an important role within the PDMP’s provider education efforts to combat the opioid misuse and overdose epidemic.

The TAC provides clinical interpretation of PDMP and advises the PDMP on methods that can be used to identify possible indicators of misuse or abuse or inappropriate prescribing behaviors. The PDMP is required by Health General §21-2A-02 to review PDMP data for possible indicators of misuse or abuse, or possible violations of law or breaches of professional standards, inform providers that are identified of the concerning prescribing behaviors, provide education to those providers, and consider referring providers to the Office of Controlled Substances Administration (OCSA) for investigation. The TAC is responsible for evaluating PDMP data and methods used to identify providers prior to the PDMP conducting outreach to prescribers and pharmacists including unsolicited reports the PDMP sends to providers. The TAC will review cases of possible violations of law or breaches of professional standards that will be referred to OCSA and provide recommendations to OCSA on the interpretation of clinical data.

The TAC may review data requests submitted to the PDMP for active investigations as requested by the investigator and according to the PDMP and provide clinical guidance and interpretation of the requested prescription monitoring data.

Structure
The TAC is comprised of nine clinical members. The below TAC members must be licensed and practicing in Maryland:

1. A board certified anesthesiologist;
2. A certified addiction medicine specialist;
3. A pharmacist,
4. A medical professional, licensed who is treating cancer patients;
5. A board certified physician specializing in the treatment of patients with pain;
6. Two medical professionals with expertise or experience in providing care for patients with substance–related or mental health disorders;
7. A dentist; and
8. A medical professional in the field of internal medicine or family practice.

**Appointments and Terms**

TAC members are unpaid volunteers appointed by the Maryland Department of Health Secretary for three-year terms. The Secretary requests nominations by enumerated professional societies that represent relevant specialty areas using the Outreach Nomination Email, Appendix A. The PDMP and Office of Appointments and Executive Nominations (OAEN) review applications and recommend nominees to the Secretary.

If a seat is replaced during the course of an active term, the new member will finish out the current term and then be eligible for possible reappointment. There is no limit on reappointments. TAC members must meet several requirements to maintain a seat.

**Requirements**

Roles and responsibilities of the TAC shift over time; TAC members will be alerted by PDMP staff of new activities, upcoming meetings, and statutory or regulatory changes that impact the functions of the TAC. Members are encouraged, but not required, to present about the PDMP at professional conferences and meetings.

**Training**

Upon acceptance of the appointment, PDMP staff will provide a recorded webinar for TAC members. The training will cover the PDMP, roles and responsibilities of the TAC, statutory authority of the TAC, expectation of TAC members, and communication guidance.

**Attendance at Meetings**

Meetings of TAC members are organized by the PDMP and occur quarterly. At least one meeting each year will be in-person. TAC meetings typically last between 1-2 hours. TAC attendance is paramount to the success of the PDMP. The PDMP submits an attendance report to the Office of Appointments and Executive Nominations (OAEN) annually. The report will include recommendations regarding members’ continuation on the TAC based on compliance with attendance requirements.

Based on the Maryland Department of Health Attendance Policy for Appointments Made by the Secretary (02.08.02 effective 10-16-19), appointees are required to attend at least 50% of meetings. Appointees who do not meet the attendance requirement may submit a waiver for the attendance requirement that is subject to the Secretary’s approval.

Attendance Requirements:
1. TAC members must provide notification to a PDMP staff member before a meeting if they are unable to attend, this is considered a ‘notified absence,’
2. TAC members cannot have two or more un-notified absences in a row, and
3. TAC members cannot have three or more notified absences in a row.

**Disclosures**

Upon appointment, TAC members must submit Financial Disclosure documentation to the State Ethics Commission per the OAEN: [https://ethics.maryland.gov/boards-commissions/](https://ethics.maryland.gov/boards-commissions/). The contact phone number for State Ethics Commission is 410-260-7770.

**Secure Data Sharing**

Every TAC member will be assigned a maryland.gov email account and access to the email encryption application Virtru. TAC members will communicate with other members and PDMP staff with this email address. To access the maryland.gov account, TAC members should follow these steps:

1. Log on to [connect.md.gov](https://connect.md.gov)
2. Click the radial circle in front of ‘Do NOT Remember me on this computer’
3. Enter [maryland.gov](https://maryland.gov) email address and click on ‘Submit’
4. Answer Knowledge Based Questions that were established when the maryland.gov email was created and click ‘Submit’
5. Enter the account’s password
6. Click on the first box below, G Suite for Maryland, to gain access to the maryland.gov email account
Communication
The TAC conducts all business through phone and email correspondence. Therefore TAC members are expected to frequently check their emails. The PDMP staff will email the personal email address provided by the TAC members to alert them that secure emails have been sent to their maryland.gov email addresses. Any emails containing PHI will be sent via Virtru to members’ maryland.gov email address. All TAC members will use Virtru when sharing feedback and data concerning any PDMP data. Email correspondence and data review are estimated at approximately two hours per month.

Data Security Guidance
PDMP reports will be sent to TAC members via their maryland.gov email addresses through an email encryption program called Virtru. TAC members are expected to protect PDMP data by not forwarding data to another email account. TAC members may only discuss the contents of identifiable PDMP data reports with other TAC members, PDMP staff, and PDMP legal counsel; disclosure of any identifying information beyond this is considered a legal violation. When discussing PDMP data, TAC members must communicate with other members using only the maryland.gov email accounts. TAC members must minimize the amount of patient-identifying information used in the body of emails. PDMP data may only be accessed on a computer that is not used by coworkers or others who should not be accessing PDMP data.

TAC members should use a known network or VPN as these data should be treated like any other clinical protected health information data. TAC members should not retrieve data reports or send messages regarding the PDMP data reports or their contents using a public WiFi connection. TAC members should always log out of their maryland.gov email account once the data review after each data review. After TAC members have completed their review of the PDMP data report, the data must be deleted from the computer, including deleting the data file from the ‘Downloads’ folder and from the computer’s ‘Recycling Bin.’ If possible, TAC members should consider password-protecting access to their ‘Downloads folder’ and computer to help protect against unauthorized access to PDMP data. If TAC members have any questions about the contents of the data reports, they should contact mdh.tac@maryland.gov. If TAC members have trouble with their maryland.gov email access, login, password, or security questions, they should contact mdh.tac@maryland.gov or Sara Roberson at 410-402-8426 or sara.roberson1@maryland.gov.

Clinical Guidance and Interpretation
The TAC provides clinical recommendations and feedback when the PDMP has reviewed data for possible inappropriate prescribing or dispensing practices and plans to send the provider an unsolicited reporting notification the PDMP decides to refer the provider to OCSA for a possible investigation. The TAC is asked to provide clinical guidance regarding indications of a possible violation of law or a possible breach of professional standards; and interpretation of the prescription monitoring data that indicates a possible violation of law or a possible breach of professional standards. The TAC also provides guidance on the methods the PDMP uses to
identify providers. When reviewing PDMP data for a specific provider, the TAC may only use PDMP data contained in the data report as basis for guidance. TAC members cannot search for patients, prescribers, dispensers in the PDMP or other protected source to obtain additional clinical or professional information. TAC members are expected to provide guidance on what is standard practice for specific specialties or general practice. TAC members can advise on whether data reflect the intended indicator of concern. Instructions for reviewing PDMP data in support of Unsolicited Reporting Notification for each criteria identified will be developed and shared with TAC members.

If there is a potential conflict of interest (COI) when a TAC member is reviewing PDMP data, TAC members should inform PDMP staff and recuse themselves from providing guidance. COI is defined as the TAC member having, or had, a significant relationship with the subject of an investigation or resultant listing on a report. The PDMP relies on TAC members to identify and inform the Program when a COI exists using the standard: whether the objectivity of the member is compromised OR whether there is an appearance of bias.

When the PDMP solicits clinical guidance and data interpretation from the TAC, members are required to:

- Send the completed feedback to mdh.tac@maryland.gov within 10 days of the request,
- Cite any outside sources or information used in providing clinical guidance, interpretation of the PDMP data and/or responding to other member comments, and
- Use the template provided for each prescriber specific request, see Appendix B.

**Investigative Data Requests**

The TAC may review data requests submitted to the PDMP for active investigations as requested by an Investigative User and according to the PDMP and provide clinical guidance and interpretation of the requested prescription monitoring data. When an investigator requests TAC review of a data report, PDMP staff will email the investigative report to TAC members and members have 10 business days to review and provide feedback. PDMP staff will collect and synthesize the TACs feedback into a TAC report and send the TAC report to the Assistant Attorney General to review. After the report has been approved, PDMP Staff will send it to the TAC and the investigator who initiated the investigative request.
Appendix A: Outreach Nomination Email

Dear [Professional Society]:

Pursuant to the Annotated Code of Maryland, Health General Article § 21-2A-07, the Prescription Drug Monitoring Program on behalf of the Secretary of the Maryland Department of Health kindly requests your assistance in fulfilling the statutory mandate to maintain a Technical Advisory Committee (TAC) to the Prescription Drug Monitoring Program (PDMP or Program). The TAC’s main role under legislation passed in 2016 is to evaluate analyzed PDMP data prior to the Program conducting proactive outreach to prescribers and pharmacists, and provide clinical interpretation on possible indicators of misuse or abuse, or possible violations of law or breaches of professional standards. As required by law, the TAC reviews PDMP data and provides clinical guidance for all unsolicited reports focusing on prescriber or dispenser professional practices. TAC review supplements quantitative data analysis tools and methods that the PDMP employs to identify potentially illegal or inappropriate prescribing or dispensing. The TAC’s guidance is taken into consideration when the PDMP is determining whether or how to engage a provider about practice issues. This is an important activity within the State’s provider education efforts to combat opioid misuse and the overdose epidemic. Starting in the fall of 2019, the TAC will also provide recommendations about whether certain situations of inappropriate prescribing or dispensing should be referred to the stated controlled dangerous substances (CDS) permit authority for investigation, based on a legislative change in 2019. In addition, the TAC may review data requests submitted to the PDMP for active investigations as requested by the investigator and according to the PDMP, and provide clinical guidance and interpretation of the prescription monitoring data requested.

The Secretary requests that you submit names and documentation for up to three nominees with the requisite professional expertise to be candidates for appointment to the TAC. The PDMP greatly appreciates the work of the TAC, and therefore would like to ensure all legislatively designated seats are filled. The PDMP requests nominations to be submitted by January 17, 2020 if possible.

Submission instructions:
- Each nominee should provide an application online: https://forms.health.maryland.gov
- Provide a curriculum vitae (CV) or resume for each nominee
- Provide a completed biographical information form and ethics exemption disclosure form for each nominee

Application packages for each nominee will be reviewed by the Department’s Office of Appointments and Executive Nominations for completeness and eligibility. Nominees may be required to submit additional information as requested before appointment decisions are completed. Please submit all responses and forms online. If you have any questions, please contact PDMP Assistant Director, Sara Roberson: sara.roberson@maryland.gov or 410-402-8426.

Statement Concerning Diversity
The Department is committed to creating geographic, ethnic, and gender diversity representation on each board and commission. This helps ensure that decisions reached more adequately reflect the viewpoints of all populations being served and profoundly contribute to advancing the group’s mission. We request your assistance in this effort and ask that you address this concern when identifying the most talented individuals to submit as nominees.

Background on the PDMP

Senate Bill 883/House Bill 1229 (2011) authorized the creation of a Prescription Monitoring Program within the Department of Health and Mental Hygiene. The program is housed in Public Health Services administration with the below purpose:

- Assist prescribers, dispensers, and public health professionals in the identification and prevention of prescription drug abuse and the identification and investigation of illegal diversion.
- Promote a balanced use of prescription data to assist appropriate law enforcement activities while preserving the professional practice of healthcare providers and the access of patients to optimal pharmaceutical care.

The PDMP monitors the prescribing and dispensing of Schedules II-V controlled substances by requiring dispensers to report information (including identifying information for the patient, prescriber, dispenser, and drug type, dosage and quantity) for each controlled substance dispensed pursuant to a prescription.

Time Commitment

TAC member terms are 3 years; if a seat is replaced during the course of an active term, the new member will finish out the current term and then be eligible for possible reappointment. The TAC has historically conducted all business through phone and email correspondence. While the role and responsibilities of the TAC are shifting, the methods of meeting and conducting business might require modifications to fit the new activities of the TAC. Phone based meetings are 1-2 hours, at least quarterly. Email correspondence and data review is estimated at approximate 2 hours per week. Finally, members are encouraged, but not required, to present about the PDMP at professional conferences and meetings.

TAC members do not receive compensation for their service.

Please let us know if you have any questions and we sincerely appreciate your assistance in fulfilling this important role within the Prescription Drug Monitoring Program.

Thank you,

Maryland PDMP
Appendix B: Template for Clinical Guidance and Interpretation
Template for each prescriber, identified by DEA #

| **Sent:**  (DATE)  |  |  |
| **Due:**  (DATE) to EMAIL ADDRESS |
| **Prescriber #1 DEA #:** |
| **Clinical Guidance:** |
| **PDMP Data Interpretation:** |
| **Recommendation on sending educational letter:** Yes/No/Abstain and explanation |