

## Materials for Response to Senate Joint Resolution No. 75 Request for Data and Information about Utilization of the PMP

Senate Joint Resolution No. 75 requests the Department of Health Professions to collect data and information about utilization of the Prescription Monitoring Program by prescribers and dispensers of controlled substances and responses to notifications sent by the Department to prescribers and dispensers. SJR No. 75 requests that certain data be provided for each month of 2010 and report this data with recommendations to the 2011 General Assembly.

Following are components of the draft of the Department of Health Professions' response to that request.

(i) *the number of registered users eligible to receive reports from the Prescription Monitoring Program.*

October of 2009 represented the first month that users could log onto the new 24/7 system, input a request for patient history, and view the report via our automated system. Prior to October, requests input into the VPMP DataCenter required a PMP staff member to manually select the patient profiles that matched and then process the request for viewing. The requestor had to wait until PMP staff viewed and responded their request in the queue. Below is the number of new users added during each month since October 2009 as a cumulative total. In February of 2010, VPMP mailed approximately 39,000 brochures describing the VPMP to all prescribers and pharmacists licensed in Virginia. This explains the spike in registrations during March 2010. The VPMP has added an average of 432 registered users each month since October. In March, 959 users were added.

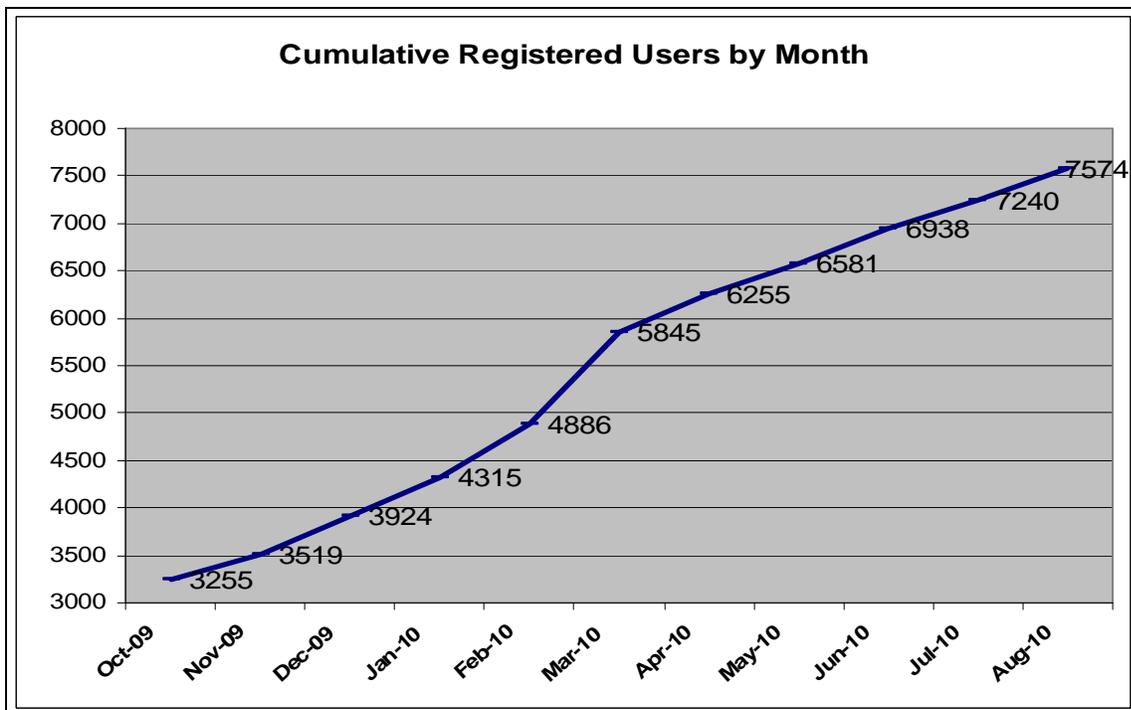


Figure 1.

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(ii) *The number of reports of dispensing of covered medications submitted to the Prescription Monitoring Program.*

The Virginia Prescription Monitoring Program (VPMP) requires pharmacies and physicians licensed to dispense controlled substances to report their records of dispensed medications twice monthly. All data from the 1<sup>st</sup> through the 15<sup>th</sup> of each month is due to VPMP by the 25<sup>th</sup> of the same month and all data from the 16<sup>th</sup> through the 31<sup>st</sup> of each month is due by the 10<sup>th</sup> of the following month.

The number of prescriptions reported to the VPMP each month has historically been, and continues to be, approximately one million records per month.

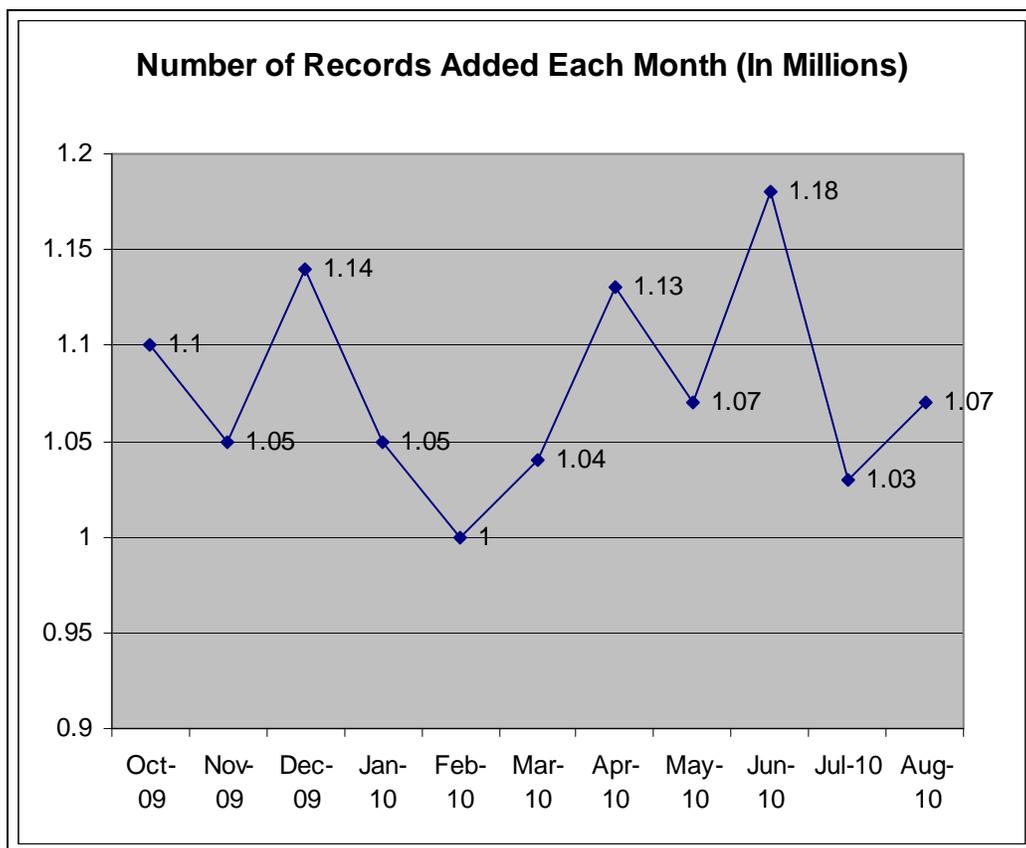


Figure 2.

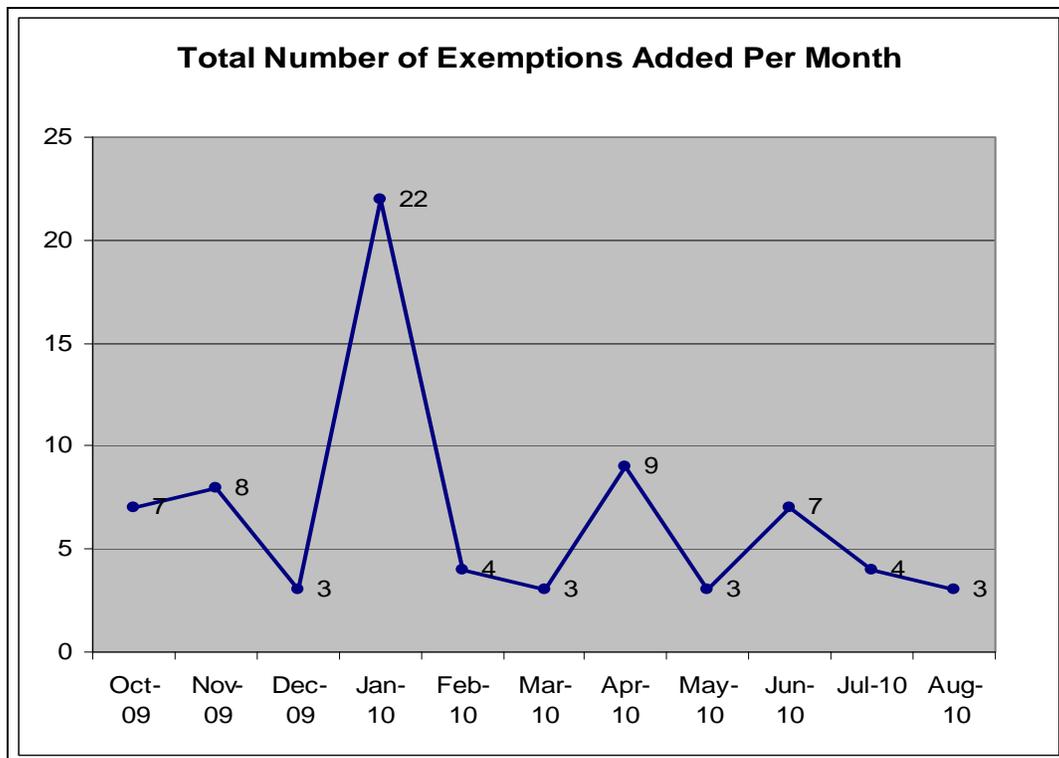
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(iii) *the number of exemptions from reporting requirements authorized.*

On a monthly basis, the VPMP exempts or waives a relatively small number of pharmacies and/or physicians licensed to dispense controlled substances. Pharmacies that are waived have attested that they dispense no Schedule II-V prescriptions and may or may not be located in Virginia. Physicians licensed to dispense controlled substances who are waived generally are members of a large group practice whereby the employing entity submits the dispensed controlled substances to VPMP on their behalf.

Pharmacies that are exempt from reporting are exempt due to the fact that they fall into one of the categories listed in the Virginia Code. These entities must apply for the exemption. These exemptions include dispensing exclusively to inpatients in hospices, dispensing by veterinarians to animals and dispensing covered substances within an appropriately licensed narcotic maintenance treatment program, among others.

As of September 2010, there are 1707 resident pharmacies, 397 non-resident pharmacies and 343 physicians licensed to sell controlled substances. Currently, 140 of the resident pharmacies are waived or exempted from reporting (8.2%); 145 of the non-resident pharmacies are waived or exempted from reporting (36.5%); and 249 physicians licensed to sell controlled substances are waived. The majority of physician licenses to sell are waived, as indicated previously, because they are members of a large group practice that submits controlled substance data on their behalf.



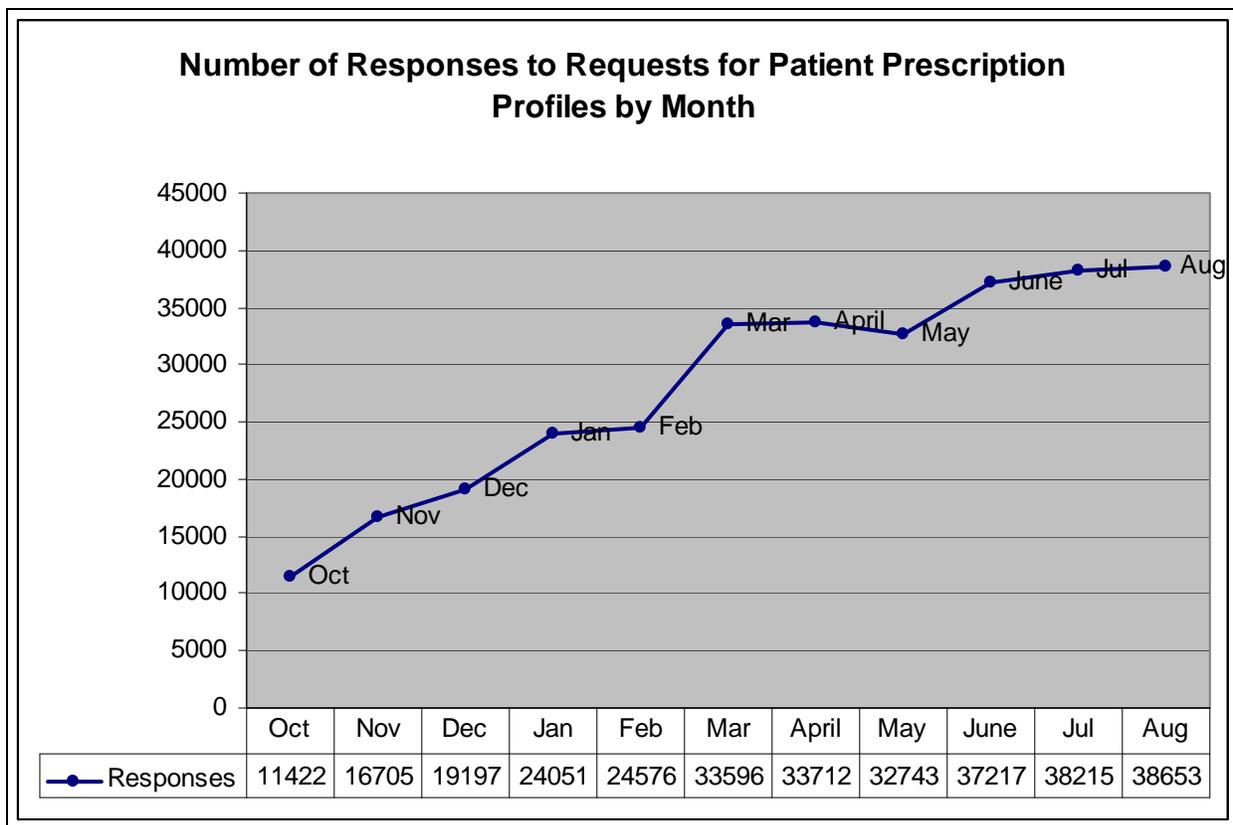
**Figure 3.**

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(iv) *the number of requests for information from registered users made and responded to*

Patient profile requests from registered users have increased several fold on a monthly basis since the introduction of our automated response feature, which was introduced in October 2009. Another surge of requests followed the distribution of VPMP brochures in February of 2010 to all prescribers and pharmacists licensed in Virginia.

Prescribers submit the majority of requests for patient information. Practitioners submitted 90.2% of all requests submitted so far in 2010. Pharmacists submitted 7.6% of the total volume, and both medical examiners and the Virginia State Police submitted slightly less than 1% of the total. Combined, these four categories of users accounted for 99.5% of all requests submitted in 2010.



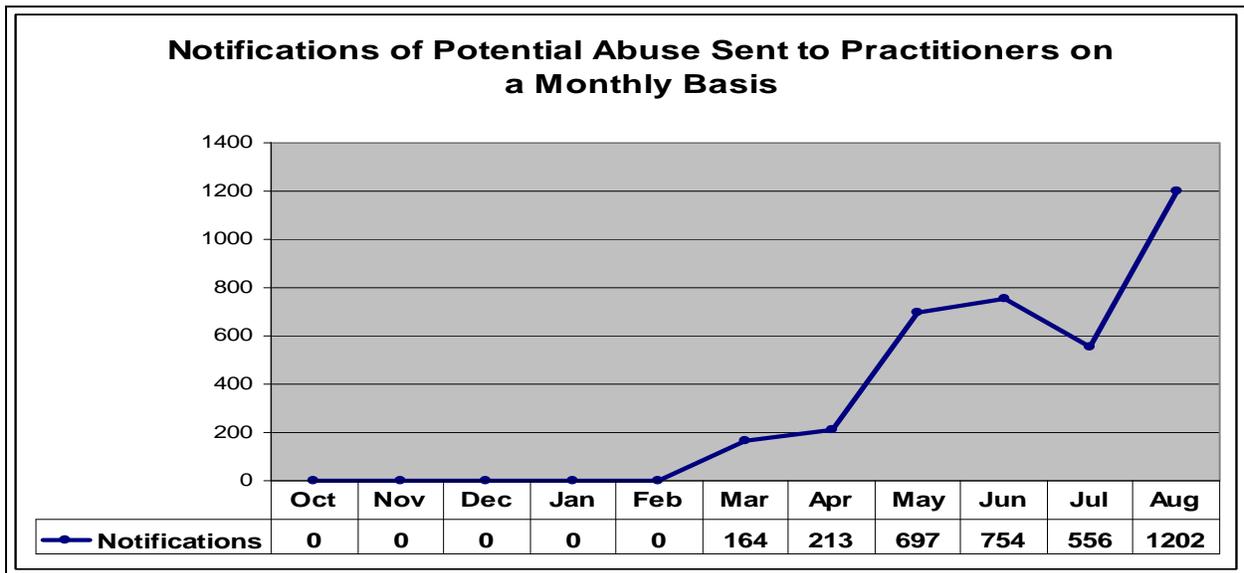
**Figure 4.**

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(v) *the number of notifications of indications of potential misuse [or abuse] of covered substances sent to prescribers and the number and nature of responses to such notifications*

Beginning in February of 2010, VPMP staff began evaluation of the 2010 prescription data for indicators of potential misuse, abuse or diversion. Queries were completed requesting the names of individuals who had received prescriptions from at least seven prescribers and dispensed from at least three pharmacies in one month's time. Reports were then generated for each of those patients for the month in question; the report is sent to each prescriber on the patient's report to alert the prescriber that he or she does not appear to be the only practitioner from whom the patient is seeking medical treatment or evaluation.

The data in Figure 5 below represents letters sent during each month. The prescription data in question was collected for the time period at least six to eight weeks earlier than the date the letters are sent. This is because there is an approximate 3 ½ week lag time inherent in the VPMP's required data collection schedule. Therefore, VPMP staff typically waits at least six weeks following the end of the report period in order to assure that the vast majority of prescription data for the notifications (e.g., "unsolicited reports") has been received and uploaded. For example, the majority of notifications sent in August included prescriptions dispensed in May and June only.



**Figure 5.**

The types of responses from prescribers receiving the notification reports generally fall into 2 broad categories: the person listed in the report is not a patient of the prescriber or the patient is no longer a patient of the prescriber. VPMP does not generally receive a great number of comments and for this reason is developing a survey mechanism that will ask registered prescribers the following: 1. Did you receive the report? 2. If you received the report how did this impact your treatment? a. no change, b. discharged patient, c. counselled patient and made referral for substance abuse treatment, d. counselled patient and made referral to pain management, e. other. 3. Did you report matter to law enforcement?

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(vi) *the number of responses to requests for information relevant to an investigation of a specific recipient, prescriber, or dispenser made, and the agency or entity to which such information was released*

Registered users of the VPMP who utilize the program for purposes other than to make treatment decisions may only access prescription history for specific individuals that have an open investigation. The Department of Health Professions (DHP) investigates complaints on licensees, both the Virginia State Police (VSP DDU) and Drug Enforcement Administration (DEA) investigate suspected drug diversion and Medical Examiners (ME) request a VPMP report on deceased individuals according to protocol in order to assist them in specifying the types of drug screens to order and assist in making cause of death determinations. The Health Practitioners' Monitoring Program (HPMP) monitors for drug utilization as specified in a Board Order. Figure 7 below shows the exact totals of requests.

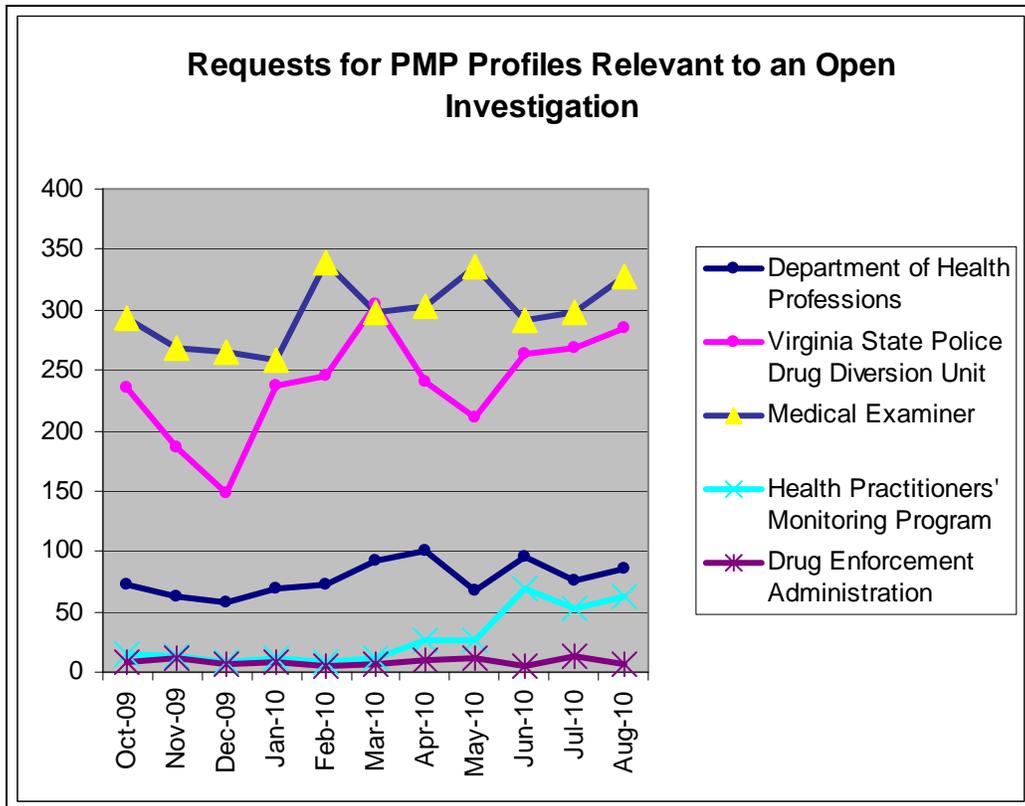


Figure 6.

	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10
<b>DHP</b>	73	63	57	69	72	93	100	68	95	76	85
<b>DDU</b>	235	186	148	237	246	305	241	211	264	268	285
<b>ME</b>	293	269	265	258	339	298	303	335	291	298	328
<b>HPMP</b>	14	13	9	11	9	12	27	26	69	52	63
<b>DEA</b>	8	11	6	8	5	6	10	11	5	13	7

Figure 7.

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(vii) *The number of disciplinary proceedings initiated by a health regulatory board against a person required to report dispensing of a covered substance to the Prescription Monitoring Program for failure to report as required.*

During 2010, one pharmacy was identified as consistently delinquent in reporting controlled substance data to VPMP. VPMP referred this case to the Board of Pharmacy for disciplinary action.

In an effort to address delinquent reporting, VPMP initiated a process in late 2009 whereby any pharmacy delinquent in reporting data in a reporting period exceeding four weeks' time or greater shall receive a certified letter in addition to the traditional letter sent by regular mail. Notification is sent two days following the end of the report period, during which time a delinquent report is generated from the data collection site. Consistently sending certified letters has improved the timely reporting of controlled substance data to the VPMP. Below is a table indicating the number of certified letters sent each month (on a bimonthly basis) to pharmacies that have failed to report some data. Historically, it appears that summer vacation and the Christmas holiday season adversely impact reporting of controlled substance data.

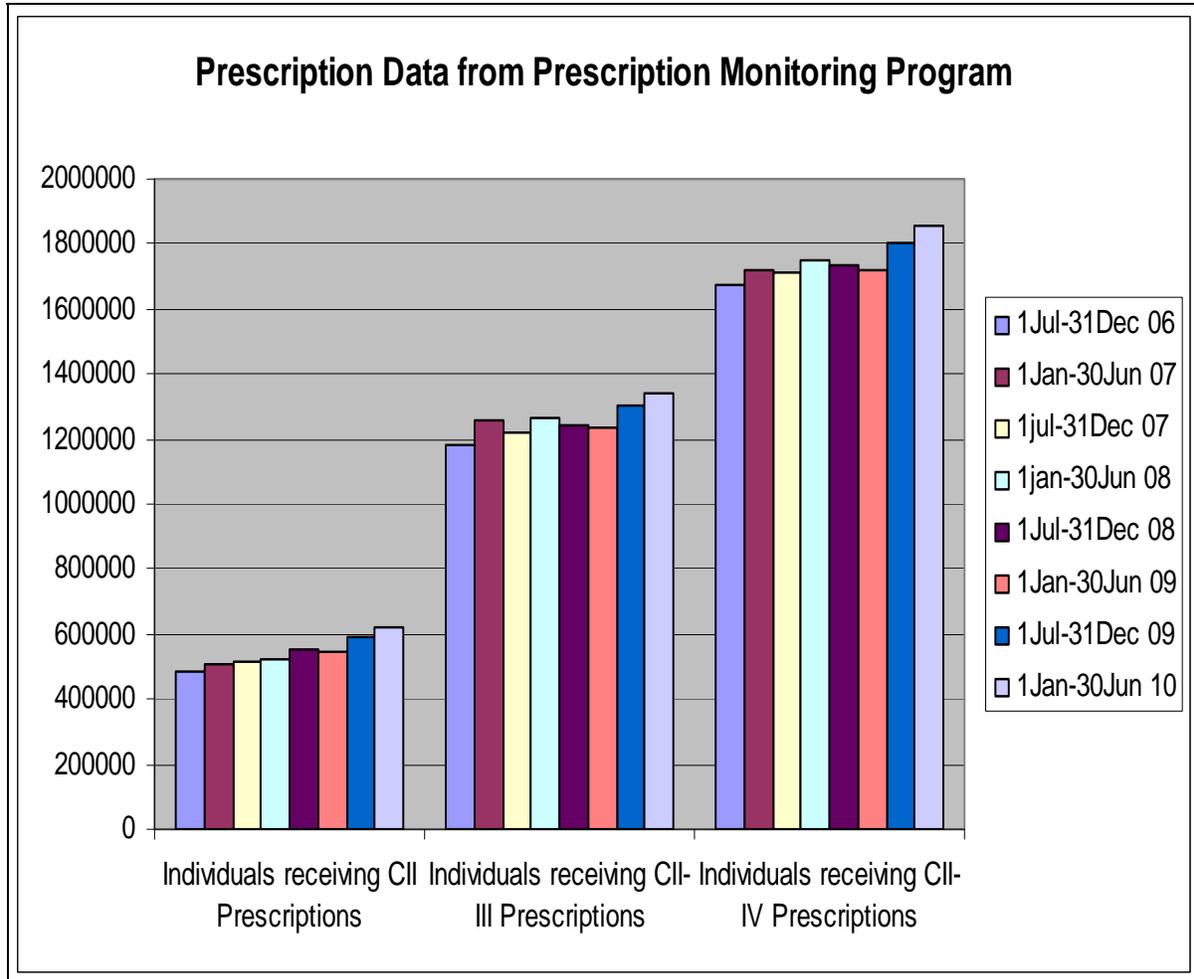
CERTIFIED LETTERS SENT	
October 2009	0
November 2009	3
December 2009	12
January 2009	22
February 2009	8
March 2009	17
April 2009	4
May 2009	1
June 2010	2
July 2010	6
August 2010	15
September 2010	NA

**Figure 8.**

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## OTHER STATISTICS

Figure 9 below shows the total number of individuals receiving (a) Class II, (b) Class II and/or III and (c) Class II, Class III and/or Class IV prescriptions during the respective time periods. This demonstrates that the existence of VPMP does not prevent individuals from receiving controlled substances for legitimate medical purposes, nor does its existence appear to have a “chilling effect” on the prescribing habits of physicians treating those individuals.

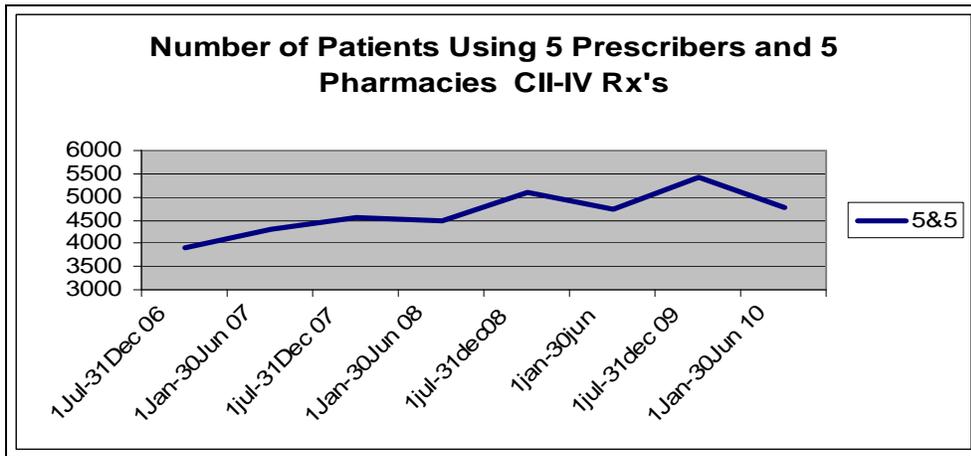


**Figure 9.**

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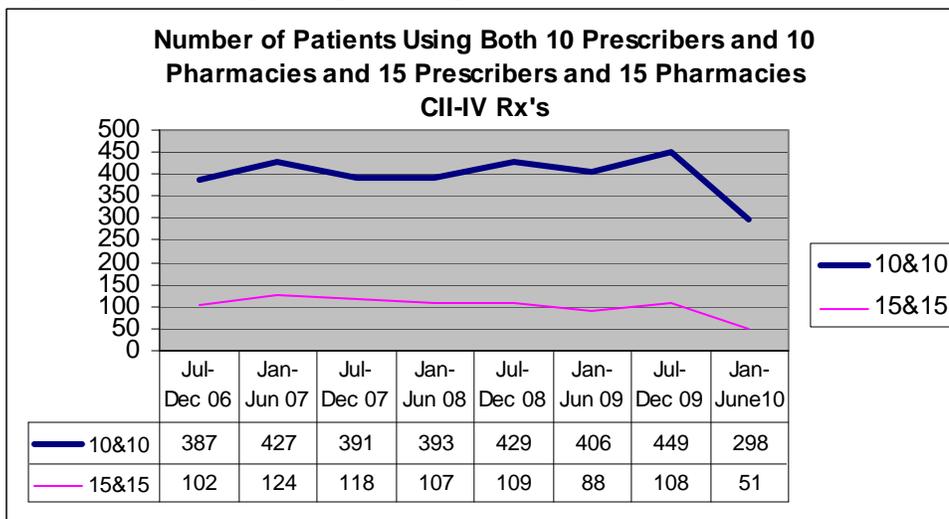
The following tables show the number of persons in the VPMP who have utilized pharmacies and prescribers in the following numbers: 5 & 5; 10 & 10; 15 & 15 during six-month periods dating back to the second half of 2006

Figure 10 shows a decline in persons utilizing five prescribers and five pharmacies during the most recent six month period. This is presumably due to the ability of prescribers to have 24/7 access to data provided by the VPMP. The utilization of five prescribers and five pharmacies is not necessarily an indication of prescription misuse, abuse or diversion, but may be a reflection of individuals either seeking care from specialists or receiving care from different prescribers within the same practice.



**Figure 10.**

Figure 11 demonstrates that access to VPMP has had an impact on those persons seeking care from ten and fifteen prescribers and pharmacists. Utilization of services at these levels is more likely an indicator of prescription drug misuse, abuse or diversion.

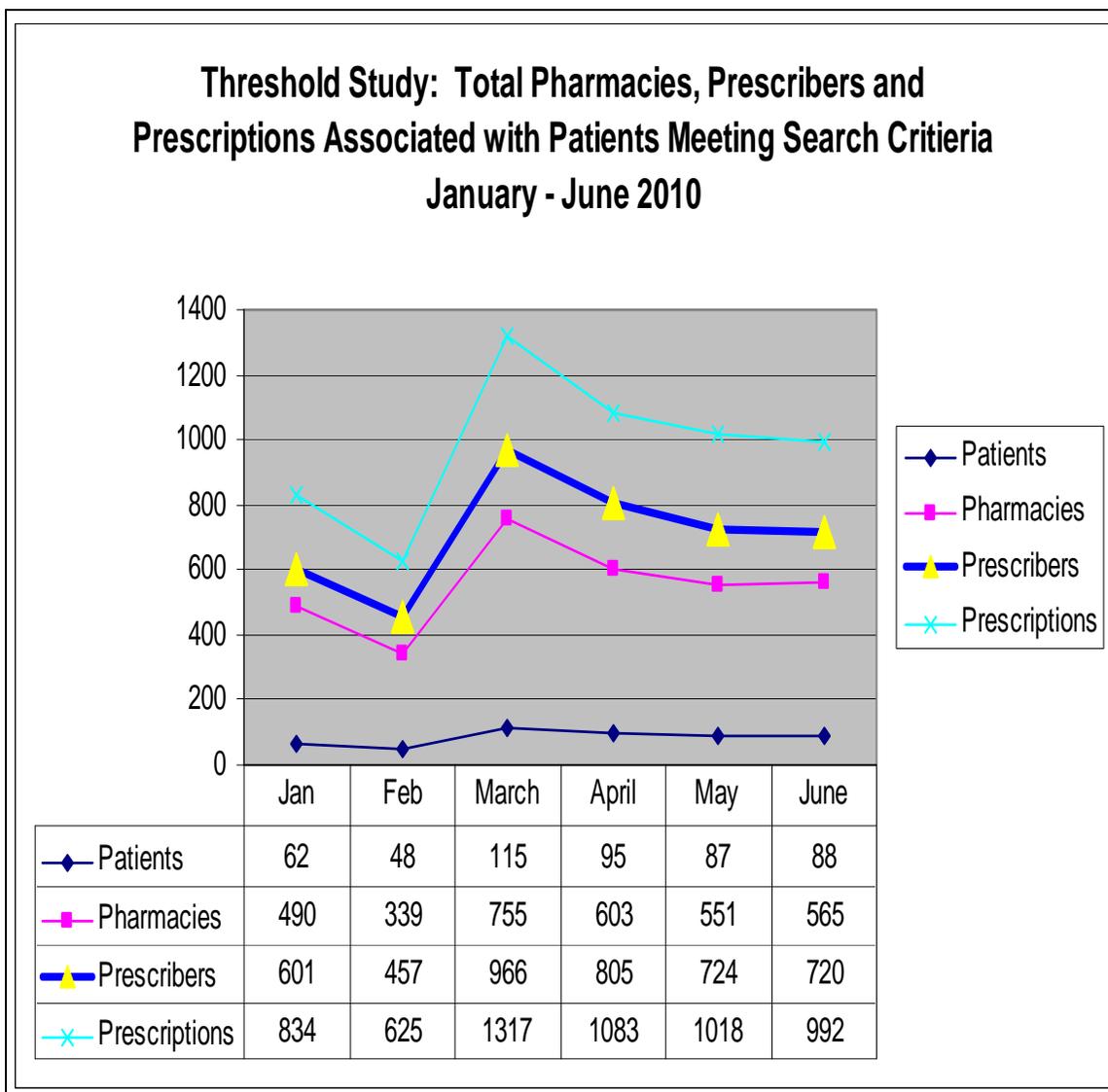


**Figure 11.**

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For notification purposes, the thresholds used by the VPMP are not the same as those referenced in Figures 10, and 11. Figure 12 below shows the total number of patients identified each month as a result of the VPMP’s threshold search. During the first six months of 2010, an average of 83 patients met the designated thresholds of at least seven physicians consulted and at least three pharmacies dispensing their medications in a one month period. These individuals utilized on average per month; 7 (seven) pharmacies and 9 (nine) prescribers to obtain 12 (twelve) prescriptions.

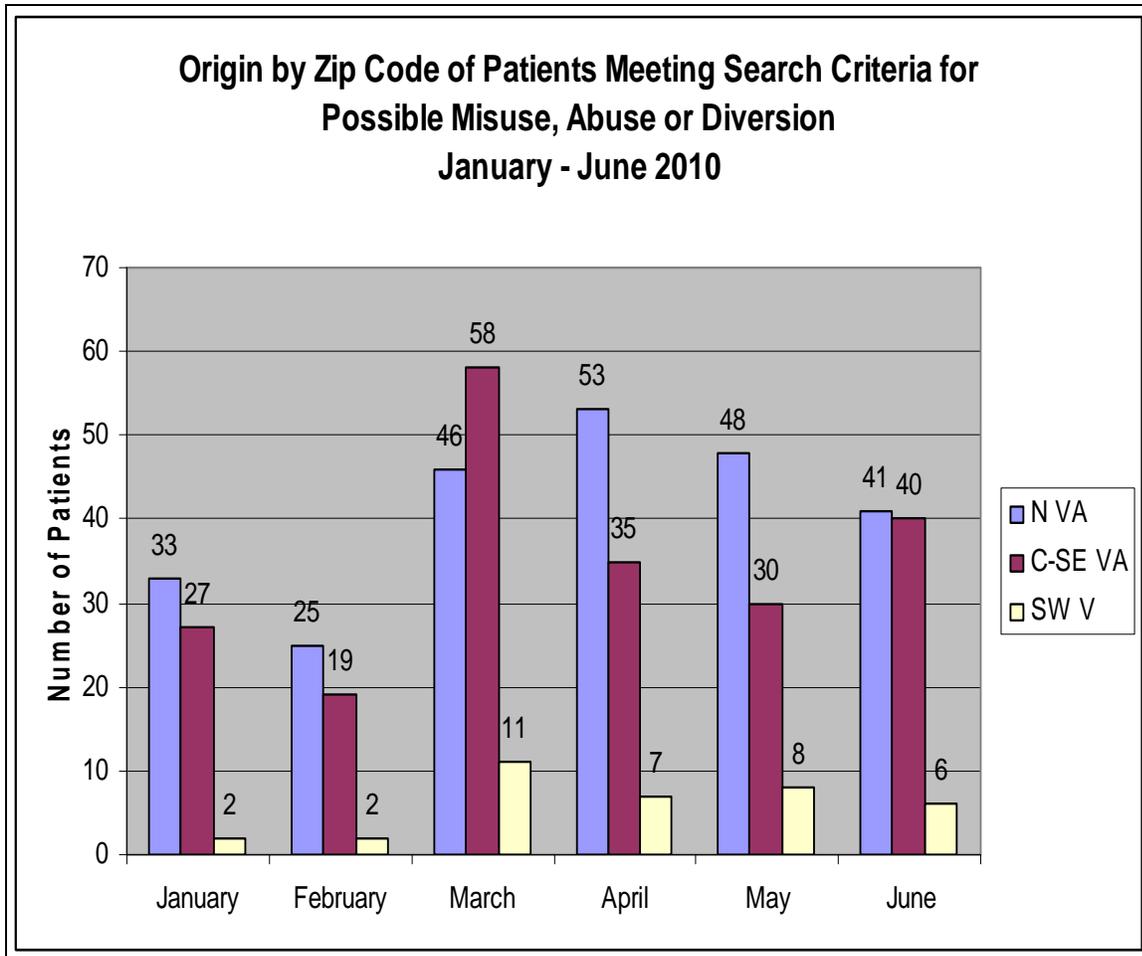
As indicated in Figure 12, there is a decline in the number of persons meeting the thresholds referenced in the paragraph above. Again, this is presumably due to the ability of prescribers and pharmacists to utilize the VPMP prior to making a treatment/dispensing decision.



**Figure 12.**

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During analysis of the notifications sent to prescribers, we also tracked the distribution of patients by zip code. While the PMP pilot project was initiated as a result of a public health crisis in Southwest Virginia, in the first half of 2010 only 7.3% of the 491 patients identified appeared to have a primary residence in Southwest Virginia. The majority of patients identified (exactly 50% of the total) identified their primary residence as located in Northern Virginia. Figure 14 shows the distribution by zip code of those patients identified in our threshold study (i.e., unsolicited reports.)



**Figure 13.**

RECOMMENDATIONS FOR CONSIDERATION

DESCRIPTION OF RECOMMENDATION	TYPE OF CHANGE REQUIRED
Add Schedule V controlled drugs as covered substances of the program	Code
Add tramadol as a covered substance of the program	Code
Add carisprodal as a covered substance of the program	Code
Add authority to add additional drugs of concern through a regulatory process	Code
Expand access to include additional federal law enforcement (FBI, Agents of FDA, HHS, Veteran's Affairs, etc) and other States' law enforcement entities	Code
Expand access to include authority for medical reviewers for workman's compensation programs	Code
Expand the number of allowed delegates per supervising prescriber and add an bi-annual renewal or re-authorization requirement	Code
Add authority to provide unsolicited information to law enforcement and regulatory agencies	Code
Change reporting requirement to "within 7 days of dispensing"	Code or regulatory
Change reporting format to ASAP version 2007, provide mechanism for Director to change reporting format by providing timeframe to come into compliance.	Regulatory
Add requirement of notarized application for prescribers, dispensers, and delegates	Regulatory
Add method of payment to reporting requirements (Cash, Medicaid, other)	Reporting Manual update
Require dispensers to report the DEA registration of the dispenser (Note: change from NCPDP#)	Reporting Manual update
Require dispensers to report the number of refills ordered	Reporting Manual update
Require dispensers to report whether the prescription was a new or refill	Reporting Manual update
Require the dispenser to report the date the prescription was written	Reporting Manual update
Require estimated number of days for which prescription should last	Reporting Manual update
Add requirement of notarized application for prescribers, dispensers, and delegates	Regulatory
<i>Notarized applications for LE and regulatory?</i>	