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**McDonnell, Brownlee Announce Maker of OxyContin Pleads Guilty to Felony
Misbranding**

Will Pay \$630 Million in Criminal Penalties

--Virginia Will Receive Over \$60 Million; Additional Funds to be Disbursed Later--

Roanoke - Virginia Attorney General Bob McDonnell, and John L. Brownlee, United States Attorney for the Western District of Virginia, announced today that earlier this morning The Purdue Frederick Company, Inc., along with its President, Chief Legal Officer, and former Chief Medical Officer pleaded guilty to charges of misbranding Purdue's addictive and highly abusable drug OxyContin. Purdue and the three executives will pay a total of \$634,515,475 in fines. The guilty pleas today are the result of a four year long criminal investigation that was initiated by the Virginia Medicaid Fraud Control Unit under the direction of then-Attorney General Jerry Kilgore.

OxyContin is a Schedule II prescription pain relief medication, classified as having the highest potential for abuse of legally available drugs. According to the State Medical Examiner in Roanoke, Dr. William Massello, between the years of 1996-2005 228 individuals died in the western part of Virginia from oxycodone overdoses. Oxycodone is the main ingredient in OxyContin.

Speaking about the penalties Attorney General Bob McDonnell noted, "The criminal behavior in this case embodies a systematic pattern of misrepresentations about the addictive nature of the product by these defendants. Purdue Fredrick and certain corporate officers, over a period of time, engaged in criminally deceptive behavior which caused OxyContin, a highly addictive drug, to be misbranded. As a result, many innocent victims suffered, particularly in our rural areas and in Southwest Virginia."

McDonnell continued noting, "In our Commonwealth, we have a proven track record of investigating and prosecuting health care fraud schemes. The guilty pleas in this case

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demonstrate the commitment of our state and federal law enforcement team to pursue corporate accountability in accordance with state and federal law. I applaud United States Attorney John Brownlee and his team for their leadership and diligence, as well as the Virginia Medicaid Fraud Control Unit, The Virginia State Police, FDA, IRS, and all of the other state and federal law enforcement agencies that worked cooperatively over the past four years to investigate these complex criminal activities and bring the defendants to justice."

United States Attorney John Brownlee remarked, "Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted Oxycontin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less abusable, and less addictive than other pain medications on the market

Brownlee further added, "Today's convictions are a testament to the outstanding work of the prosecutors and agents who spent years investigating this important case."

The Purdue Frederick Company, Inc., and the three executives have admitted that Purdue fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without FDA approval of these claims. The Purdue Frederick Company, Inc. and Purdue Pharma, L.P. are part of a worldwide group of related and associated entities engaged in the pharmaceutical business. These entities manufacture, market, and distribute OxyContin, an extended-release form of oxycodone.

The company, pleaded guilty to felony misbranding OxyContin with the intent to defraud and mislead. President and Chief Operating Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard Udell, and former Executive Vice President of Worldwide Medical Affairs Paul D. Goldenheim, pleaded guilty to a misdemeanor charge of misbranding OxyContin. All the pleas were entered in United States District Court in Abingdon this morning.

Pursuant to written plea agreements, Purdue and the executives will pay a total of \$634,515,475.00.

Purdue's payments will include:

\$276.1 million forfeited to the United States

\$160 million paid to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs

\$130 million set aside to resolve private civil claims (monies remaining after 36 months will be paid to the United States)

\$5.3 million paid to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations

\$20 million paid to fund the Virginia Prescription Monitoring Program for the foreseeable future

In addition, Purdue will pay the maximum statutory criminal fine of \$500,000.

Purdue's top executives will pay the following amounts to the Virginia Attorney General's Medicaid Fraud Control Unit:

\$19 million paid by Michael Friedman

\$8 million paid by Howard R. Udell

\$7.5 million paid by Dr. Paul D. Goldenheim

Each executive will also pay a \$5,000 criminal fine.

According to the Statement of Facts filed with the Court, beginning in January 1996 and continuing through June 30, 2001, Purdue's market research found that "[t]he biggest negative of [OxyContin] was the abuse potential." Despite this finding, Purdue's supervisors and employees falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal than other pain medications. Purdue misbranded OxyContin in three specific ways:

1. Purdue sales representatives falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids. This message was presented to some health care providers through the use of graphs that exaggerated the differences between blood plasma levels achieved by OxyContin compared to the levels of other pain relief medications.

Purdue supervisors and employees participated in the misbranding in the following ways:

A. Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

B. Purdue supervisors and employees permitted new Purdue sales representatives to use similar exaggerated graphical depictions during role-play training at Purdue's headquarters in Stamford, Connecticut.

2. Purdue supervisors and employees drafted an article about a study of the use of OxyContin in osteoarthritis patients that was published in a medical journal on March 27,

2000. On June 26, 2000, each sales representative was provided a copy of the article together with a "marketing tip" that stated that the article was available for use in achieving sales success. Sales representatives distributed copies of the article to health care providers to falsely or misleadingly represent that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms. The article also indicated that patients on such doses would not develop tolerance. The marketing tip that accompanied the article stated that one of the twelve key points was, "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants." These marketing claims were made even though Purdue representatives were well aware of the following information:

A. The year before the article was published and distributed to sales representatives, Purdue received an analysis of the osteoarthritis study and a second study from a United Kingdom company affiliated with Purdue that listed eight patients in the osteoarthritis study "who had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

B. In May of 2000, Purdue received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms. Executives also learned that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms ha[d] come up quite a bit . . . in Medical Services lately (at least 3 calls in the last 2 days)."

C. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study that listed eleven study patients who reported adverse experience due to possible withdrawal symptoms during the study's respite periods and stated "[u]pon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms;" Even after receiving this information, on March 28, 2001, supervisors and employees decided not to write up the findings because of a concern that it might "add to the current negative press."

D. Supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger to or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians['] mind[s]."

3. Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria,

had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The statement was later amended to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Purdue supervisors and employees took part in the misbranding in the following ways:

- A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote OxyContin.
- B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.
- C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
- D. By March 2000, Purdue had received reports of OxyContin abuse and diversion occurring in different communities but allowed sales staff to continue promoting and marketing OxyContin in this manner.

The case was investigated by the Virginia Attorney General's Medicaid Fraud Control Unit; Food and Drug Administration, Office of Criminal Investigations; Internal Revenue Service Criminal Investigation; the Department of Health and Human Services Office of Inspector General; Department of Labor, Office of Inspector General; Defense Criminal Investigative Service; Virginia State Police; and West Virginia State Police. The case was prosecuted by Assistant United States Attorneys Rick Mountcastle, Randy Ramseyer and Sharon Burnham and U.S. Department of Justice, Office of Consumer Litigation. Trial Attorneys Barbara Wells and Elizabeth Stein.

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BRIEFING PAPER

Virginia Department of Health Professions

Prescription Monitoring Program

May 24, 2007

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- II. Executive Summary**
- III. Findings and Observations of Prescription Monitoring Program to Date**
 - A. Data Base**
 - B. Education for Prescribers and Public**
 - C. Performance**
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 - A. Data Base Enhancements and Maintenance**
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Annex 1: Funding Stream Chart

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I. Introduction

The Prescription Monitoring Program (PMP) was started as a pilot program pursuant to Virginia General Assembly legislation in 2003 and covered Schedule II controlled substance prescriptions dispensed in southwest Virginia. The program was originally designed to assist (1) law enforcement agencies investigating instances of drug diversion, (2) regulatory boards in determining appropriate prescribing and dispensing of Schedule II controlled substances, (3) prescribers in making appropriate medical treatment decisions for patients requesting Schedule II controlled substances, and (4) the fraud unit of the Department of Medical Assistance Services to reduce the occurrence of Medicaid fraud. The program expanded statewide in June 2006 and now covers prescriptions dispensed in Schedules II, III, and IV.

An Advisory Committee comprised of stakeholders throughout Virginia advises and assists the Department of Health Professions (DHP).

The PMP collects data twice monthly from approximately 2000 dispensers that include resident pharmacies, mail order pharmacies, and dispensing physicians. The prescriptions are loaded into a secure database where certain authorized users may request information from the program. Authorized users are prescribers, pharmacists, certain law enforcement personnel (must have an open investigation), regulatory personnel, Office of the Chief Medical Examiner, and patients over the age of eighteen. Data may also be provided for research and education purposes with the provision that all personal identifying information is removed. Financial limitations have prevented the provision of immediate real time access to information.

The PMP educates prescribers in the use of the data collection in tracking of doctor shopping; provides training for prescribers in pain management and typical provider shopping behaviors. Financial constraints have limited the impact on the physician community.

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II. Executive Summary:

This Briefing Paper is intended to provide information on the program's impact to date in meeting the legislative directive.

Specifically:

1. Has tracking of prescriptions dispensed been conducted in a capable manner?

The program has worked to ensure that the requirements for tracking prescription data has been easy for dispensers to comply with, ensure the confidentiality and security of the data, and availability to authorized users in an easy to understand format. We have enhanced the program to allow dispensers to use secure web technology and file transfer protocol to report data, which also allows for data to be loaded into the database more quickly. These technologies also provide immediate feedback to dispensers as to file receipt and any errors or other problems with their transmissions. The PMP is constantly looking for new ways to improve the reporting process and inform dispensers of requirements.

2. Has the program addressed public health dangers?

Prior to 2003, drug deaths due to prescription drugs in Virginia were increasing every year. Since the inception of the PMP, drug deaths have largely stabilized. Since 2003, the rate of wholesale distribution of oxycodone, hydrocodone, and methadone products have continued to increase but at a much lower rate than prior to the implementation of the PMP.

3. Has the program assisted law enforcement efforts?

During the pilot program, data showed a 53% decrease in man-hours spent conducting pharmacy profiles in southwest Virginia by agents of the State Police Drug Diversion Unit. Arrests increased by 31% in the region during the same time period. Data from the Drug Diversion Unit also appears to show that illegal activity had moved outside the program area. Complaints received statewide by the unit increased 26% while decreasing in the program area by 47%. Additionally, investigations by the Drug Diversion

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Unit used to take up to 3 months to complete. With the PMP, investigations are normally complete within a month, generating huge man-hour savings.

4. Has the program assisted prescribers in making appropriate medical treatment decisions?

Since 2003, the rate of wholesale distribution of oxycodone, hydrocodone, and methadone products have continued to increase but at a much lower rate than prior to the implementation of the PMP. Anecdotally, prescribers who were uncomfortable prescribing certain medications for pain, now do so because they have a tool that helps them confirm treatment history and patient compliance. Prescribers are the largest user group of the PMP making over 70% of requests to the program. In just over 4 months into 2007, the PMP has fulfilled more requests (6333) than were fulfilled in all of 2006. The program expects that filling of requests will increase to over 2500 requests a month within the next 18 months.

5. Finally, what additional resources are needed for program gaps/ maximization of efforts?

With additional funding from the settlement:

Data Base *enhancements to improve ease of use and extension of its user population to include more of the 35,000 physicians in Virginia (800 are presently using the data base)*

Webpage *enhancements to provide dedicated web pages with full information to all citizens of Virginia on the entire range of activities and resources provided by PMP and epidemiologically -based Geographical Information System (GIS) maps created from PMP data for controlled substance prescriptions dispensed within Virginia with constant updates on trend analysis for all controlled substance prescriptions in Virginia. (See model for Kentucky, the first PMP program: <http://chfs.ky.gov/oig/KASPER.htm>)*

Public Education for prescribers and the public *to provide constant and consistent information about the need for continuing education, and public safety as well as the appropriate use of pain medication. Outreach efforts would target primary doctors' compliance and education with relevant*

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media, with outreach to the general public for the purpose of education on (1) program resources (2) effective addiction treatment available (including the recent approval by the FDA of office-based use of other addiction medications) and (3) information regarding the consequences and impact of addiction.

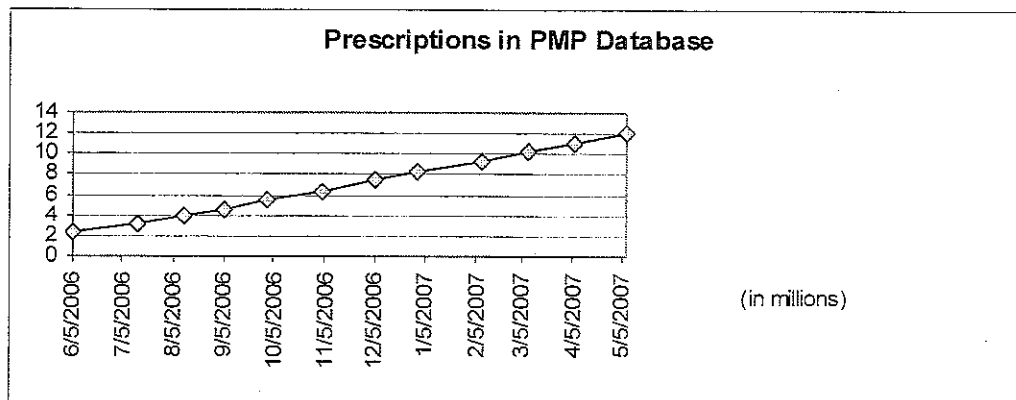
These needs are further described in this brief, including a draft communication plan, in Section IV. Unmet Needs to be Addressed with Settlement Monies

In fiscal year 2009, the program will no longer be able to rely on federal funds for the operation and maintenance of the PMP. Without the settlement money, operational funding of the program would come from licensing fees from the Boards of Medicine, Nursing, Optometry, and Dentistry based on a formula of the number of prescribers licensed by each board. This would require that license fees be increased by each of these boards.

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III. Findings and Observations of Prescription Monitoring Program to Date

A. Data Base



- In just over 4 months into 2007, the PMP has fulfilled more requests than were fulfilled in all of 2006 (6333). Over two-thirds of requests were made by prescribers, with pharmacists making the second most requests. It is anticipated the program will fill an excess of 2500 requests a month within the next 18 months.
- The PMP is planning to implement 24/7 access to the data in the database in late fall 2007. This implementation will greatly assist emergency rooms and urgent care centers besieged by patients seeking drugs without medical cause and free up valuable medical access to patients in need of urgent medical care.
- The PMP is adding approximately one million records a month to the database. Data of this magnitude requires that systems perform at top proficiency, provide timely access and are user-friendly while providing security for the data. Access to the data is strictly controlled with only authorized users having access and is secured within a firewall at DHP.

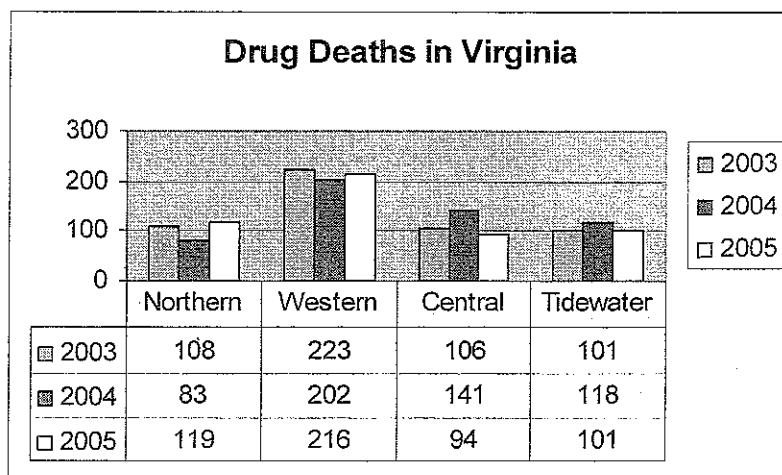
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B. Education

- **The program undertook an educational effort which included articles for Board and professional association newsletters, periodic briefings to the Boards of Health Professions, Pharmacy, and Veterinary Medicine and speaking at meetings of various groups such as the Virginia Drug Court Association and the Virginia Pharmacists Association.**
- **The program also sponsored a one day conference in October 2004 for stakeholders and policy makers to discuss the issues surrounding prescription drug abuse and how the program can be used as a tool in preventing the misuse, abuse, and diversion of controlled substances. Over 120 policy makers and stakeholders attended.**
- **In 2006, the program coordinated a one day seminar for over 100 prescribers and pharmacists that provided 5.5 hours of continuing medical education on addiction, pain management, research findings on deaths determined as caused by prescription drugs from southwest Virginia, Board of Medicine guidance on pain management, and an overview of the prescription monitoring program.**
- **The PMP will partner with other state agencies and education centers as opportunities arise to address prescription drug abuse. This will include education for citizens on the proper security and disposal of prescription drugs, medical education to health care professionals through seminars and online courses, and the development of a "map" of Virginia highlighting high usage areas of certain prescription drugs to assist in resource planning for education, treatment, and law enforcement activities.**

C. Performance

In the 2006 *Achieving Balance in State Pain Policy, A Progress Report Card*, issued by the Pain & Policy Studies Group, University of Wisconsin School of Medicine and Public Health, Virginia was one of only 2 states (Michigan the other) to receive an "A" rating. The evaluation is guided by what the Studies Group calls the "Central Principle of Balance" representing the obligation of government to prevent the abuse and diversion of controlled substances while ensuring that the drugs are available for legitimate medical needs.



- Investigations by the State Police Drug Diversion Unit used to take up to 3 months to complete. With the PMP, investigations are normally complete within a month, generating huge man-hour savings.
- Prior to 2003, drug deaths due to prescription drugs were increasing every year. Since the inception of the PMP, drug deaths in Virginia are no longer increasing.
- Since 2003, the rate of wholesale distribution of oxycodone, hydrocodone, and methadone products have continued to increase, but at a much smaller rate than prior to the implementation of the PMP.

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- Anecdotally, prescribers who were uncomfortable prescribing certain medications for pain, now do so because they have a tool that helps them confirm treatment history and patient compliance.

D. Funding

The PMP has largely been funded by federal funds through Harold Rogers Prescription Drug Monitoring Program grants administered by the Bureau of Justice Assistance within the U.S. Department of Justice. Additionally, \$182,000 from a court settlement (United States v. Dinkar N. Patel 10-25-99) was used to assist in the implementation of the program and \$302,000 from a discontinued controlled substance registration program was used to purchase software to expand the program statewide. From 2003 through the end of June 2007, \$1,094,369 will have been spent to implement, operate and enhance the PMP. The funding has paid for (1) personnel, (2) equipment, (3) data collection contracts, (4) software, and (5) education/marketing efforts.

(1) Personnel:

The Director of DHP has overall responsibility and authority for the operation of the PMP and serves as the legislative and regulatory liaison for the program.

The Program Manager is responsible for grant management efforts, coordinates and supervises the daily operation and evaluation of the program, promotes the use of the program among those who are eligible to query, serves as staff to the PMP Advisory Committee, and attends conferences related to prescription monitoring programs in order to keep abreast of new technologies, pending federal legislation, and new efforts of other states.

The program has a full-time administrative assistant who provides program and administrative support for the Prescription Monitoring Program. Duties performed include responding to requests for information from the program in accordance with law and regulation and preparing correspondence relating to the reporting of information to the program and maintaining an office filing system that

ensures access to program information while properly securing contents; responding to telephone and written inquiries related to the program, providing only public information consistent with the laws and policies of the Department; researching and preparing responses to Freedom of Information Act Requests related to the Prescription Monitoring Program; assisting in the collection of additional information required to evaluate the success of the PMP and assisting the Program Manager in development and distribution of reports; making all necessary arrangements for Advisory Committee meetings to include agenda and notice preparation and distribution; preparing correspondence; and maintaining and ordering needed supplies.

An additional part-time administrative assistant will be hired in June 2007 and a full time administrative assistant may be hired in the future to perform similar duties to assist in the daily administration of the program at such time as the number of daily inquiries increases to warrant additional staff.

An information technology specialist with knowledge and experience working at a technical level in a relational database application or system, internet web pages updates and searches, and networked PC Windows's environment will be hired in late 2008. This person will assist in maintaining the database, preparing ad-hoc reports, tracking compliance of reporting and assist with collecting data from other sources for the continuing evaluation of the program.

PMP support is also provided by the Department of Health Professions administrative, financial and information technology staff.

(2) Equipment, (3) data collection contracts, (4) software and (5) education/marketing efforts:

Expenditures for fiscal year 2007 are expected to be approximately \$300,000. Estimated expenditures for fiscal year 2008 will be in the \$700,000 range, of which \$260,00 is for software enhancements to allow for 24/7 access to the program's database and to align the database for possible data-sharing with other state prescription monitoring programs in the future. Personnel costs to support the program make up the bulk of the remaining balance of the

Increase for FY2008. FY2008 expenditures will be covered by grant funds.

**Estimated budget for current operations and planned enhancements
FY09 and FY10:**

Category	FY09	FY10
Personnel	\$300,455	\$312, 473
Education	\$18,000	\$18,000
Information Technology Support	\$45,000	\$45,000
Supplies (postage, office sup)	\$2,500	\$3,000
Consultants/contracts	\$132,500	\$132,500
Other costs (printing, etc)	\$13,000	\$15,000
Total	\$511,455	\$525,973

V. Unmet Needs

A. Data Base Enhancements and Maintenance

- **Electronic monitoring program - to track prescription drug activity in real time, which will be of great benefit in emergency rooms and urgent care centers.**
- **Epidemiologist - to provide Geographical Information System (GIS) maps created from PMP data based upon the reported patient address, for controlled substance prescriptions dispensed within Virginia with constant updates on trend analysis for all controlled substance prescriptions in Virginia.**
- **Web master - to provide the full information to all citizens of Virginia on the entire range of activities and resources provided by PMP. See model:
<http://chfs.ky.gov/oig/KASPER.htm>**

B. Education for Prescribers and Public

- Continuing education module (web accessible) is in development for prescribers and pharmacists. This will provide consistent and convenient information to educate the provider. DHP is partnering with Virginia Commonwealth University to design and house the training modules.
- Outreach coordinator to visit primary doctors' offices and hospitals. Primary care physicians play a critical role in screening, assessing and referring people with potential substance abuse problems.
- Outreach to general public for the purpose of education on (1) program resources (2) effective addiction treatment available (including the recent approval by the FDA of office-based use of other addiction medications) and (3) information regarding the consequences and impact of addiction.

Draft communication plan:

1. Focus on market segments that are predisposed to the product's need: Southwest Virginia, which has the highest incidence of prescription medicine abuse, would be the target of a radio campaign & a billboard campaign.

Radio:

Roanoke major media market of 5 stations, including Lynchburg and Blacksburg for a cost of \$20,000;
Bristol major media market, 4 stations for a cost of \$11,000
15 minor markets through the Southwest for \$30,400
Splash campaign for a total of 200 gross rating points per week

Billboard:

10 in Southwest, \$350 per posting site, include production, development costs, and rent for one month. (This rate is the public relations special discount rate offered by the Outdoor Advertising Association of Virginia.)

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- 2. Focus on early adopters in the target segment of the central Virginia densely populated regions of Richmond and the neighboring city of Petersburg with billboards in 50 sites.**
- 3. Provide information to the retail outlets of doctors' offices and pharmacies with a pamphlet for consumer information on the PMP program to educate patients at the point of service about the role of the prescriber.**
- 4. Expose participants with some experience with one or more of the professional prescribers to 2 workshops (focus groups) with 8 participants each and a range of ages socio-economic backgrounds, male and female and ethnic minorities to evaluate message development in light of promoting compliance and representing the interests of prescribers. Further qualitative research on any message statement prior to any communication launch done with a workshop of physicians and pharmacists.**
- 5. Encourage information sharing and interaction between primary invested state agencies (social services and mental health) for the purpose of social/professional interactions to accelerate further adoption of the program through all respected leaders in the field.**
- 6. Awareness-tracking survey instrument**

According to enforcement and monitoring literature, providing information raises compliance rates. The goal is to convert a non-compliant, or non-interested, or non-adopting prescriber to a belief in the worth of reporting; to move that belief into an attitude that influences that professional as well as others; and to move that attitude into a value of the public protection partnership mandate of DHP & prescribers through compliance in reporting prescription drug abuse to the DHP database.

ANNEX 1 - Funding Stream

Fiscal Year is July 1 through June 30.

Funding Sources:

Source	Amount	Description
2003 Federal Grant	\$180,000	Implementation of Prescription Monitoring Program
Matching funds: Octagon	\$180,069	Implementation of Prescription Monitoring Program
2004 Federal Grant	\$82,500	Education conference, education efforts, survey
2005 Federal Grant	\$350,000	Expansion of program
Legacy registration funds	\$302,000	Procurement of software to support expansion of program
2006 Federal Grant	\$400,000	Expansion of program
2007 Federal Grant	\$400,000	Procurement of software to allow for 24/7 access to program and sharing of data with other applications
TOTAL	\$1,894,569	(Includes 2007 grant application request)

FY2003 through FY2008 are funded by the resources cited above.

EXPENDITURES

Fiscal Year	PERSONNEL ¹	EDUCATION ²	INFORMATION TECHNOLOGY SUPPORT ³	SUPPLIES ⁴	CONTRACTS ⁵	OTHER COSTS ⁶	TOTAL
FY2003			\$14,642	\$80		\$244	\$14,966
FY2004*	\$46,689	\$2,722		\$1,245	\$31,763	\$1,802	\$84,221
FY2005**	\$66,712	\$17,457		\$1,630	\$36,315	\$6,040	\$128,154
FY2006***	\$132,157	\$12,423	\$302,000	\$931	\$68,007	\$16,973	\$532,491
FY2007 TO DATE	\$125,236	\$5,551	\$30,000	\$1,290	\$160,000	\$4,807	\$326,884
FY2008 projected****	\$225,236	\$17,913	\$45,000	\$2,500	\$353,500	\$12,410	\$656,559
FY2009 projected*****	\$300,455	\$18,000	\$45,000	\$2,500	\$132,500	\$13,000	\$511,455
FY2010 projected	\$312,473	\$18,000	\$45,000	\$3,000	\$132,500	\$15,000	\$525,973

*FY2004-Personnel: 1 part-time program manager, 1 part-time administrative assistant

**FY2005-Personnel: 1 full-time program manager, 1 part-time administrative assistant

***FY2006-Information Technology: New software to support expansion of program

***FY2006-Personnel: 1 full-time program manager, 1 full-time administrative assistant

****FY2008-Personnel: 1 full-time program manager, 1 full-time administrative assistant, 1 part-time administrative assistant, 1 full-time information technology specialist

****FY2008-Contracts: Includes software for 24/7 access and data-sharing capability

*****FY2009-Personnel: 1 full-time program manager, 2 full-time administrative assistants, 1 part-time administrative assistant, 1 full-time information technology specialist

¹ Personnel: Salaries, wages, taxes, fringe benefits

² Education: Travel, meals, lodging, room rentals, etc for presentations and education

³ Information Technology Support: Software, computer hardware, VITA support

⁴ Supplies: Postal services, office supplies, office equipment

⁵ Contracts: Data collection, software maintenance, subscriptions, consultant fees, other contracts

⁶ Other Costs: Phone, printing, production services, building capital leases, misc.

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WWW.DHP.VIRGINIA.GOV**

Dear Sir or Madam:

Attached is a prescription profile report from Virginia's Prescription Monitoring Program, "PMP", of a person who has obtained prescriptions for Schedule II-IV controlled substances from a pre-determined number of different prescribers and pharmacies. There may be a legitimate reason for exceeding this threshold, but obtaining prescriptions from this many different prescribers and pharmacies can also be indicative of a practice called "doctor shopping" in order to obtain drugs. You are receiving the report because you are listed in the report as one of the prescribers of controlled substances for this person.

By providing you the attached report, PMP is not judging the appropriateness of your treatment of this patient or of the appropriateness of the patient's using multiple prescribers and pharmacies. The mission of PMP is to promote access to appropriate care while deterring the misuse, abuse, and diversion of controlled substances. PMP is well aware that some patients have special needs and conditions that justify prescribing large quantities of controlled substances or justify seeing multiple prescribers. PMP is also aware that many times patients who may be addicted to or abusing controlled substances use various methods to obtain those controlled substances, and that you may not be aware of all of your patient's activities. Well informed practitioners will use their professional expertise to assist patients who may be addicted to or abusing controlled substances. PMP believes that providing you with this information will lead to optimum care for your patient. If the prescriptions were issued by you, please consider how you should discuss your concerns (if any) with your patient as you deem appropriate.

If you did not prescribe controlled substances for the person in this report, you may want to contact the pharmacy or pharmacies listed in the report as dispensing your prescriptions. Sometimes the problem is that the pharmacy incorrectly records the prescriber identifier in the data it reports. Other times the prescriptions may be forgeries.

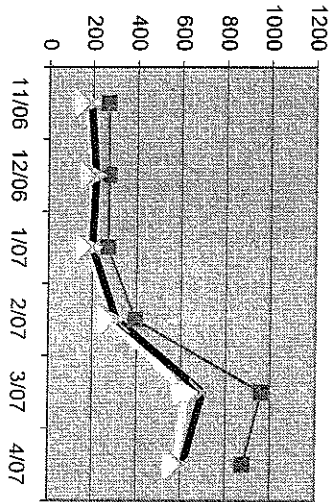
This report is confidential and intended to be used for informational and assessment purposes. By law, the report itself may not be further distributed to anyone. You may keep this report in the patient chart, but it should be marked as confidential and not copied or forwarded to other parties. You may routinely request and receive reports on any of your patients or potential patients to determine their prescription history. You may find resource information on requesting such reports, as well as on pain management, addiction treatment, reporting of known or suspected criminal activity, and other resources at www.dhp.virginia.gov under Services for Practitioners and then Prescription Monitoring Program.

Sincerely,

Ralph A. Orr, Program Manager
Prescription Monitoring Program

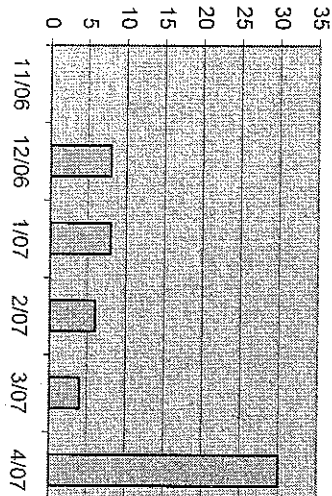
Month	#of Patients	#of Prescriptions	#of Pharmacies	#of dosage units	#of Prescribers	Previous reports sent
11/06	22	269	174	10163	192	0
12/06	28	273	202	8163	215	8
1/07	27	269	183	10435	199	8
2/07	46	394	283	15107	309	6
3/07	104	960	620	39109	697	4
4/07	94	877	577	34354	610	30

Threshold Reports Summary



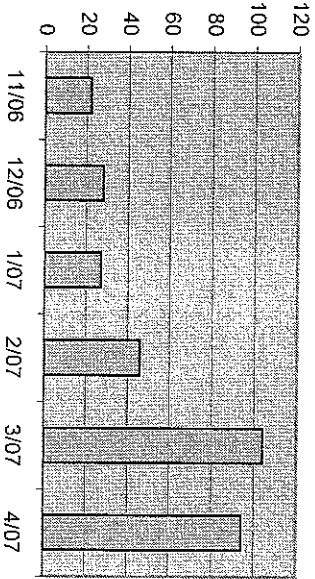
— #of Prescriptions
 — #of Pharmacies
 — #of Prescribers

Previous reports sent



— Previous reports sent

#of Patients



— #of Patients

125

PT ID	#of Prescriptions	#of Pharmacies	#of dosage units	#of Prescribers	Report Month
572912	19	15	289	17	November-06
	24	18	442	23	December-06
	14	13	155	14	January-07
	13	10	172	13	February-07
	11	9	165	11	March-07
	8	6	107	7	April-07
196980	35	26	980	21	November-06
	36	28	1276	23	December-06
	29	20	823	16	January-07
	14	6	463	7	February-07
	11	6	551	7	March-07
	8	5	540	5	April-07
834208	13	10	167	13	November-06
	9	9	129	9	December-06
	10	9	140	9	January-07
	11	10	139	10	February-07
	20	13	333	15	March-07
464214	8	7	127	7	November-06
	16	15	259	15	December-06
	14	13	207	13	January-07
	12	11	179	11	February-07
	5	5	94	5	March-07
	10	10	162	10	April-07

BACKGROUND INFORMATION:
ONLINE CME PROJECT
CHRONIC NONMALIGNANT PAIN MANAGEMENT
DHP AND VCU SCHOOL OF MEDICINE

DHP Mission:

To enhance the delivery of safe and competent health care by licensing qualified health care professionals, enforcing standards of practice, and providing information to both practitioners and consumers of health care services.

PMP Mission:

Promote access to appropriate pharmaceutical care while deterring the misuse, abuse, and diversion of controlled substances.

Prescribers receive little or no training on pain management in medical school but once they are in practice are confronted with patients with pain in almost every type of specialty, from family practice to orthopedic surgeon. Because of this lack of training some prescribers are hesitant to prescribe controlled substances for pain and others may be misled by patients to prescribe inappropriately.

This project will provide education to prescribers on pain management, prescribing for chronic pain, educate them on the requirements of the Board of Medicine and state and federal law and regulations pertaining to the treatment of pain, and inform them how to use the Prescription Monitoring Program as a tool to assist in the management of patients with chronic pain and non-chronic pain.

There are currently over 35,000 prescribers licensed by the Board of Medicine in Virginia and over 8,000 pharmacists. However, the prescription monitoring program has only registered 800 users for the program's website. This will be a great tool to increase awareness of the program while also providing a complete set of tools applicable to the various health professionals that are involved with the treatment of pain on a daily basis. Because credit for continuing medical education (CME) can be awarded by the Board of Medicine for the completion of the project's online modules; prescribers will be able to receive CME credit at no cost to them which in the past has proved to be a huge incentive for encouraging participation.

The project provides a great opportunity for 2 state agencies to partner together to make a positive impact on the delivery of quality healthcare to the citizens of Virginia utilizing each agencies unique expertise.

Funding for this project will be provided by the prescription monitoring program through funds awarded by a federal grant administered by the Bureau of Justice Assistance.

VCU Chronic Nonmalignant Pain Management An Online Competency Based Curriculum

Leanne M. Yanni, MD
Creator & Editor
Assistant Professor
VCU Medical Center

Background

- Pain management is challenging
 - Topic of pain management crosses disciplines
 - Lack of coordination of care between generalists and specialists
 - Variation in chronic pain syndromes
 - Lack of evidence-based guidelines
 - Limited provider training
 - Lack of training resources and practice tools
 - Provider fears of legal implications

IM Resident Chart Review

- Inconsistent documentation of pain assessment and past history
 - Prior medical records
 - Potential "red flag" behaviors including substance and legal history
 - Pharmacy records
- Underutilization of a multi-modal approach to treatment including nonpharmacologic therapies
- Underutilization of important clinical practice tools to recognize and/or avert misuse
 - Office visits, urine drug screening

IM Resident Attitudes

- Over half reported their experience negatively impacted their view of primary care
- Nearly all residents are less confident in their ability to treat pain than other conditions
 - Over half rated preparation as fair or poor
- No resident found treatment of pain rewarding

Primary Goals

- Standardize education in chronic pain management
- Create online module for independent learning
- Target range of user levels
 - Students, residents, practitioners
- Integrate ACGME Competencies
- Provide primary care perspective but make applicable across disciplines
- Provide ongoing access to tools, resources, and references
 - Tables, templates, agreements

The Process

- 2004
 - Developed Objectives and Outline
- 2005
 - Recruited interdisciplinary team of writers
- July-October 2005
 - Wrote content and developed tables
 - Evidenced-based
 - Case-based questions
 - Pharmacology and summary tables
- November 2005 to March 2006
 - Edited content and tables
- December – July 2006
 - Designed web module

The Process

- July-September 2006
 - National reviewers recruited to review curriculum
- August 2006
 - Integrated into VCU SOM 3rd year IM Clerkship
- October 2006
 - CME made available
- December 2006
 - Content and design updates completed
- January 2007
 - Multi-institutional GME study began

Structure of the Curriculum

- Web-based
- 6 sections, 20 objectives
- 2 hours to complete
- Registration
- Pretest for each section
- Clinical content question and content for each objective with feedback
- Posttest for entire module (20 questions)

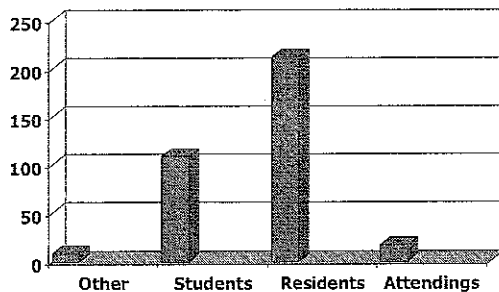
Sections of CNMP Module

- Overview and Assessment
- Treatment
- Common syndromes: Fibromyalgia
- Common syndromes: Neuropathic Pain
- Identifying and meeting challenges
- Legal and regulatory concerns

Unique Features

- ACGME competency based objectives
- Pharmacology and summary tables with print feature
- Clinical Practice Tools
 - Pain policy, agreement, and visit templates
 - Patient education instrument
 - Tables of urine drug screen interpretation
- Web-links and References
- Resources accessible after completion of curriculum

Completion to Date



Reviewer Data

- Opened to reviewers: August 4, 2006
- Evaluated reviewer responses: January 3, 2007
- Total number of reviewers: 24
- Total number of institutions represented: 18
 - Stanford, Brown, UNC – Chapel Hill, University of Massachusetts, Maine Medical Center, Indiana University, NYU
- Total number of specialties represented: 8
 - IM, FM, Psychiatry, EM, Orthopedics, PM&R, Pain Management

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Reviewer Data

- Having completed the curriculum, will you access any of the resources in this module?
Yes = 100%
- Would you recommend this curriculum to your colleagues?
Yes = 100%
- As a result of the curriculum, will you make any changes in your behavior or practice?
Yes = 71.4%

Reviewer Data

- If so, what changes?
 - "Change medication agreement, use urine drug screening"
 - "Change contract and procedure for follow-up"
 - "Use template. Specific appointments for pain."
 - "Create standardized office visit forms, different urine screening policy and procedures, update my own lecture"
 - "Many..."

Reviewer Comments

- "...I just finished reviewing the course and thought it was great I liked the content, the format, the fact that you could link directly to so many things, the actual items you need to conduct a proper pain management visit were there."
- "Thanks very much for sharing your work with us. The website you've developed is impressive for its comprehensive coverage of chronic pain issues and for the resources you've gathered together in a user-friendly site."

Resident Data

- Is the assessment and treatment of patients chronic nonmalignant pain more important to you as a result of using this module?
– 85% Yes
- As a result of the curriculum, will you make any changes in your behavior or practice?
■ 76% Yes

Resident Data

- If so, what changes?
 - "I plan to be better informed about the various types of pain meds and not be afraid to titrate up as necessary. I also will not assume that everyone is 'drug seeking.'"
 - "Increased utilization of multimodal approach to chronic pain."
 - "More frequent office visits for patients with pain, more thorough evaluation prior to starting meds..."
 - "Careful prescribing habits regarding complete documentation."

Resident Comments

- "Thank you so much for your involvement in the modules. They are extremely helpful and the embedded documents/tables I am finding to be very valuable."
- "Excellent curriculum - well written, comprehensive yet easy to navigate and not overwhelmingly detailed."

Student Data

- Is the assessment and treatment of patients chronic nonmalignant pain more important to you as a result of using this module?
 - 96% Yes

Student Comments

- "It was very helpful in understanding chronic pain. It makes working with patients less frustrating and makes me more understanding of what they are dealing with. I am not sure where I would have gotten this content in my regular curriculum and it is really important so thanks!"
- "I feel that this is a topic not often discussed, however, it permeates every aspect of the medical profession. I think this is useful in being able to tell physicians how to handle these complex patients along with their PMH."

Financial Support for Program

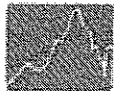
- Program created without funding
 - Tremendous investment of effort and time
- Financial support necessary
 - Research Assistance
 - Continuation of study on attitudes, knowledge, and practice
 - Advance studies to practicing providers
 - CME Administrative Costs
 - Marketing
 - Development: new content and content updates
 - Development: design updates
 - Development: advanced web-development
 - Program access
 - Program tracking of completion and competencies
 - Customize to learner needs

The Curriculum Team: Content

- Creator, editor, content contributor, and principle investigator
 - Leanne Yanni, MD
- Content contributors:
 - Betty Anne Johnson, MD, PhD
 - Laura Morgan, PharmD
 - Mike Weaver, MD
 - Sarah Beth Harrington, MD
 - Carl Wolf, PhD

The Curriculum Team: Design

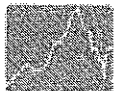
- Office of Faculty and Instructional Development
 - John Priestley, MA
 - Instructional design, web design/development, and maintenance
 - Chris Stephens
 - Web programming and administration
 - Jeanne Schlesinger, Med
 - Project management, instructional design, and photography
 - Elizabeth Micalizzi-Seitz
 - Web development



Planned System Improvements

Power Search

Version 4.1



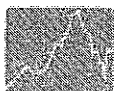
Power Search

- Match records using identifiers such as first name, last name, gender, address information, numerical identifiers, date of birth etc.
- Automate matching and linking of patient records.
- Link multiple patient records which are similar using sophisticated matching processes.



Power Search

- **Group Maintenance**
 - The Group Maintenance function is used to manually link and unlink patients/practitioners who may have multiple record occurrences.
- **Upload process**
 - During prescription uploads, similar patient linking is automatically done using Power Search.
- **Security Profile**
 - The Power Search module is implemented as a "System Portal Function" and is assignable at the user security profile level. This feature restricts the Power Search module for only the users who have been given access by the Administrator.



Version 4.1

- Power Search Capable
- Auto Response-24/7 access
- The Administrator has the ability to give the user the option to open reports in either an Excel or PDF format. This option is user based, not application based. The new reports are more descriptive and user friendly.

[illegible]

- Supports ASAP 1995 and ASAP 2005 formats of prescription reporting
- Contact Us: The Contact Us functionality allows PMP users to contact an Administrator from within the portal for assistance.
- In PMP V4.1, Request Statuses have been made user configurable and can be changed in the web.config file. Example – An Administrator can rename “Fulfilled” status for requests to “Ready”



Department of Health Professions

PMP Fall Conference

November 16, 2007

9-5

Place: TBD



Department of Health Professions

Purpose

- Involve more prescribers as partners in the Prescription Monitoring Program
- Update, generally, on the status of the program
- Message: 500 physicians are enrolled in PMP; double that number by giving information that can be easily adopted regarding patient evaluation, treatment plans, informed consent, monitoring, patient management and compliance with state laws.



Department of Health Professions

Possible Titles?

- Prescribers, You Need to Know This
- Physician...Help your patients, help yourself
- Responsible prescribing of controlled substances
- Prescribing Controlled Substances Toolbox
- Is it time to team up? Joining forces with PMP can make for better patient services and a practice that third-party payers find more attractive



Department of Health Professions

Agenda

- Responsible Opioid Prescribing
 - Book based on FSMB Model Policy
- The Connected Physician Part 1-Online CME Pain Management course
- The Connected Physician Part 2-PMP website 24/7 access
- Virginia regulations for responsible opioid prescribing



Department of Health Professions

Agenda

- Assessment of impact of Perdue Settlement
- Balanced Pain Policy Initiative
 - National research findings
- Opioid mortality in Southwestern Virginia by Dr. Martha Wunsch
- Panel discussion



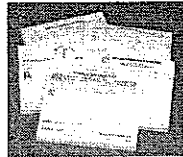
Education and Outreach, Prescription Monitoring Program

Report to Advisory Committee
July 25, 2007
By Betty Jolly, Policy Education



#1 Reaching Physicians

Challenge: curbing
doctor shopping
30,000 licensed doctors: 549
signed up



Education and Outreach PMP
7/25/07



Informational meetings have been primary
vehicle for education and outreach for physicians

2 large conferences targeting physicians:

OCTOBER 2004 Richmond
PRESCRIPTION MONITORING: WHERE DO WE GO FROM HERE?

APRIL 2006 Roanoke
CONTROLLED SUBSTANCES: USE, MISUSE AND ABUSE THE
ROLE OF THE HEALTH PROFESSIONAL

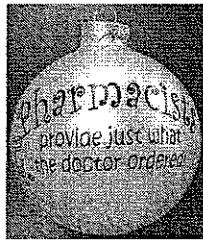
&

Numerous regional/local presentations to
associations & hospital medical staff

Education and Outreach PMP
7/25/07

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#2: Becoming Partners with Pharmacists in Data Collection



Education and Outreach PMP
7/25/07

Building the Data Base

2002-2007: Constant Collection of Prescription Date & Frequent Reminders of Mandate to Report Have Been Primary Vehicle for Education and Compliance Delivery to Pharmacist.

Education and Outreach PMP
7/25/07

#3: shareholders
advisory committee, MSV, VHHA,
professional associations



Education and Outreach PMP
7/25/07

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Has it made a difference?

- 2002-2003:
 - approximately 300 pharmacies and other dispensers submitting data twice a month.
- 2004-2005:
 - 2005 General Assembly expanded program statewide & included prescriptions dispensed in Schedules II, III, and IV.
- 2006-2007:
 - 2006: Processed 6333 requests (more than 3 times the requests fulfilled in 2005)
 - 2007: 14 million plus records
 - Surpassed the 2006 number of requests by May of 2007.

Education and Outreach PMP
7/25/07



Going Forward with Education & Outreach

For Physicians:

- Continue conferences & presentations – Richmond conference scheduled for 11/16/07;
- Provide web program with continuing education credits accessed at doctors' convenience;
- Point of Service educational information on program to doctors' offices,

Education and Outreach PMP
7/25/07



Going Forward with Education & Outreach

For Pharmacists:

- Tool Kit: Posters, Charts and General Information, re: KASPER Model;.
- Provide web program with continuing education credits accessed at pharmacists' convenience;
- Point of Service educational information on program to pharmacists' offices and hospital pharmacies.

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7/25/07

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Going Forward with Education & Outreach

For Shareholders, including public consciousness raising:

- #1 Focus on market segments that are predisposed to the product's need: Southwest Virginia, which has the highest incidence of prescription medicine abuse, with a radio campaign & a billboard campaign.

Education and Outreach PMP
7/25/07

Mass media

- Radio:

Rosnoke major media market of 5 stations, including Lynchburg and Blacksburg Bristol major media market, 4 stations

15 minor markets through the Southwest for \$30,400

200 gross rating points per week + PSAs



- Billboard:

10 in Southwest, \$350 per posting site, includes production, development costs, and rent for one month.

- Newspaper Pop Ups

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7/25/07

Mass Media

- #2. Focus on early adopters in the target segment of the central Virginia densely populated regions of Richmond (state capitol) and the neighboring city of Petersburg with billboard in 50 sites.



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7/25/07

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Target Media

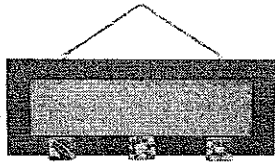
- Trade Show appearances w/booth and pamphlets
- Ads in association media pieces
- Ads in association conference brochures
- Continuing speeches/updates on PMP
- Cooperation in state agency events presented by mental health, health, enforcement and offered role in appropriate PMP presentations to agencies



Education and Outreach PMP
7/25/07

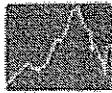
Your Ideas? Please.

What are we missing?



Education and Outreach PMP
7/25/07

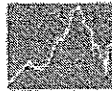
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Department of Health Professions

Prescription Monitoring Program

Program Statistics
And
Update

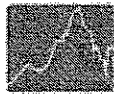


Department of Health Professions

The Move is ON!

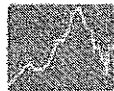
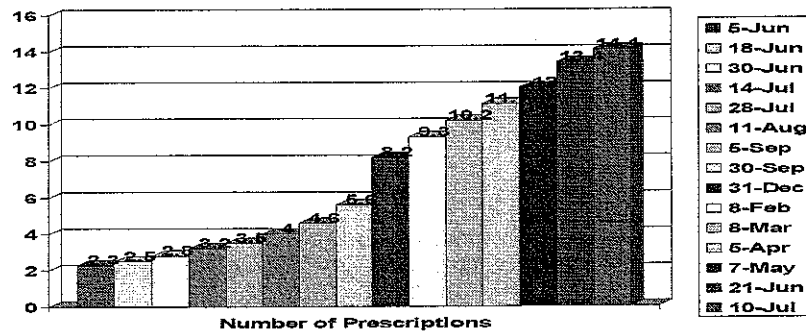
- New address effective August 20, 2007
 - Prescription Monitoring Program
 - 9960 Mayland Drive, Suite 300
 - Richmond, VA 23233-1463
- New Main Number: 804-367-4566
- Secondary Number: 804-367-4409
- Fax: TBD

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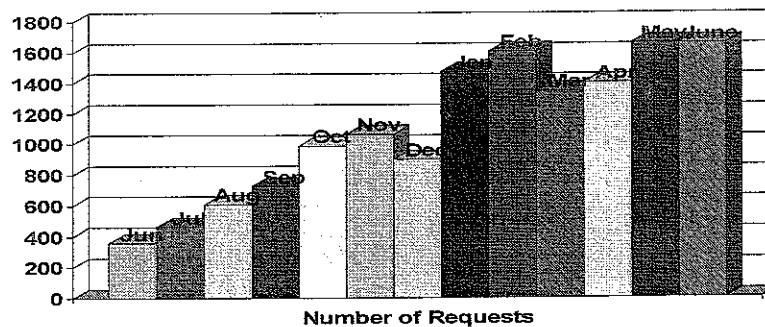
Department of Health Professions

Records in Database



Department of Health Professions

Program Requests Fulfilled



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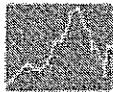


Department of Health Professions

Website Registrations

	1/5/07	7/6/2007	# of Requests 2007
Users	608	921	9363
Prescribers	335	535	6714
Pharmacists	167	257	1333
DHP Personnel	47	61	365
Drug Diversion Unit	23	23	658
Medical Examiner	18	20	164
HPIP	4	4	60
DEA	5	10	69

Note: 6333 Total requests for all of 2006.



Department of Health Professions

Education Outreach

- Newsletters
- Brochure
- Danville Presentation
- VPHA
- Project Remote sponsored presentations

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