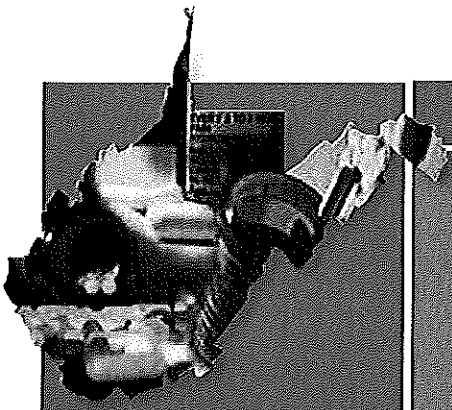
C.36

West Virginia State Medical Association (2011) Physician Leadership in Addressing Prescription Drug Diversion



Physician Leadership in Addressing Prescription Drug Diversion

Reducing Prescription Drug Abuse, Misuse and Diversion WVSMA Policy Recommendations

WEST VIRGINIA State Medical Association

October 2011

Message from the Chairman, Select Committee on Prescription Drug Diversion

Our nation has seen a significant increase in the illicit use of controlled substances over the past decade. The diversion of prescription medications has risen to epidemic levels. West Virginia, not unlike our counterparts in the rest of Appalachia and many other parts of the country, is reeling from its effects on our citizens and communities.

Many stakeholders are attempting to find solutions to address this crisis. The West Virginia State Medical Association (WVSMA) is the largest physician advocacy organization in the state. We are deeply concerned about the health of our state and are dedicated to ensuring all citizens receive quality and appropriate care. We see first hand the problems associated with drug diversion, misuse and addiction and know it is our responsibility to help lead the effort to address this epidemic.

As president of the WVSMA, I formed a select committee in the spring of this year to develop a comprehensive set of physician led recommendations. We spent the balance of the spring and summer on this project and offer now these proposals for our State's elected leaders and policy makers to consider. We sincerely hope this will serve as a platform for discussion and welcome input from all.

We take our responsibility as physicians seriously and are dedicated to working with all to find practicable solutions to address this serious problem.

Humbly,

John H. Schmidt III, MD
WVSMA President, 2010-2011

A special "Thank you" to the following individuals who contributed to the development of these recommendations.

James Becker, MD
MaryAnn N. Cater, DO
Tim Deer, MD
Senator Dan Foster, MD
Senator Evan H. Jenkins
James Kaplan, MD
Robert Knittle, MS
Alvin "Woody" Moss, MD
John H. Schmidt III, MD
Thom Stevens
Senator Ron Stollings, MD
Amy N. Tolliver, MS

Promote a More Proactive Prescription Monitoring Program

Establish a Prescription Monitoring Program (PMP) advisory committee and case review committee to assist the WV Board of Pharmacy in operating the PMP, establish continuing education/public outreach programs and to perform database reviews based on established and recognized clinical criteria to identify and detect inappropriate and/or possible illegal activity.

West Virginia was a national leader in the early establishment of the PMP almost a decade ago. Many states have since developed their own controlled substances tracking systems and over time "best practice" models have emerged. One example seen in many recently enacted state drug monitoring laws is a multi-disciplinary advisory committee connected to the monitoring program to assist with the implementation and functioning of the controlled substances database. The West Virginia Board of Pharmacy is to be commended for joining the InterConnect System to link our PMP to a national database sponsored by the National Association of Boards of Pharmacy.

The West Virginia Board of Pharmacy does a good job in overseeing the operation of our State's PMP, but as the scope of its use and demands on the system increase, assistance from a broader stakeholder group would be of great value. West Virginia should develop a multi-disciplinary PMP advisory committee to assist the Board in developing appropriate methods and criteria to utilize the dispensing information of controlled substances in a more proactive manner. The goal is to help promote early identification of inappropriate prescribing activity or individual abuse, misuse and diversion of controlled substances.

The PMP advisory committee should be comprised almost entirely of clinical representation and should also assist in developing education programs for prescribers, dispensers and the general public. Additionally, the PMP advisory committee should be authorized to establish a select review committee, comprised of both clinical experts and prosecutors, whose primary purpose is to perform a more detailed analysis of suspected improper or illegal activity on a case-by-case basis and make appropriate referral of improper or illegal activity.

Establish a reporting process for the PMP advisory committee to inform professional licensure boards of suspected inappropriate and/or illegal activity and ensure the professional licensing boards have clear authority to fully investigate such reports.

Through the query process and case review work of the newly established PMP advisory committee and select review committee, reasonable suspicion may be found regarding certain individuals engagement in inappropriate or possible illegal activity. For example, the individual could be a suspected "doctor shopper" who obtains several prescriptions from multiple physicians, or a prescriber who writes prescriptions for controlled substances which appear to be outside appropriate clinical and ethical guidelines, or a dispenser who inappropriately distributes controlled substance medications.

A referral process for the PMP advisory committee and select review committee must be established. For cases involving a licensed health professional (physician, dentist, pharmacist, nurse, physician assistant) current West Virginia law and state agency rules set specific guidelines on how complaint and disciplinary investigations are initiated and conducted by the licensing boards (i.e., West Virginia Board of Medicine, West Virginia Board of Osteopathy, West Virginia Board of Dental Examiners, West Virginia Board of Pharmacy, West Virginia Board of Examiners for Registered Professional Nurses). The law and rules governing these licensing boards must be reviewed and updated where needed to clearly authorize a full investigation and appropriate licensure sanctions if determined that clinical and ethical guidelines were not being followed by the prescriber or dispenser. The licensing boards must also have clear authority to refer their investigatory findings to proper law enforcement agencies and prosecutors if the conduct reviewed indicates possible criminal activity.

Require the Board of Pharmacy to provide a comprehensive annual report on the PMP as part of their annual report to the Legislature.

It is important to have continued monitoring and review of the PMP. As part of their annual report, a comprehensive report should be required of the WV Board of Pharmacy on the PMP database operations and actions of the PMP advisory committee and the select review

committee. This will enable stakeholders, lawmakers, and policymakers to gain important information on the effectiveness of the PMP and allow a platform for discussion on recommended changes.

Establish funding under the WV Board of Pharmacy to enable the implementation of additional programs and responsibilities of the PMP.

Over the last decade, the scope of services expected and financial resources required of the West Virginia Board of Pharmacy to maintain and manage the PMP have grown. The Board is a special revenue agency that relies primarily on pharmacy and pharmacist licensure fees. While most state databases are overseen by their state board of pharmacy, in some states the controlled substances database is housed and maintained by a state law enforcement agency with significantly higher funding and personnel resources.

West Virginia's concerted effort to fight the controlled substances abuse and misuse epidemic will place even greater responsibilities on the WV Board of Pharmacy and the PMP. The success of the PMP as a tool in the fight against drug diversion is contingent upon the Board having the resources necessary to effectively utilize it to its highest potential. New funding and support must be identified. Similar funding resources may also be needed to implement new investigatory, education, record keeping and disciplinary actions by other professional licensure boards (i.e., West Virginia Board of Medicine, West Virginia Board of Osteopathy, West Virginia Board of Dental Examiners, West Virginia Board of Examiners for Registered Professional Nurses).

Enhance PMP Reporting, Review and Confidentiality Requirements

Require reporting of dispensing information of controlled substances to the West Virginia Board of Pharmacy's PMP within 24 hours.

West Virginia law requires key information (i.e., patient name, prescribing physician, drug name, dosage, number of refills) for Schedule II – IV controlled substances dispensed in the state to be reported to the PMP no more often than seven days. This reporting requirement was put in statute when the PMP was initially established almost a decade ago and fit the technology of the time. With advances in information exchange, reporting capabilities have improved significantly. West Virginia's out-of-date controlled substances reporting delay enables individuals to exploit the system by getting multiple prescriptions filled within a short period of time to avoid detection. The statutory reporting period of dispensing information to the PMP must be shortened to within 24-hours.

Require the name of the person who received the prescription from the dispenser, if other than the patient, and the source or method of payment be added to the PMP reporting criteria.

It is important to have all relevant and necessary data associated with each dispensed controlled substance reported to the PMP. Current state law requires the patient's name, prescriber, drug name and quantity prescribed, and other relevant information be reported by the dispenser to the PMP. West Virginia law does not, however, require the reporting of the name of the person who actually picks-up or receives the prescription from the dispenser, if other than the patient. This information is important for tracking who is actually in possession of the controlled substance. Also, it is important in the fight against the abuse, misuse, and diversion of controlled substances to know the method of payment when the prescription is picked up at the pharmacy or given to the patient by the dispensing physician.

Establish new, enhanced methadone reporting requirements to the PMP.

Methadone, when dispensed in an Opioid Treatment Center (OTC) for purposes of drug addiction treatment, is not reported to state prescription monitoring programs because of a special methadone privacy exemption contained in federal law that preempts state reporting requirements. Though the OTCs are required to review the PMP when dispensing methadone to patients, health care providers who are treating the same patients in

other health care settings see no information in the PMP about patients' methadone treatment. A complete medication history is critical to safe, quality health care. Many patients are unwilling or afraid of disclosing their methadone treatment to their health care provider and may not understand the life and death consequences of their failure to do so. A patient's methadone treatment is critical information that every health care provider should know when making treatment decisions and should be required to be incorporated into the PMP reporting database.

Establish a process whereby the prescriber or dispenser must review the PMP information under certain circumstances.

The PMP is a powerful tool that all health care prescribers and dispensers are encouraged to integrate into their practice and use frequently when prescribing or dispensing controlled substances. The West Virginia Board of Pharmacy is working with its contracted vendor that hosts and maintains the PMP to make the database more "user friendly". However, security features such as the requirement that health care providers reset their password every thirty days and the need to check for multiple variations of name listings can cause a search of the database by the provider or dispenser to take more than a brief period. Health care providers and dispensers may also have a long established relationship with the patient or the patient's treatment raises no cause for concern for drug misuse, abuse or diversion. Required checking of the PMP database for terminally-ill hospice patients also seems unnecessary.

For these and many other reasons, requiring that the database must be searched prior to issuing or dispensing each and every controlled substance for every individual patient would prove too burdensome. When prescribing drugs with the highest risk of abuse and addiction or when other factors indicate a cause for concern, it may be necessary for health care providers and dispensers to be required to check the PMP prior to prescribing or dispensing a controlled substance. The West Virginia Board of Pharmacy and the PMP advisory committee should consider under certain circumstances a process whereby the prescriber and/or dispenser must review the PMP database.

Enhance penalties for unlawful access and/or disclosure of PMP information.

The PMP contains highly confidential personal health information. All data must be maintained and treated with the utmost of care and any unlawful access, use or disclosure of the information must carry with it strong criminal penalties.

Expand immunity protections to prescribers and dispensers who report any individual suspected of attempting to illegally obtain a controlled substance.

A recent survey of West Virginia prescribers found that a significant percentage were reluctant to report suspected illegal activity to law enforcement out of fear of possible litigation. State law does provide important protections from lawsuits if a health care provider makes a prescribing or dispensing decision for a patient based on information received from reviewing the PMP database. A similar immunity must be established for health care providers and dispensers who report any suspected illegal activity.

Establish a process for the State Medical Examiner to notify and provide information to the appropriate licensure boards and the PMP select review committee when the coroner determines a prescribed controlled substance contributed to an overdose death.

Tragically, the first sign that a provider may be prescribing drugs outside the standard of care is when a death occurs. Though typically there are many contributing factors to overdose deaths, if one of those factors is a controlled substance prescribed to the decedent then a review may be warranted. Under current law, our State Medical Examiner has direct access to the PMP and can use the database of controlled substance information in his or her investigation. A process should be established enabling the Medical Examiner to submit his findings to the PMP select review committee and appropriate licensure boards.

Better Control of Scheduled Drugs

Enable the WV Board of Pharmacy and/or WV Public Health Commissioner to limit the manufacture, sale, distribution or possession of newly identified substances/products deemed hazardous to the public health.

West Virginia recently experienced an alarming number of overdoses including deaths attributed to the use of synthetic cocaine and synthetic marijuana. These products were legally sold because the chemical compounds used in their manufacturing process were not considered controlled substances under state law. The West Virginia legislature outlawed these substances in March 2011 and added additional language to include chemical derivatives in an effort to forestall slight chemical alterations to dodge the statute's strong prohibition. On September 7, 2011 the DEA announced an emergency ban on these chemicals. While the West Virginia legislature and the DEA were able to address this most recent crisis, quicker action is needed when new substances are discovered.

A new administrative process should be implemented whereby a state agency can take swift action to restrict, within constitutional limits, the manufacture/sale/distribution/possession of newly identified substances that pose an imminent hazard to the public.

Update the list of scheduled drugs in state code to comply with federal law.

The list of scheduled drugs in West Virginia code is not currently up to date with the list in federal code. This creates a 'loophole' that could allow criminal prosecution under federal law but not state law even though the activity involved the same controlled substance. As new drugs are added to the federal list it is important to update the state list so that our law stays current.

Encourage E-Prescribing of Controlled Substances

Many physicians are implementing new health information technologies in their practices such as electronic medical records. One of the first steps typically taken by a physician is the use of e-prescribing which alleviates the need for a written prescription on a typical prescription pad to be given to a patient. Instead, the physician electronically sends the prescription directly to the pharmacy requested by the patient. Until recently, the DEA prohibited e-prescribing of controlled substances. The e-prescription ban on controlled substances has now been lifted. The West Virginia Board of Pharmacy's legislative rules however, have an internal conflict regarding the authorization of e-prescribing of controlled substances that needs resolved. While the Board of Pharmacy is currently allowing e-prescriptions for controlled substances, a clarification of their rules is needed.

Additionally, some e-prescribing software vendors and West Virginia pharmacies are not yet online to enable e-prescribing of controlled substances. Work needs to be done to encourage a quicker uptake of such systems.

Make Tramadol (Ultram®) a schedule IV drug.

Tramadol was approved for marketing as a non-controlled prescription drug in 1995 under the trade name of Ultram®. Although the initial claims were that it produced only very weak narcotic effects and a low risk of addiction, recent data suggests that the risks may be greater. New concern over this prescription medication has led several other states to take action and make Tramadol a Schedule IV controlled substance. West Virginia should do the same.

Establish regulation of pain clinics and medical practices that specialize or have a high concentration of patients being treated for pain.

Significant attention and concern over the large number of "pain clinics" being opened in some states has led to new state laws requiring special licensure and regulation of such facilities. Rogue health care providers and pharmacists who contribute to the controlled substance drug diversion by inappropriately prescribing and dispensing these drugs cast a shadow across the appropriate practice of medicine and pharmacy. Clinics and practices which operate as a pain clinic or have a high concentration of patients on pain medications should be kept to strict standards to ensure appropriate care is being delivered to patients. West Virginia should carefully review the recently enacted state laws from other states like Ohio, Tennessee and Florida and consider appropriate measures for our State to properly ensure health care facilities are providing safe, appropriate care.

Establish restrictions on the quantity of controlled substances that can be dispensed to a patient in-office.

Dispensing of controlled substances in-office rather than from a pharmacy can create avenues for inappropriate abuse, misuse and diversion of prescription medication because it is more difficult to monitor improper prescribing and dispensing under these circumstances. Limiting the quantity of certain controlled substances that may be dispensed in-office should be considered. Enhanced procedures for stricter requirements for dispensing licenses issued by professional licensure boards are encouraged.

Make pseudoephedrine and other drugs considered precursors to methamphetamine schedule IV prescription drugs.

Though lawmakers have required that pseudoephedrine be placed behind the pharmacy counter and have implemented purchase restrictions, this has not sufficiently curbed its diversion for the illegal manufacturing of methamphetamine. Drug seekers have learned how to outsmart the system. Making pseudoephedrine and other drugs considered precursors to methamphetamine scheduled drugs available only by prescription has proven effective in other states and is a necessary next step that should be taken in West Virginia.

Support the development of a Medicaid pharmacy lock-in program.

Possible doctor shopping can be curbed through payer developed programs that restrict certain enrollees to obtain their prescriptions from a limited number of designated pharmacies. This enables more oversight and may reduce misuse for certain at-risk populations. Medicaid is currently reviewing options for implementing such a program and should be supported in this effort.

Improve Education Training and Certification

The WV Bureau for Public Health, Department of Health and Human Resources, should initiate a public information campaign targeted at educating the public in West Virginia that there is a risk of death from prescription drug overdose and that taking a medication not prescribed for oneself is potentially fatal.

While most major causes of preventable death are declining, drug abuse is an exception, with preventable drug-induced deaths, specifically those due to prescription-type drug abuse, rising steadily in the United States. According to preliminary data from the U.S. Centers for Disease Control and Prevention (CDC) accidental deaths from prescription drug overdose has exceeded motor vehicle accidents, killing at least 37,485 people nationwide in 2009. In West Virginia drug-induced deaths per 100,000 residents has risen from 6.86 in 2000 to 26.17 in 2008 – second highest in the nation. More than one person dies each day in West Virginia from drug overdose. Our State Medical Examiner reported 573 unintentional drug related deaths in 2008. By comparison, in 1998 there were 61 such deaths. This is an epidemic.

The growing prevalence of using prescription drugs without appropriate physician supervision poses a significantly greater potential hazard to our communities than even illicit drug abuse. Because these are drugs that can be obtained from a doctor, potential abusers, including our children, may not perceive the extreme hazards intrinsic to using these types of drugs, or that pharmaceutical drug abuse behaviors, such as using non-prescribed drugs or sharing drugs with others, is illegal.

The WV Bureau for Public Health should initiate a public information campaign to raise awareness of the magnitude of this crisis, and expand existing programs to educate the public in the safe use of all prescription drugs.

Authorize first responders to administer an opioid antagonist in certain emergency situations involving suspected opioid overdose.

As noted above, unintentional drug overdose deaths from opiate derived substances have reached epidemic proportions. Intranasal naloxone provides a safe, rapid, effective way to manage suspected opioid overdoses in the field. If all first responders (paramedics, EMS, law enforcement, etc.) had the option to access an opioid antagonist (i.e. Naloxone Hydrochloride) and were trained for the treatment of a drug overdose by intranasal administration, more lives would be saved.

Additionally, intranasal administration of naloxone is a feasible approach for opioid overdose rescue at home that can be easily delivered by caregivers (relatives, friends, or others who monitor a patient's response to opioids).

According to some experts, there is growing support for regularly pairing naloxone with all new prescriptions of long-term opioids, or in association with opioid rotation or dose increases, and in other circumstances. Under this scenario, practitioners would routinely prescribe intranasal naloxone (along with providing necessary instruction for its use) to accompany the respective opioid prescription whenever there is concern about possible overmedication or overdose; under current law, this is permissible in every state in the U.S.

Require all law enforcement officers permitted access to the PMP to complete recommended training/education programs.

West Virginia's PMP was initially created to serve as a tool for health care professionals to monitor and track the controlled substances dispensed to patients. More and more, prescription monitoring programs here and around the country are also being used as a law enforcement tool to investigate suspected illegal activity. With increased access to the personal health information contained in prescription monitoring programs, new standards are being developed to help ensure non-health care professionals are properly trained in protecting the confidentiality of patient data.

West Virginia law allows certain law enforcement officers to access the PMP for the purpose of investigating suspected illegal activity but contains no mandated training or education requirements. The law must be updated to require the training and education necessary to ensure the confidentiality of personal health information is protected. Such statutory changes should include requirements for law enforcement personnel to be part of a federally affiliated drug enforcement task force and have successfully completed the U.S. Drug Enforcement Administration Training and National Association of Drug Diversion Investigation Training.

Promote greater use of pain treatment agreements with patients for opioid analgesic medications in appropriate circumstances.

It is increasingly common for physicians to require their patients to sign a "Pain Treatment Agreement" as a condition of receiving therapy for chronic pain, particularly when opioid analgesic medications are prescribed. Formalized written agreements improve communication between physicians and patients and help promote a trusting relationship. Greater use of such agreements should be advanced through education programs to all prescribers with a special focused effort on high prescribing physicians of targeted medications. Communication tools should also be developed and made available to patients in an effort to help them better understand the important role such agreements play in their therapeutic care.

Codify the West Virginia Controlled Substances Advisory Board.

Governor Wise created by Executive Order the West Virginia Partnership to Promote Community Well Being ("Partnership") in an effort to address a broad range of critical issues impacting the people of West Virginia. The Partnership has been retained under both the Manchin and Tomblin administrations and continues to work pro-actively. One very successful initiative of the Partnership was the creation of the West Virginia Controlled Substances Advisory Board ("Board").

The Board is a multi-disciplinary team of professionals representing the groups (health care providers; local, state and federal law enforcement; pharmacists and pharmacies; addiction experts and counselors; prosecutors; drug manufacturers; elected government officials, etc.) who are dedicated to seeking solutions to the prescription drug crisis. The Board has provided an important platform from which individuals from all sides of the issue can work together and build consensus. The Board has been integral in crafting successful legislation over the past two years to fight the prescription drug epidemic. It is important to recognize this Board for the critical work it is doing and secure its continued operations by codifying its structure in state code.