



1845 E. Southern Avenue, Tempe, AZ85282 (480) 838-3385

January 7, 2011

Director Will Humble
Arizona Department of Health Services
150 N 18th Avenue
Phoenix, AZ85007

Re: Comments on Informal Draft Rules for Medical Marijuana

Dear Director Humble:

On behalf of the Arizona Pharmacy Alliance (AzPA) the comments below follow our review of the Informal Draft Rule language published by your Agency regarding implementation of the Medical Marijuana Initiative (Proposition 203). The Arizona Pharmacy Alliance is the only organization in the state that represents pharmacy professionals, including: pharmacists, pharmacy technicians and student pharmacists. Our mission is to provide optimal patient care, foster safe and effective medication therapy, promote innovative practice, and empower members to serve the health care needs of the public.

Changes to State Law are Inconsistent with Federal Law

Any law which bypasses the normal approval and distribution process for medications, including the State regulated drug distribution system and licensed pharmacies, is of grave concern to AzPA. Since the new Arizona law allows marijuana use for medical purposes, it should be treated as a medication. To support the safe distribution and use of medical marijuana, AzPA supports changes to federal law that would re-classify marijuana from a C-I to C-II so that it could legally be prescribed by medical and nursing providers and managed by pharmacists through licensed pharmacies. Support for reclassification should not be construed as support for the use of medical marijuana as a means to treat specific health conditions since marijuana does not have a USP monograph nor is it approved by the FDA. It is simply a pragmatic recognition that more and more states are beginning to allow use of marijuana within a medical context. AzPA commits to raising this issue with national pharmacy organizations and the Arizona Congressional delegation. Until federal law allows marijuana to be legally managed by pharmacists and licensed pharmacies, AzPA strongly recommends that pharmacists avoid direct involvement with activities related to the dispensing of marijuana to avoid violations of Federal law that may place professional licensure and participation in Medicare and Medicaid at risk.

Prescription Drug Monitoring Program

AzPA recommends that licensed users of medical marijuana be identified in the State of Arizona's Prescription Drug Monitoring Program (PDMP) database, which is already available to health care professionals who need to know about controlled substance use to protect the safety of the patients they treat. Although ADHS has proposed its own database, your Agency's initiative only permits law enforcement officials access. By requiring dispensaries to report medical marijuana dispensing to the State's PDMP database, health care professionals are able to facilitate safer treatment options for their patients.

Pharmacists are Medication Experts.

Although AzPA is concerned about the dispensing of marijuana by pharmacists, AzPA recommends pharmacists' involvement in the care of the patients receiving medical marijuana to ensure safe and effective use. The Institute for Safe Medication Practices, in a document entitled, *Protecting U.S. Citizens from Inappropriate Medication Use*, writes that pharmacists are uniquely positioned to provide solutions to the problem of medication misuse. Pharmacists are widely accessible and have the ability to improve care, enhance communication among healthcare providers, and optimize medication use, resulting in better patient outcomes. Pharmacists also can help eliminate unnecessary healthcare costs through medication therapy management (MTM), which involves reviewing and monitoring medication use, counseling patients, and conducting wellness and disease-prevention programs. Engaging the pharmacist as a resource for ensuring safe medication use will greatly improve the health of the patient.

Since the rules do require patient education and a medical director, AzPA recommends that the rules should also require that a pharmacist provide medication therapy management services at least annually, including a comprehensive medication review which would include a review of medication history, including all prescription and non-prescription medications and supplements that the qualifying patient is currently using. Since medical marijuana use is approved for qualifying patients with complex illnesses, the risk for drug-drug and drug-condition interactions is significant. MTM services will ensure safe medication use as well as detection and management of adverse drug reactions related to medical marijuana. The pharmacist could easily provide these clinical services through a collaborative practice agreement with the medical director. This team approach is necessary to prevent unforeseen complications and unnecessary costs associated with adverse drug events, especially new adverse drug events associated with the addition of an understudied substance to the patient's medication regimen. Reducing health care expenses through medication misadventure avoidance should be a top priority of the Agency.

Finally, many patients that receive medical marijuana as outpatients will not be able to continue their therapy if admitted into the hospital because of smoking bans in Arizona facilities. We recommend that health-systems and hospitals work with their pharmacists to develop protocols to address the absence of marijuana during the acute and long term in-patient stay.

Quality Assurance

Now that marijuana is purported to treat medical conditions, it should be regulated as a medication. Pharmacies follow USP guidelines for the preparation and dispensing of medications. When pharmaceuticals are compounded by pharmacies, the pharmacist routinely sends compounds for testing on a regular basis to ensure accuracy and safety of the medication. As such, dispensaries and growers should be required to have each "lot" or "batch" tested for percentage of THC to appropriately label the strength of the medication. This practice is necessary to prevent overdoses and unwanted drug-drug interactions. In addition, it would emphasize that Arizona intends to treat the marijuana as medication rather than a recreational drug. Under the proposal drafted by your Agency, marijuana is only measured by weight without regard to dose. With traditional medications, volume and weight do not always translate to dose or potency. It is common knowledge that the level of THC in 2.5 oz of marijuana vary greatly depending on the type of plant and preparation of the plant. The draft rules do not make any distinction in this area and do not require such disclosure. Proper labeling would allow a physician to recommend marijuana to their patient with a specific THC dose, thus ensuring patient safety. Use of THC in food or cigarettes should also require similar labeling.

Dispensaries Oversight

To ensure safety to the public at large, AzPA strongly recommends that dispensaries be held to an equally high standard of quality and safety regulations as pharmacies. Pharmacies are required to comply with copious Federal and State statutes and regulations overseen by the Arizona State Board of Pharmacy. Likewise, medical marijuana dispensaries should be routinely inspected and held to similar standards by ADHS.

AzPA recommends that ADHS only approve permits for dispensaries that publish policy and procedures focused on patient safety, quality assurance standards focused on product quality, and provide accurate methods to label dosing. Policies and procedures must include a mechanism (managed by the Medical Director and Clinical Pharmacist) to assess the effect medical marijuana has on a patient's other medical conditions, safety, pharmacokinetics, and efficacy of concurrent medications. Your regulations must ensure that each dispensary has policies and procedures that address inventory control, qualifying patient recordkeeping, security, patient education, and prevention of fraud, waste & abuse.

Post Marketing Surveillance

As with all medications, new unpredicted adverse effects can present after widespread public use (e.g. Vioxx). Since medical marijuana has not been reviewed for safety or efficacy by the FDA, the risk for unpredicted adverse events may be greater. Consequently, AzPA recommends that ADHS implement post marketing surveillance through pharmacists at the Arizona Poison and Drug Information Center at The University of Arizona to track adverse drug events and monitor quality, safety and efficacy.

Thank you for the opportunity to submit public comments. Please do not hesitate to call if you have any questions.

Respectfully Submitted,

A handwritten signature in black ink that reads "Mindy D. Smith". The signature is written in a cursive, flowing style.

Mindy D. Smith, BSP Pharm, R.Ph.
Chief Executive Officer