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Summary of draft Arizona medical marijuana rules

On December 17, 2010, the Arizona Department of Health Services (DHS) released draft rules for Arizona's newly created Medical Marijuana Program. At 47 pages, these rules appear to be comprehensive and well-thought out, and generally track Prop 203, Arizona's new medical marijuana law, closely. We encourage you to take a closer look at the draft rules, and then submit a public comment, praising the effective parts of the rules, while asking the DHS to change the more problematic sections. You have until January 7 to submit your comments in this round, and there will be another round of public comments in February 2011. Both the draft rules and the electronic comment form can be found at <http://www.azdhs.gov/prop203>.

Here are some of the more notable sections to review:

- The law provides that dispensaries and qualifying patients (if they live more than 25 miles from a dispensary) may cultivate marijuana plants in an enclosed, locked facility. The rules lay out exactly what is an “enclosed” facility, including: a building with four walls and a roof, an indoor room or closet, and an area surrounded by four solid 12-foot walls and covered by various types of strong but permeable roofs. (R9-17-101(10))
- The law does not authorize the smoking of medical marijuana in a “public place”. The rules provide a definition of “public place” that includes: airports, banks, bars, child care facilities, common areas of apartment buildings and hotels, entertainment and sports venues, libraries, office buildings, parks, parking lots, restaurants, stores, sidewalks, and warehouses. (R9-17-101(18)).
- The draft rules set the fees included in the law. Initial dispensary registration costs \$5,000 and renewal costs \$1,000. To change a dispensary or dispensary cultivation site's location costs \$2,500. All dispensary and dispensary staff fees must cover the costs of administration — including a web-based verification system, so MPP believes these fees are reasonable. A qualifying patient must pay \$150 for a registry identification card, and a designated caregiver and dispensary agent, \$200, and equivalent fees for renewal. (R9-17-102) **There does not appear to be a sliding scale or lower cost card available for low income patients, as most other states have done, which should be remedied.** Other states have lower fees for recipients of Supplemental Security Income (SSI), Social Security Disability Insurance (SSDI), and Medicaid.
- The draft reiterates the law's process for adding a debilitating medical condition. DHS will notify the petitioner whether it will reject the request or schedule a public hearing within 90 calendar days of receiving the request. After holding a public hearing, DHS must notify the petitioner of the decision within 180 calendar days of receiving the initial request. (R9-17-105)
- The draft includes a table that specifies timelines for all of the different administrative processes. (R9-17-107)
- The draft requires that a physician's written certification must be dated within 90 calendar days before the submission of the qualifying patient's application to DHS. (R9-17-202(F)(5))
- The draft adds the requirement that, in order to write a written certification, a patient's Arizona physician must either 1) have had a professional relationship with the patient for at least one year

that included at least four visits for the debilitating medical condition, or 2) have taken primary responsibility for the care of the patient's debilitating medical condition after compiling a medical history, conducting a comprehensive exam, and reviewing medical records. The physician must also certify that he or she has reviewed all other medication being taken by the patient for potential interactions with marijuana, and that he or she will continue to assess the patient and the patient's use of medical marijuana throughout the physician-patient relationship. (R9-17-202(F)(5)) **While it is reasonable and important to ensure that a physician has a *bona fide* relationship with a patient, this language may be overly restrictive and may prevent veterans from qualifying for the program.** Veterans Administration hospital doctors — who often have primary responsibility for treating veterans — often cannot recommend medical marijuana, which may leave veterans with no way to get a written certification for a legitimate qualifying condition.

- The draft reiterates the law's provision listing the reasons DHS may deny or revoke a registry identification card application, including: if the applicant has previously had a card revoked, if the applicant provides false information, if the applicant diverts medical marijuana to a non-cardholder, and if a designated caregiver gets convicted of an excluded felony offense. (R9-17-205)
- The draft mandates that a principal officer or board member of a dispensary must have been an Arizona resident for the two years immediately preceding the dispensary application submission date. (R9-17-302) **This provision is stricter than in most other medical marijuana states, and may limit too narrowly the pool of potential dispensary officers and board members. It may also prevent Arizona dispensaries from benefiting from the expertise of persons with experience running successful, law-abiding dispensaries in other states.**
- The principal officer or board member also may not be a physician making qualifying patient recommendations or a law enforcement officer, and may not owe unpaid taxes or child support or be in default on a government-issued student loan. The draft also lays out the copious materials that must be included in the dispensary application. (R9-17-302)
- The draft mandates that a dispensary may not transfer or assign a dispensary registration certificate, and while a dispensary may move, it may not cultivate, manufacture, or distribute marijuana until DHS issues a registration certification for the new location. (R9-17-303)
- The draft notes that if DHS receives a nonanonymous allegation of a dispensary's noncompliance, it may conduct an unannounced inspection. If DHS finds a violation, it provides written notice, and the dispensary has 20 working days to provide written notice of the corrective actions. (R9-17-306)
- The draft requires a dispensary to develop and implement policies regarding: job descriptions and employment contracts, personnel supervision, business records, inventory control, qualifying patient records and confidentiality, and patient education and support. (R9-17-307)
- The draft mandates that 70% of a dispensary's cultivated marijuana must be provided to qualifying patients or designated caregivers, while the remaining 30% may be provided to other registered dispensaries. Up to 30% of the marijuana provided to patients and caregivers may be acquired from outside the dispensary, from another registered dispensary, patient, or caregiver. (R9-17-307) **MPP believes this restriction is unnecessary and not in the best interests of patients.** Some dispensaries may be better positioned to excel in cultivation, while others may be best suited solely to dispense marijuana. Pharmacies are not forced to produce any of the medication they dispense and it makes sense to allow more flexibility. The proposed rule is very problematic, and will likely create acute shortages in rural areas. Those patients within 25 miles of a rural dispensary unable to meet demand will have no secondary option for safe access to their medicine. This draft rule is also likely to drive costs up significantly. **Please submit comments asking DHS to reject this rule in favor of the creation of an open wholesale relationship between dispensaries that does not limit how much of a dispensary's supply must be self-produced and how much may be**

acquired from other registered dispensaries. This will assure consistent supply to rural Arizona, easy access for all qualifying patients, and lower costs due to increased competition of organizations trying to meet demand.

- The draft requires a dispensary to have a medical director, who may only serve as such for three dispensaries at once. During hours of operation, the medical director must either be on-site or easily contacted. The medical director will oversee the development and dissemination of educational materials about alternative medical options for debilitating medical conditions, medical marijuana side effects and contraindications, safe marijuana administration techniques, signs of substance abuse, and a system for the patient to document the debilitating condition that includes a log book and rating scale for pain. A medical director, who must be an Arizona doctor or osteopath with a current license, may not write recommendations or establish a doctor-patient relationship with a qualifying patient. (R9-17-101(15), 310) **This requirement, as it is currently written, is likely too restrictive and may make it difficult for most prospective dispensary operators to apply.** Because of the continued illegality of medical marijuana on the federal level and many doctors' hesitance to embrace "new" medicines soon after they are made available, it is possible that there may not be 45 doctors willing to serve in this position, working so closely with dispensaries. **Opening up the medical director position to other health professionals would ease the restrictions. In your comments, you may suggest allowing nurse-practitioners/advance practice nurses, public health PhDs, and Arizona doctors and osteopaths with nonactive (but not invalid) licenses to serve in that capacity as well.**
- The draft, like the law, requires a dispensary agent to verify the patient's or caregiver's identity and validity of the registry identification card. It also requires the agent to verify that the amount of medical marijuana requested would not cause the patient to exceed 2.5 ounces during any 14-calendar-day period. Further, it calls for the preservation of a qualifying patient record until five years after the last visit (R9-17-311, 312) **Five years seems excessive, and all records should be kept by patient and caregiver ID number, not by full name.**
- The draft requires a dispensary to set up a methodical inventory control system. It must document each day's beginning and ending inventory, harvests, disposal of unusable marijuana, and any transactions. Its cultivation documentation must include the strain of seeds planted, type of soil used, date seeds were planted, and watering schedule. When harvesting, the date and amount must be documented, as well as the date and method of disposal of unusable marijuana. In transactions with patients, caregivers, and dispensaries, a dispensary must document a description of the medical marijuana (including the amount and strain), the names and ID card numbers of the parties, and the date of the transaction. There are also special rules for transferring medical marijuana to a food establishment for infusion into an edible food product. These documents are to be kept for five years. A dispensary agent (who is designated to have oversight over this system) will conduct a system audit at least once every 30 calendar days. (R9-17-313) **These rules seem complex, but fair, and designed to keep medical marijuana transactions orderly and transparent. Five years seems excessive, and all records should be kept by patient and caregiver ID number, not by full name.**
- The draft ensures that the medical marijuana provided for a patient by a dispensary must include: the dispensary's and patient's ID number, the amount and strain of the marijuana, the name of the cultivator/provider, the date the marijuana was acquired, harvested, or manufactured, and a list of the chemical additives, including nonorganic pesticides, herbicides, and fertilizers used in the cultivation and production of the marijuana. For edible food products containing medical marijuana, a dispensary must also include the total weight of the food product, and the following warning: "This product is infused with medical marijuana and was produced without regulatory oversight for health, safety, or efficacy. There may be health risks associated with the consumption of the product." If DHS requests, a dispensary must provide a sample of its inventory of sufficient quantity to enable an analysis. (R9-17-314) **These rules seem fair, and a good idea, even though**

they will involve some work. These rules will help protect seriously ill patients from ingesting contaminants like pesticides, or mold, and will establish accountability for cultivators and providers. You may want to suggest alternative food product warnings.

- The draft has very extensive security requirements for dispensaries. A dispensary shall ensure access to the cultivation site is limited to principal officers, board members, and designated dispensary agents. It allows transportation of marijuana and paraphernalia, and limits it between the dispensary and the cultivation site, a patient, another dispensary, or a contracting food establishment. (R9-17-315(A, B) **These are commonsense measures.**
- A dispensary is also required to have the following lengthy list of security equipment: devices to detect unauthorized intrusion, exterior lighting, panic buttons, electronic monitoring (which includes at least one 19 inch call-up monitor, a video printer, video cameras having at least a resolution of 704 x 480 covering all the entrances and exits and at each point of sale location and grow room, storage of video recordings, a failure notification system, and the capability to provide authorized remote viewing over the Internet). (R9-17-315(C)) **The list contains many good ideas, but may be extensive enough that it requires a significant investment in addition to all of the fees and supplies, such that it may reduce the pool of possible dispensary operators.**
- The draft requires that a dispensary must ensure that edible food products it provides are prepared at a facility that has a food establishment permit issued according to state law, local ordinances, and local health department requirements. The dispensary must provide the facility's food establishment permit to DHS before providing edible food products, upon contracting with the facility, and every 12 months after that while the contract is in effect. A dispensary is ultimately responsible for the content and quality of any edible food product that it provides. (R9-17-316) **Establishing accountability to maintain the safety and quality of edible food products is a good idea, as is all parties following local food preparation law and regulations.**
- The draft requires that any building or equipment used in the cultivation and preparation of the medical marijuana be maintained in a clean and sanitary condition. Specifically, it requires that medical marijuana and edible food products are securely covered and protected from flies, dust, dirt, and all other contamination. Moreover, it requires that refuse, dirt and waste are removed from the dispensary and cultivation site daily, and that all equipment, machinery, trucks, platforms, racks, tables, and shelves are cleaned daily. It also requires that a dispensary agent cleans her or his hands before and during the preparation of medical marijuana, after handling soiled equipment or utensils, after touching bare human body parts, and after using the toilet room. If the dispensary agent is working directly with the medical marijuana preparation, the agent's fingernails must be trimmed, protective apparel must be worn, and no nail polish or artificial nails may be worn without gloves. Also, if the medical director determines that a dispensary agent has a health condition that may adversely affect the safety or quality of the medical marijuana, the medical director may prohibit the agent from contact with any equipment or materials used directly with medical marijuana. (R9-17-317) **These are helpful measures that will protect the safety of patients and lessen the risk of lawsuits against dispensaries.**
- In addition to the law's mandate that a dispensary must be at least 500 feet from a school, the draft requires dispensaries to provide parking, and to contain at least one toilet room and one handwashing sink outside of the toilet room. The dispensary must also separate medical marijuana storage from toxic/flammable materials storage, and provide an area that can be sanitized and set aside only for packaging and preparation (if the dispensary is doing it on site). (R9-17-318)