Arizona Department of Health Services Comprehensive Analysis of Current Management & Operations of the Arizona Medical Marijuana Program

Arizona Department of Health Services
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Revision 1

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EXECUTIVE SUMMARY

The mission of the Arizona Department of Health Services ("ADHS") is "to protect the physical and mental health of the people of this state and to promote the highest standards for licensed health care institutions, emergency services and care facilities for adults and children" (Laws 2010, Ch. 8, Section 3).

We have been asked to prepare a report assessing, analyzing and reviewing current management and operations of the Arizona Medical Marijuana Program ("AMMP") by ADHS.

The Arizona Medical Marijuana Initiative, or Proposition 203, was included on the November 2, 2010 ballot and approved by Arizona voters. The Proposition was certified on November 13, 2010, becoming the Arizona Medical Marijuana Act ("AMMA"), A.R.S. Title 36, and Chapter 28.1. The AMMA and related Medical Marijuana Program Rules (the "Program Rules"), A.A.C. Title 9, Chapter 17, allow for the registration, certification, and regulation of qualifying patients, designated caregivers and nonprofit medical marijuana dispensaries ("Dispensary" or "Dispensaries") by ADHS. Additionally, the AMMA provides a regulatory framework allowing for, among other things, cultivation, transportation, dispensing, and personal consumption of medical marijuana by qualified registrants within the state of Arizona.

The passage of Proposition 203 proved to be a unique challenge for ADHS as well as all of the respective government agencies charged with establishing regulatory protocols for this nascent medical program, approved by the will of the people, into the sunlight. Previously, a number of states had experimented with state level legalization of medical marijuana. But in each instance, the specter of a federal shutdown caused substantial uncertainty among state regulators on how best (if at all) to set up compliance systems and related infrastructure. More importantly, only a handful of states were rigorously attempting to seriously address wide scale proliferation of legal medical marijuana. This left ADHS with few models on how best to construct the AMMP.

After the passage of Proposition 203, ADHS effectively had 120 days to create the AMMP. "Staff from across the Department joined together to create a plan. The colossal undertaking included information technology systems for applications, reporting, and validating; staff combed through the rules in other states to help write the Arizona rules for how the program would work, how people could apply for the different types of licenses, when they could apply, how to add new debilitating diseases, among other things. Even though the initiative allowed the Department to avoid the normal rulemaking process, staff asked twice for written public comment and held four public hearings to gather public opinion." (http://azdhs.gov/licensing/medical-marijuana/index.php#resources-historic)

The legalization of medical marijuana in Arizona created a mountain of issues for ADHS, both foreseeable and unforeseeable. Not the least of which was (and remaining to this day) the federal prohibition on all forms of marijuana cultivation, transportation, distribution or use. The federal prohibition effectively cordoned off ADHS from federal agencies it would naturally have affiliated with, including the Drug Enforcement Administration ("DEA"), the Food and Drug Administration ("FDA") and the Office of the Treasury. This limitation, coupled with the already daunting task of developing the regulatory oversight and structure for a program in an industry which was previously illegal (and remains illegal federally), only made ADHS' management and oversight of the AMMP more challenging.

The complexities involved in medical marijuana oversight and compliance are evident beginning with the simple definition of "marijuana" and its subset "usable marijuana" under AMMA in comparison with the definitions of "marijuana" in the Arizona Criminal Code.

The AMMA defines marijuana as "… all parts of any plant of the genus cannabis whether growing or not, and the seeds of such plant." And continues with the definition of "Usable Marijuana" as "… the dried flowers of the marijuana plant, and any mixture or preparation thereof, but does not include the seeds, stalks and roots of the plant and does not include the weight of any non-marijuana ingredients combined with marijuana and prepared for consumption as food or drink." (A.R.S. §36-2801(8)(15))

The Criminal Code defines marijuana as "…all parts of any plant of the genus cannabis, from which the resin has not been extracted, whether growing or not, and the seeds of such plant." "Cannabis" (a narcotic drug under the Criminal Code) is defined as: "… the following substances under whatever names they may be designated: (a) The resin extracted from any part of a plant of the genus cannabis, and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or its resin. Cannabis does not include oil or cake made from the seeds of such plant, any fiber, compound, manufacture, salt, derivative, mixture or preparation of the mature stalks of such plant except the resin extracted from the stalks or any fiber, oil or cake or the sterilized seed of such plant which is incapable of germination; and (b) Every compound, manufacture, salt, derivative, mixture or preparation of such resin or tetrahydrocannabinol." (A.R.S. § 13-3401(4) and (20)(w))

This confusion, for several years placed a cloud over whether or not many of the popular processed medical marijuana products offered (including oils, extracts, salves, tinctures, etc.) in many (if not most) of the licensed dispensaries state wide were legally allowable. Thereby further exacerbating the challenges and complexities faced by ADHS in its ongoing regulation of all forms of medical marijuana in Arizona.

Whatever one's opinions or impressions are of medical marijuana, it remains a controlled substance. Its wide spread usage has substantial public health and safety ramifications similar to any other controlled substance, including alcohol and tobacco. Some of the acute health concerns regarding medical marijuana usage include accidental poisoning, anxiety, cognitive impairment, accident risks, dependence, respiratory health, cardiovascular health, and mental illness.[1] Its very nature as a plant (and not a synthesized drug) makes it inherently difficult to regulate. This, coupled with the all cash nature of commercial marijuana (due to federal anti-money laundering laws) provides a regulatory theater that is unique and often opaque.

1.0 INTRODUCTION

1.1 Purpose of Study

Elliott D. Pollack & Company, in conjunction with Beacon Information Designs was retained by ADHS to provide a foundation for thinking about the AMMP, what's done well, where potential compliance gaps may exist, and what might enhance AMMP oversight and management.

This document was prepared in order to assess current AMMP management including its compliance systems, records and processes. This report compares the AMMP to other states as well as analogous systems operated by the DEA and/or the Arizona State Board of Pharmacy ("ASBP").

[1] Jonathan P. Caulkins, Beau Kilmer, Mark A.R. Kleiman, Robert J. MacCoun, Gregory Midgette, Pat Oglesby, Rosalie Liccardo Pacaula, Peter H. Reuter, "Considering Marijuana Legalization, Insights for Vermont and Other Jurisdictions; Issued by the RAND Corporation, 2015.

The report also aims to inform the reader on the various ramifications of certain policy considerations involving medical marijuana. The authors purposely limited the set of recommendations to just a few items that: (1) would offer the greatest immediate benefits, and (2) actually have the highest probability of becoming adoptable policy or law (as applicable).

The purpose of this report is to provide a list of practical recommendations, albeit some that will require difficult choices. It is also meant to confirm the many things that ADHS does exceptionally well given the constraints under AMMA and federal law, while also providing additive examples of processes that work and don't work elsewhere in other states.

Section 2.0 describes the creation of the AMMP and its limitations, which were created, in part, by the constraints of Proposition 203 and the overarching federal prohibition of all forms of marijuana creation, distribution and consumption. This section continues with the effect of litigation on AMMA interpretation. It finishes with a summary of areas of emphasis we focused on during interviews with ADHS staff and in reviewing ADHS policies, procedures and protocols.

Section 3.0 explores what other states are doing to manage their respective medical marijuana programs in comparison to the AMMP. Included is a particularized look at how various states handle the areas of emphasis we looked at in Section 2.0.

Section 4.0 reviews and compares the AMMP with DEA and/or ASBP protocols. This discussion uses the focus areas considered in Section 2.0 as primary points of discussion.

This sets the stage for Section 5.0 in which a series of recommendations and possible legislative amendments or even a potential updated citizen initiative are proposed, with an eye towards the likely ongoing expansion of the AMMP in terms of additional qualifying patient, qualifying physicians and expanded medical marijuana cultivation and distribution.

A cursory summary of the recommendations is provided below. However, details were not fully developed in this section, and the report must be read in its entirety for a comprehensive understanding of the items contained herein.

Recommendation I: Increased licensing requirements

Recommendation II: Expanded patient registry – to include increased real time data flow between the various registrants – physicians, qualifying patients, designated caregivers, Dispensaries, ADHS, and other enforcement agencies, to include identity verification prior to issuing a qualifying patient or dispensary agent card

Recommendation III: Authorize the creation of a centralized (ADHS managed) inventory tracking system – with direct interfacing with each of the licensed Dispensaries - with an eye towards better recording and capturing information on the wholesale marijuana market

Recommendation IV: Establish licensing and standards for independent laboratory testing of medical marijuana: including testing of the leaf as well as medical marijuana infused products ("MIPS"), extracts and concentrates for potency, homogeneity, contaminants, including pesticides and confirmation of THC/CBD levels

Recommendation V: Expanded requirements for packaging, labeling, child proofing to include points of origin for all medical marijuana products, including donations

Recommendation VI: Enforce Inspection protocols including use of unannounced Inspections and expanded inspections protocols. Move away from "surveys" and educate to enforce

Recommendation VII: Increased inspection protocols and compliance oversight to qualify for having a kitchen and manufacturing MIPS, extracts, concentrates, etc.

Recommendation VIII: Provide additional enforcement tools to ADHS to allow for civil monetary penalties, additional license restrictions (i.e. suspensions)

Recommendation IX: Expanded education and training – requirements to have Dispensary owners, dispensary agents (including medical directors), designated caregivers and physicians undergo periodic training (continuing education), enhanced qualifying patient communication requirements

Recommendation X: Expanded public communications to allow for broad dissemination of information relating to disaster communications, standing of licensees and public awareness messaging

Recommendation XI – Use of proceeds

Finally, Section 6.0 expects to provide the reader a summation of the report and some overarching conclusions.

1.2 Acknowledgements

The authors of this report are deeply indebted to many people in Arizona and across the nation involved from a regulatory and commercial perspective with medical marijuana. Without their dedicated time and thoughtful insights, the development of the accompanying analysis and recommendations would have been impossible.

We wish to specifically thank Arizona Department of Health Director Dr. Cara Christ and Assistant Director Colby Bower for their willingness to allow open access to key employees thereby ensuring a successful comprehensive review. The enthusiasm and candor of Division of Public Health Licensing Services personnel, including Branch Chief Tom Salow; Bureau Chiefs Carla Berg and Krystal Colburn, Team Leads, Robin Rodriguez, Wayne Tolbert and Don Gibson; Inspector Amber Norman and IT Quality Manager Claudia Montez was deeply appreciated.

Additional thanks are also extended to Arizona Attorney General Mark Brnovich, Assistant Attorney General Laura Flores and other department staff. We greatly appreciate the willingness of other agencies to assist with our assessment including Maricopa County Attorney Bill Montgomery, Arizona State Board of Pharmacy - Prescription Drug Monitoring Program Director Dean Wright, RPh, Lieutenant Darren Viner and Sergeant Steve Reed with Phoenix Police Department, Drug Enforcement Bureau and Dr. Cecelia Rosales, M.S., Assistant Dean, Phoenix Campus, Director of Phoenix Programs.

We benefitted from on-site interviews and materials from various City of Denver officials. Chief Jered Garcia, as well as Inspector Charisse Harris from the Department of Excise and Licenses provided key insight into the process of licensing and regulating marijuana business in Colorado. Danica Lee, Program Manager and Marley Bordovsky, Assistant Section Director of the Environmental Public Health Division described their methodology

in conducting routine inspections of infused product facilities as well as investigations relating to health concerns for marijuana infused products.

Lastly, the authors are very appreciative of those currently participating in the Arizona Medical Marijuana Program and their willingness to meet with us and provide their perspectives. We were fortunate enough to meet with qualifying patients, recommending physicians, patient care directors, industry legal experts and Dispensary owners. The willingness of all participants to take the time to speak frankly and openly about the AMMA and ADHS has given this report significant added balance.

1.3 Methodology of Information Gathering Process

A qualitative approach was primarily used to complete this assessment. Initially, the authors completed multiple on-site meetings with ADHS staff to conduct an assessment of current operational practices and management of the AMMP.

Following those discussions, interviews were held with a diverse group of AMMP participants or observers including state, county and local law enforcement, as well as with regulators in other states, researchers and industry stakeholders. Each interviewee provided an overview of their role within the AMMP and identified challenges they faced with the Program, and discussed opportunities and concerns related to the existing laws governing medical marijuana and Program constraints.

Finally, extensive research and analysis of occurred including reviews of medical marijuana programs in twenty-three states, as well as the District of Columbia with currently approved medical marijuana programs.

This research produced the findings detailed in this report, along with recommendations to ADHS.

1.4 Standard of Care

This report was performed in accordance with generally accepted practices of this profession. We have endeavored to meet this standard of care but may be limited by conditions encountered during performance, or inability to review information not received by the report date. In conducting the limited scope of services described herein, certain sources of information and public records were not reviewed. No warranties, express or implied, are intended or made. The limitations herein must be considered when the user of this report formulates opinions as to the risks associated with said recommendations or otherwise uses the report for any other purpose. These risks may be further evaluated – but not eliminated – through additional research, investigation, and assessment.

1.5 Additional Scope Limitations/Exceptions

Reasonable attempts were made to obtain information within the scope and time constraints set forth by the client. Information obtained in this report was received from several sources that we believe to be reliable; nonetheless, the authenticity or reliability of these sources is not warranted hereunder. Pertinent documents are referred in the text of this report and attached as appendix. This report represents our service to you as of the report date and constitutes our final document; its text may not be altered after final issuance. Further, these services are not to be construed as legal interpretation or advice.

2.0 THE ARIZONA MEDICAL MARIJUANA PROGRAM

2.1 Current AMMP

2.1.1 How We Got Here?

Taking a step back, it's important to give some perspective on the creation (and limitations) of the Proposition and the resultant Medical Marijuana Program Rules.

The Proposition was created through a citizen's initiative to provide a complex regulatory structure involving, among other things:

- a patient registry, including designated caregivers, qualifying patients, qualifying physicians;
- extensive licensing and approvals necessary to operate Dispensaries;
- inventory tracking of medical marijuana (whether for wholesale or retail distribution);
- the opportunity (in certain circumstances) to personally cultivate marijuana
- regulations regarding commercial cultivation, including location, storage, security and transport;
- a process to confirm or deny multiple qualifying conditions;
- enforcement tools including announced and unannounced inspections, financial audits and related administrative penalties.

The Proposition was also limiting in certain instances, including substantial confidentiality restrictions, very little regarding the regulation of medical marijuana infused products, very limited language on medical marijuana testing, and limited controls relating to the wholesale medical marijuana market, among other things.

In particular, the confidentiality provisions contained in A.R.S. §36-2810, geared towards qualifying patient confidentiality, and likely well intended, considerably constrained ADHS' ability to interface with other state and local governmental agencies. These constraints, in many cases, and as better described later in this report, substantially curtail compliance and enforcement options.

This Includes:

- inability to issue public notices on which Dispensaries are in fact licensed, and where they are located;
- inability to issue notices on which Dispensaries are in good standing;
- inability to issue notices on Dispensaries that have been subject to administrative penalty;
- the ability of police enforcement to interface with the patient registry in instances where qualifying patients don't have their card while in legal possession of medical marijuana;
- the inability of law enforcement to interface with ADHS inventory tracking on transportation of medical marijuana from cultivation facility to Dispensary;
- the inability of the Attorney General's Office and county prosecutors to access data on conduct relating to licensee activities including notices of deficiency, complaints and general administrative issues;

Despite these limitations, ADHS responded actively and efficiently to the adoption of AMMA by promulgating extensive rules governing all aspects medical marijuana and closely following the laws required under AMMA. As part of the rulemaking process, ADHS sought written public comment, and held multiple public hearings. Concurrently, ADHS needed to balance this process with a healthy nod to the federal government's ongoing

prohibition of any form of legalized marijuana[2]. Ultimately, the Program Rules were published and ADHS developed related comprehensive internal policies and procedures.

Since the AMMP's inception, ADHS has awarded 94 Dispensary licenses (89 are currently operating with 70 cultivation sites.) As of October 31, 2015, there are nearly 85,000 registered qualifying patients and 637 licensed designated caregivers and 2,060 dispensary agents.[3] This makes Arizona's medical marijuana program either the 4th or 5th largest in the country as of this writing.

[2] A memorandum by the Department of Justice on August 29, 2013 (by Deputy Attorney General James J. Cole) softened the federal prohibition on marijuana somewhat by issuing guidelines to federal prosecutors setting forth eight points of emphasis states could follow in order to limit federal involvement in state sanctioned marijuana programs.

[3] Arizona Department of Health Services, Arizona Medical Marijuana Program, October 2015 Monthly Report.

Exhibit 1 – Arizona Medical Marijuana Act Key Dates

2.1.2 ADHS Policies, Procedures and Protocols

When talking with a sampling of commercial licensees, qualifying patients, and recommending physicians a common thread emerged. Almost uniformly, when asked about ADHS efficiency and responsiveness, the answers came back strongly supportive of ADHS. In particular, ADHS got very favorable comments relating to efficiency in processing applications, registry cards, permits and inspections.

On the other hand, when asked about policy guidance from ADHS on rules interpretation or general information on the AMMP, the most common response was that ADHS was exceedingly restrained and generally non-responsive. A typical response from ADHS was that the Department wasn't able to provide legal advice, or was unable to provide the requested information. A Dispensary licensee we interviewed expressed frustration with ADHS' policy on rules interpretations. He said he had made several inquiries to ADHS on what he described as several opaque rules. The response he received, in each instance, was that the Department wasn't able to provide legal advice.

In our discussions with ADHS and its counsel, this issue relates back to ADHS' strict interpretation of A.R.S. §36-2810 (Confidentiality). In particular, the relevant portion stating that information is not "subject to disclosure to any individual or public or private entity, except as necessary for authorized employees of the Department to perform official duties of the Department pursuant to this Chapter." (A.R.S. §36-2810). ADHS has adopted a blanket prohibition on disclosure of any data, unless expressly otherwise authorized. More formally stated, ADHS treats all AMMP data as protected under the Health Insurance Portability and Protection Act ("HIPPA").

In fairness, the frustrations caused by §36-2810's confidentiality requirements are shared not just by participants in the industry but also by ADHS Staff. We received strong comment from various members of the staff that they would like to be able to communicate with the general public, qualifying patients and law enforcement about a wide variety of things. Some examples are:

- disclosure of where Dispensaries are located;
- whether or not Dispensaries have been cited for any deficiencies;
- and conversely, to be able to disclose publicly those Dispensaries that are in good standing.

A perverse consequence of §36-2810 occurs when the Department receives complaints regarding the existence of unlicensed dispensaries – a weekly event according to staff. Under AMMA, ADHS does not have enforcement authority over unlicensed dispensaries. Since they are not under the Department's purview, they are unable to investigate the complaint. More importantly, due to §36-2810, they are unable to share the existence of the complaint with law enforcement to allow the subject complaint to be reviewed and possibly prosecuted.

Another limit imposed upon ADHS Staff by §36-2810 is an interpretation that the confidentiality restrictions extend to protect physicians who recommend medical marijuana from having to comply with the release of basic records and other information not subject to HIPPA protection. (The Gear lawsuit described later in this report.)

ADHS has an impressive record of efficiently managing the applications process, including applications relating to:

- card registrations for qualifying patients and designated caregivers
- Dispensary and related cultivation facility and kitchen licensing

- Dispensary agent and Dispensary owner licensing
- requests to relocate licensed Dispensaries

ADHS also has a fully developed an active team of inspectors, and a customized data management system relating to patient registry and inventory tracking.

ADHS has implemented a detailed protocol for reviewing applications for expansion of qualifying conditions under the AMMP. This protocol was created with an eye towards transparency and includes rigorous review by staff and medical professionals.

2.1.3 Litigation History and Impact on AMMP

There have been numerous lawsuits impacting the AMMP since the passage of Proposition 203. We will address several of these lawsuits, with an emphasis on those impacting the areas of focus discussed in this report.

The most prominent suit was filed in 2011 by the state of Arizona and then Governor Brewer in federal court seeking to block implementation of the Program. Brewer, ADHS and DPS officials sought clarification about whether or not the AMMP was preempted by federal drug laws. In particular, Brewer and state health officials asked the court to determine if going forward with the AMMP would put state employees at risk of federal prosecution. During its pendency, the lawsuit didn't block the process for qualifying patients to seek registration cards, but it did put on hold ADHS licensing of Dispensaries. In January, 2012, the federal judge hearing the matter dismissed the suit saying the state had not shown that federal prosecutors in Arizona had threatened to prosecute state or local employees for following Arizona law, nor had it shown that any harm would come absent a ruling from the court. This ruling cleared the way for full implementation of the AMMP and, within 10 months of the ruling, the first licensed Dispensary opened in Arizona.

In Zander Welton v. State of Arizona, et al., CV 2013-014852, (Ariz. 2014), a Maricopa County judge ruled that the AMMA allows qualifying patients to use medical marijuana extracts. The Maricopa County Attorney and others had argued that there was a prohibition on "concentrating the chemicals in the marijuana flower." The court concluded, "The language of the AMMA and its ballot materials make clear that proponents and voters intended the AMMA to provide access to medicine for debilitating medical conditions without fear of criminal prosecution. The AMMA does not limit the form in which that medicine can be administered. Nor does it prohibit the use of extracts, such as CBD oil."

This decision, while not entirely settled law, considerably eased commercial industry concerns that products containing processed medical marijuana were illegal. Unfortunately, the AMMA and the Program Rules largely do not contemplate the regulation of processed medical marijuana products such as extracts, concentrates, edibles, and marijuana infused products ("MIPs"). A gap we will spend considerable time discussing throughout this report.

A recent decision in a case involving physicians' immunity under AMMA, State of Arizona v. Robert Gear, No.1 CA-CR 13-0852 (Ariz. Ct of App. 2014), further restricts ADHS from monitoring the process physicians use to certify that a patient qualifies for a medical marijuana card. This case (currently under appeal before the Arizona Supreme Court), confirmed the right of physicians to effectively cite blanket immunity from disclosing his/her process in certifying a patient for a medical marijuana card. More importantly, it restrains physicians from providing confirmation to ADHS that the patient qualification process required under AMMA, including the requirement that qualifying patient's medical records from the previous 12 months be reviewed prior to certifying

a recommendation, had in fact occurred. The effect of this decision is that ADHS is effectively barred from inspecting physicians suspected of acting as a "rubber stamp" regarding issuance of certifications.

2.1.4 Focus Areas:

(a) Regulation and controls of MIPs, concentrates, and edibles

Licensed Dispensaries in Arizona (at least those that we have visited) typically offer a wide variety of products containing processed medical marijuana. Starting with 100% raw marijuana or "usable marijuana" under AMMA, and including MIPs, extracts, lotions and concentrates containing medical marijuana, there are likely 100's of variable ways currently to use medical marijuana in Arizona. MIPs alone take on many forms including all types of foods, drinks, and candies, among other things.

The AMMA contains very little language regarding controls on the production and distribution of products that are derived from medical marijuana but are not usable medical marijuana. In talking with ADHS staff, outside counsel and County Attorney Montgomery, the reason largely given for this surprising gap in the regulations is that AMMA was written originally to only contemplate the sale and ingestion of raw (whole plant) or usable medical marijuana.

As described above in the Welton case, efforts to limit the proliferation of products not considered "usable marijuana" have largely fallen short. Thereby leaving a substantial public safety concern for ADHS and public officials interested in better controlling the wide spread proliferation of products which are not certified by the FDA or (effectively) by ADHS.

While limited in comparison to other states allowing similar products, there are some controls in place governing the manufacture of medical marijuana infused edible food products including:

- licensed Dispensaries, prior to preparing, selling or dispensing medical marijuana infused edible products, must obtain advance written authorization from ADHS. (R9-17-319 (A)(1));
- the Dispensary preparing the products are in compliance with the food safety standards as required by 9 A.A.C. 8, Article 1. (R9-17-319 (A)(2));
- if the products are not prepared at the Dispensary, a copy must be obtained of the ADHS authorization allowing the Dispensary that produced the products. (R9-17-319 (A)(3));
- any Dispensary selling the products must ensure that the products are sold or dispensed in conformity with 9 A.A.C. 8, Article 1. (R9-17-319 (A)(4));
- a Dispensary selling these products is responsible for the content and quality of any edible food product sold or dispensed by the Dispensary. (R9-17-319 (A)(4));
- Cleaning and sanitation requirements relating to the production of medical marijuana (R9-17-320).

Effectively, ADHS is left with the above to determine whether or not the almost unlimited variety of manufactured products (not just edibles) are fit for human use and that product preparation is completed in a safe and secure fashion. The types of products include such things as "shatter", lotions, salves, tinctures, chemical extracts. None of which were contemplated whatsoever under AMMA.

The licensing team at ADHS charged with inspecting these kitchens do as good a job as they can under the circumstances, and as better discussed later in this document in the Inspections Section. But they have not been given the same or similar compliance tools as their contemporaries in other states when it comes to oversight and

review of the wide range and types of processed medical marijuana products in commercial use across Arizona. And the guidance given to commercial operators by ADHS relating to health and safety issues involved with the production of medical marijuana based products is very minimal.

(b) Medical marijuana testing

Neither the AMMA or the Program Rules require testing of medical marijuana prior to its sale or dispensation.[4] Furthermore, any independent laboratory testing of medical marijuana in Arizona occurs without regulatory oversight, standards or licensure by ADHS.

While not unique among states having similar medical marijuana programs, Arizona certainly lags behind many other states who have adopted fairly rigorous medical marijuana testing requirements. The states implementing these requirements have typically required that it occur using third party testing labs.

In Section 3 of this report, a summary of how various states deal with medical marijuana testing is presented. It is important to note that medical marijuana is a complex non-narcotic offering multiple strains, products and variable uses, all seeking to address numerous qualifying medical conditions. It is cultivated in variety of fashions and its various strains run the gamut of potency and mental/physical effects.

"The marijuana plant contains dozens of cannabinoids and another 300 possibly active chemicals, many with unknown effects and interactions. To date, two cannabinoids have received the greatest attention: delta-9 THC (commonly known as THC) and CBD. THC is the main psychoactive compound in marijuana that causes people to feel high, while CBD is a naturally occurring counterbalance to that compound that, when present in sufficient amounts, can reduce the sensation of feeling high and reduce anxiety, which THC sometimes promotes. Cannabinoid receptors are found throughout the body, and both THC and CBD have other properties that make them potentially medically useful (Hermann and Schneider, 2012; Koppel et al, 2014)."[5]

Many licensed Dispensaries in Arizona voluntarily engage in some fashion of product testing either doing so internally or using a third party testing agent. A common comment from the various commercial participants we interviewed was that independent third party testing is very important. During these discussions we heard concerns about a significant lack of transparency within the industry in terms of the veracity of the types and strains of medical marijuana that are being marketed to qualifying patients' state wide. In particular, several commercial interviewees' suggested that it was very important, from a public health perspective, to have medical marijuana tested and then make the results of the testing available to qualifying patients, so that they could make balanced decisions on where they acquire their medicine (and in what form).

A patient care director at a Phoenix Dispensary said that the Dispensary she works for completes voluntary medical marijuana testing, using an independent third party lab. Her general comment regarding the veracity of the medical marijuana tested was that the results were often inconsistent and unreliable. The focus of the testing was largely looking for molds, pesticides and other contaminants as well as THC/CBD levels.

[4] R9-17-317(D) states that Dispensaries provide samples of medical marijuana upon request to the Department in order to conduct analysis. In discussions with ADHS staff, this never occurs due to a determination that, under AMMA, staff are not legally allowed to possess marijuana absent a qualifying patient certification or designated caregiver certification, and that the AMMA doesn't provide for medical marijuana to be housed onsite at ADHS.
[5] Jonathan P., Beau Kilmer, Mark A.R. Kleiman, Robert J. MacCoun, Gregory Midgette, Pat Oglesby, Rosalie Liccardo Pacaula, Peter H. Reuter, "Considering Marijuana Legalization, Insights for Vermont and Other Jurisdictions; Issued by the RAND Corporation, 2015.

ADHS Staff in interviews stated that the lack of testing and related product labeling requirements make it very difficult for them to cite deficiencies in product offerings. They commented further that this presents an obvious and major concern in that patients are getting sold a wide variety of medical marijuana products without any verifications of potency, homogeneity, contaminants, etc.

ADHS' current reliance on licensed Dispensaries to self-regulate when it comes to medical marijuana testing is akin to allowing the proverbial rooster in the hen house. Other than possible reputational issues with qualifying patients, licensed Dispensary's have very little incentive or downside risk to adopt rigorous standards when it comes to medical marijuana quality assurance.

This issue and how best to address it going forward will be better addressed in Section 3 and in the recommendations contained in Section 5 of this report.

(c) Inventory reporting and tracking

Both the AMMA and the Program Rules place significant emphasis on inventory controls relating to the cultivation of medical marijuana, the wholesale medical marijuana market, the retail market as well as the transportation of medical marijuana along all stops of the commercial chain of custody.

Licensed Dispensaries are required to use rigorous internal inventory control systems for the tracking of medical marijuana. These systems are expected to track, on at least a daily basis, "beginning inventory, acquisitions, harvests, sales, disbursements, disposal of unusable medical marijuana, and ending inventory." (R9-17-316(C)(1), as well as:

- track any acquisitions of medical marijuana from designated caregivers, qualifying patients, or other dispensaries;
- provide specific descriptions of the medical marijuana acquired;
- record each batch of medical marijuana cultivated, harvested and disposed of, by plant, strain, seed and cutting;
- provide a description of the edible food products produced internally or from another Dispensary, by weight, type, and batch number;
- include a listing of all chemical additives used in cultivation
- provide the name and registry identification number for each dispensary agents responsible for any medical marijuana related transaction.

Additionally, each licensee must designate a dispensary agent who has oversight of the system. A designated dispensary agent must conduct at least once every 30 calendar days, an audit of inventory subject to GAAP principles.

Of note, the rules relating to inventory tracking do not require tracking of extracts, non-edibles, MIPs or concentrates. There also are some soft spots in the requirements relating to transportation of medical marijuana to other Dispensaries or to qualifying patients/designated caregivers (R9-17-318(B-E), including limited requirements on the specifics relating to the medical marijuana that's being transported and no requirements or reconciliation of medical marijuana that doesn't get acquired pursuant to a delivery (whether wholesale or retail).

More importantly, there is no requirement that a licensee's inventory tracking systems interface directly with an equivalent ADHS system, thereby preventing ADHS from having real-time access to track anomalies or trends which may trigger inspections or follow ups if there are issues with the respective Dispensary's system and related records.

The Department staff raised several concerns about the inventory tracking process. One comment was that it is not expressly required by ADHS that delivery of medical marijuana be made to a cardholder's address. Furthermore, ADHS does not verify that an address provided at the time of the application is in fact the actual residence of the qualifying patient. By not requiring that a qualifying patient receives delivery only at a verified address, the risk of a diversion issue or a fraudulent transaction is increased. Thereby allowing possible gaps in the system where medical marijuana can be delivered to individuals outside the system.

With no centralized inventory tracking system, it's impossible for ADHS to monitor, on a real-time basis, the distribution of medical marijuana (whether donated, sold or destroyed) across the commercial marketplace. This is a significant worry when considering the all cash nature of the medical marijuana industry and the ongoing black market for medical marijuana and/or transportation of medical marijuana across state lines (a federal point of emphasis.)

(d) Patient registry

Also referred to in the Program Rules as a "medical marijuana electronic verification system", in AMMA as a "verification system" and by ADHS as the "AZ Medical Marijuana Card Verification/Point of Sale System", the registry is intended to track medical marijuana transactions involving qualifying patients, designated caregivers as well as verifying that a qualifying patient has obtained a certification for medical marijuana from a licensed physician. Additionally, it provides a method of monitoring all of the dispensary agents, employees and owners involved in commercial medical marijuana operations. All participants in the registry are given a unique, alpha-numeric code as a personal identifier.

Prior to a medical marijuana card being issued to a qualifying patient, all required documents, including a certification from a physician is entered into the ADHS patient registry.

ADHS has a long term contract with ASBP to confirm that recommending physicians have accessed the State Prescription Drug Monitoring Program ("PMP") to review qualifying patient prescription histories as required by A.A.C. R9-17-202. i (iii). Data regarding physician certifications is sent on an excel spreadsheet from ADHS to ASBP. Technically, ASBP receives a CD containing a CSV file with qualifying physician name and license number. ASBP then runs a confirmatory cross check against the PMP to confirm whether or not the qualifying physician accessed the PMP.

Currently, the format of information ASBP receives from ADHS regarding naturopathic physicians is in conflict with the format required by the PMP. License numbers of naturopathic physicians contain a hyphen. Unfortunately, the use of a hyphen is not compatible with the PMP format so it does not verify that naturopathic doctors accessed the PMP.

A solution for this compatibility issue would be for ADHS to provide the physician's name, license number and DEA number to ASBP for a PMP query, subject to ARS 36-2606, effective December 31, 2015. By utilizing the DEA number (which does not contain a hyphen) to query the system will allow the ASBP to confirm that naturopathic doctors accessed the PMP.

Currently, ADHS gathers only the total number of certifications issued by a physician and ASBP confirms that the physician accessed the PMP at least that many times in a month. To further enhance the AMMP, the information gathered by ADHS for ASBP to review should specifically correlate to the qualifying patient for whom the certification was written. This would allow ASBP to reconcile a physician's PMP access to each specific qualifying patient.

One of the primary goals of the registry is to prohibit sales of marijuana to patients and designated caregivers in excess of the limits allowed under AMMA (A.R.S. §36-2806.2(3) allows up to 2.5 ounces in aggregate per qualifying patient during any 14-day period). The registry works as follows:

- qualifying patient gives registry card;
- dispensary agent swipes card to access ADHS registry portal to confirm validity of the card;
- ADHS rules require the dispensary agent to simultaneously enter any sale into their internal inventory tracking and/or point of sale system;
- the ADHS system will alert dispensary agent if the qualifying patients quantity of medical marijuana is in excess of 2.5 oz.;
- this alert should cause the dispensary agent to stop the sale;
- concurrently, when a sale is completed, the dispensary agent must enter into the Dispensary's system.

The ADHS system will not allow a dispensary agent to complete a single transaction in excess of 2.5 ounces. However, the ADHS system WILL allow for a dispensary agent to sell individual transactions which may exceed 2.5 ounces in aggregate.

In the event of a sale in excess of the 2.5 oz. limit, the licensee must voluntarily disclose this event to ADHS within 72 hours and/or self-remediate or adjust the transaction so that it falls within the legal limits. Failure to comply will result in a notice of violation being issued to the Dispensary.

This gap in the system, coupled with the requirement that ADHS give at least 5 days advance notice of a regular inspection, or in the alternative the typical 2 days' notice of a compliance inspection, can allow a bad actor ample time to prepare a separate set of records to mask an event in which a qualifying patient purchases more than 2.5 ounces. This coupled with the all cash nature of commercial medical marijuana makes it very easy for illegal diversion of medical marijuana to occur. (Section 2.1.4(g) has additional commentary on ADHS inspections and procedures.)

Finally, pursuant to A.R.S. §36-2807(B), "The verification system must allow law enforcement personnel…to enter a registry identification number and verify whether the number corresponds with a current, valid identification card." The registry does in fact manage this requirement quite well. Law enforcement, when coming across an issue involving medical marijuana:

- can ask for a qualifying patient's registry card,
- can input the qualifying patient's unique alpha numeric code,
- can access the ADHS registry to confirm that the qualifying patient (or dispensary agent, or designated caregiver as the case may be) may lawfully possess the medical marijuana.

However, one significant limitation exists. Due to the confidentiality requirements of A.R.S. §36-2810, law enforcement can only access the ADHS registry with the qualifying patient's tangible card. If the qualifying patient doesn't have the card on his/her person the police can't query the system using the qualifying patient's

name and date of birth. Instead, the police officer's only option is to temporarily detain or arrest the qualifying patient for unlawful possession of medical marijuana.

(e) Use of AMMP proceeds

Establishment of the rules, regulations and fee schedules of the AMMP was not driven by a desire for revenue, but the commitment to create a robust regulatory framework and sufficient revenue required for activation and operation of the AMMP.

To date, proceeds received have been utilized for general oversight, education and administration of the AMMP. This has included contracting with a handful of organizations and government agencies to provide expertise in research, assessment and data management. Additionally, ADHS has entered into two pilot programs with Phoenix and Tucson police departments to support additional investigation and enforcement efforts. ADHS staff specifically asked us to explore additional uses for proceeds from the AMMP and below is an overview of suggested enrichments to the program:

- development, implementation and management of a comprehensive centralized inventory management system;
- additional enforcement resources to allow for more frequent and complex inspections, greater support for local law enforcement agencies to investigate complaints, and in-depth financial reviews of both operations and owners;
- creation of training curriculum for certifying physicians, dispensary owners and agents;
- launch a state wide public awareness campaign aimed at improving citizen awareness on the AMMP and guidelines for storage and usage of medical marijuana;
- support of substance abuse programs;
- establishment of a medical marijuana research grant program to document qualifying patient results using medical marijuana for various qualifying conditions.

(f) Wholesale medical marijuana market

In discussions with various commercial participants as well as the Phoenix Police Department, Drug Enforcement Bureau, ADHS staff and Maricopa County Attorney Montgomery, a consistent theme emerged. They uniformly agreed that a substantial percentage of the wholesale medical marijuana arriving at Dispensaries is via donated medical marijuana and/or medical marijuana that's received without a commercial transaction being recorded.

An Arizona licensed dispensary owner was much exercised about an imbalance he perceives in the wholesale medical marijuana market. He stated that he either sells medical marijuana that he cultivates in a licensed facility or purchases (when necessary) from other licensed Dispensaries. His very strongly stated belief is that other licensed dispensary owners receive wholesale medical marijuana via "donation" or from the black market. He continued to comment that "nobody gives medical marijuana away for free, it's simply too expensive to cultivate, harvest and manipulate to be given away in large quantities."

The concept behind the donation system was due in large part to the dearth of available medical marijuana to meet qualifying patient needs in the early days of the Program – prior to the wide spread licensing of dispensaries with cultivation facilities. Now, with 70 licensed cultivation facilities across the state, the supply issues which constricted the market for medical marijuana in the Program's early days logically should no longer exist.

It would be naïve to believe that large scale donations of medical marijuana are being made without some form of consideration passing between the donator, whom by law can only be a designated caregiver or a qualifying patient and the licensee. And yet, according to commercial participants and enforcement officials alike, the donations market for medical marijuana is thriving.

The result of these donations is that the actual nature of commercial transactions involving the sale of medical marijuana aren't getting recorded as the actual consideration given for each medical marijuana transaction is most likely a cash transaction conducted off the books, or otherwise captured in some form of a consulting arrangement. This activity fosters a black market environment which is contrary to AMMA's goal of making medical marijuana a legitimate, state sanctioned well regulated industry.

Furthermore, the lack of more stringent regulatory controls over medical marijuana cultivation, in particular personal cultivation and related "donations" has led to the existence of "hubs" or "farmers markets" where the unlicensed dispensing of medical marijuana occurs, often to qualifying patients but also to the general public. It is unclear how many hubs have been discovered or how many (if any) are currently in existence. A popular website servicing the industry lists in excess of 35 "hubs" or "hub related businesses" in the state. It is believed by law enforcement that the omission of a comma "missing comma" in the AMMA (A.R.S 36-28-11 B3) centering on the value of a transfer has led to the ambiguity of the legitimacy of "hubs" or "hub related businesses". It reads "for offering or providing medical marijuana to a qualifying patient or a designated caregiver for the qualifying patient's medical use or to a registered nonprofit medical Dispensary if nothing of value is transferred in return and the person giving the medical marijuana does not knowingly cause the recipient to possess more than the allowable amount of medical marijuana."

ADHS staff often receives complaints from the general public regarding "hubs", which in turn is passed along to the appropriate law enforcement agency for investigation. According to the Phoenix Police Department, Drug Enforcement Bureau, they have been successful in prosecuting "hubs" which are operating in a clandestine manner. These prosecution events further verify that the only manner in which medical marijuana can be sold or transferred in Arizona is through a licensed Dispensary or designated caregiver.

Additionally, when applying for a qualifying patient card, a picture ID is required as well as an address, but there is no requirement that the address be the applicants physical residence. To provide more stringent enforcement of the home cultivation and delivery provisions of AMMP[6][7], and to eliminate the ambiguity of the legitimacy of a "hub" the applicant should be required to submit further information (i.e. utility bill, lease or mortgage statement) verifying the address is in fact the physical residence of the applicant. Further, it should be a requirement that all medical marijuana deliveries to a qualifying patient be made to the physical address on file with ADHS or a licensed health care facility.

The current lack of a centralized database, from which ADHS and enforcement officials alike can access, real time, information about approved cultivation, Dispensaries, and registry participants places considerable limits on the information necessary to support law enforcement efforts. Effective tools for law enforcement would include access to data including complaints against licensees, and notices of deficiency to allow more objective assistance.

[6] A.A.R. R9-17-202F(1)g provides that if a qualifying patient lives at least 25 miles from an operating Dispensary, personal cultivation may occur by either the qualifying patient or their personal caregiver.
[7] Regarding medical marijuana deliveries, A.A.R. R9-17-304 does not provide any requirements that deliveries are made to a qualifying patient's address.

(g) Inspections/surveys and financial audits

The Bureau of Special Licensing (a branch within Public Health Licensing Services) handles the inspections. They are typically initiated with a Notice of Inspections Rights form being issued to the Dispensary. The notice states that the inspection is conducted pursuant to A.R.S. §§41-1009 and 36-2806H as well as R9, Chapter 17 (the Program Rules).

R9-17-309 of the Program Rules largely governs ADHS' ability to conduct inspections of licensed Dispensaries. All inspections, subject to certain exceptions outlined below, occur on a mutually agreed upon date between the Department and the Dispensary no less than five working days after written notice is submitted by the Department, unless the Department agrees to a later date and time (R9-17-309(B).

In the event of a complaint of non-compliance by a non-anonymous source, or if the Department identifies a violation, unannounced inspections may occur (R9-17-309(C-E). Thereafter, follow up inspections range from unannounced to a 2-day notice depending upon the underlying circumstances.

The Department staff confirmed that monetary fines aren't levied for infractions. They also commented that the most effective form of penalty is a notice of deficiency ("NOD"). An NOD can lead to additional inspections requirements and act as a precursor to further sanctions against the Dispensary, including possible license revocation.

The actual inspection documents contain a checklist in which the inspector reviews and confirms or takes issue with the Dispensary's conformity with the rules relating to:

- administration
- Medical Director requirements and protocols
- dispensing medical marijuana
- maintenance of qualifying patient records
- the inventory control system and related records
- product labeling
- security
- the production of edible food products
- cleaning and sanitation
- physical plant requirements.

The checklist concludes with a confirmation page, signed by both the licensed surveyor(s) and the Dispensary facility representative that: (a) an exit interview was conducted; (b) deficiencies were discussed with the facility representative; (c) the Department reserves the right to amend findings based on program review; and (d) the plan of correction is due within 20 days of the statement of deficiencies.

The Department currently has 4 surveyors charged with oversight of all surveys state wide (the Department uses the term survey rather than inspection). All surveys are performed with two surveyors. Dispensary and cultivation sites are surveyed twice per year. If viable complaints are issued, sites may be surveyed more often. Each site is given 5 days' notice (as required under the Program Rules), unless the survey is due to a complaint, in which instance 2 days' notice is generally given (and unannounced in certain instances). Depending upon the circumstance of the survey, the Department is often flexible with confirming survey dates greater than 5 days

from the date of notice. All surveys are limited to 2.5 hours with a primary focus placed on health and safety reviews. Records are spot checked during surveys, unless there's a reason to probe more deeply.

Some common infractions found during surveys include:

- audible alarm for cameras are disconnected or not working;
- security camera coverage is inadequate;
- failure to maintain 30 days of recordings;
- failure to record completion times on trip plans;
- failure to include the dispensary agent registry number on trip plans;
- kitchens and facilities are dirty.

Further comments and suggestions from the Department staff urged that additional sanitation education be required of each Dispensary and its dispensary agents. As it is not at all unusual to come across unsanitary Dispensary/cultivation environments including dirty kitchens with items prepared on dirty surfaces, drying medical marijuana flowers in front of bathrooms or under dirty vents, etc. They expressed worry that an outbreak or epidemic could occur given some of the less than acceptable standards at certain Dispensaries. They also recommended that the individual counties need to be inspecting the Dispensaries in their locales as an added deterrent.[8]

A patient care director with one licensed Dispensary described ADHS inspections as fair and consistent. She continued with saying they occur every six months or so. The emphasis typically is on inventory reconciliation, particularly relating to confirmation of batch numbers and sales to qualifying patients. She stated that the Dispensary she worked for had never dealt with an unscheduled inspection, as it had never had a violation issue of any consequence.

On the other hand, a dispensary owner described the survey/inspection process as "cursory at best". He felt that the inventory record keeping requirements should be more closely scrutinized and that actual document review should occur, rather than the "typical cursory inspection that occurs every six months." His belief and that of a commercial medical marijuana lawyer we spoke with was that the cursory nature of inspections allowed bad actors to operate on the fringes without fear of reprisal or sanction. The dispensary owner also expressed frustration at having to go through "a CPA audit with Henry Horne & Co. when the results of the audit are never reviewed or considered by the Department."

The dispensary owner's final and most vocal complaint about ADHS' surveys was the lack of emphasis placed on reviewing Dispensary records relating to wholesale purchases of medical marijuana, and in particular via donation. His belief is that a significant amount of wholesale medical marijuana is arriving on Dispensary shelves from the black market. Thereby creating substantial economic imbalance to those dispensaries who actually respect AMMA rules regarding procurement of medical marijuana from licensed, legitimate entities.

[8] We agree with this recommendation and that each licensed Dispensary should be required to obtain a food establishment operating permit or its equivalent in each county. (In the case of Maricopa County, the Maricopa County Environmental Services Department oversees and inspects all food establishments.) The kitchens then would be regulated by their respective county's environmental health code or equivalent. This would take some pressure off of ADHS and reinforce health and public safety.

Regarding donations of medical marijuana, a dispensary agent we interviewed stated that ADHS surveyors did in fact do periodic "spot checks" of Dispensary donations records and they asked related questions about the nature of the donations.

Financial audits initially were contemplated by the Department and are allowed under AMMA. But these stalled as the AICPA came out initially with pronouncements limiting the accounting community being involved with medical marijuana related matters. However, this stance by the AICPA has been considerably softened. Currently, financial audits relating to licensed Dispensaries do not occur. Thereby arguably giving a pass to those licensed dispensaries that don't follow the rules relating to wholesale medical marijuana and diversion of medical marijuana generally. (Current inspections primarily focus on sanitation requirements.)

ADHS surveyors inspect kitchens and certify their conformity with the Arizona's food handling statute (9 A.A.C. 8, Article 1).

In Coconino County, policies and procedures have been developed regarding the operations of Dispensary kitchens and local officials inspect the three dispensaries located in county. These inspections surpass basic sanitation requirements and include safety protocols and operational best practices. No other county has alerted ADHS about local kitchen inspections.

ADHS typically doesn't call law enforcement when there are issues with inspections – using the confidentiality restraints contained in A.R.S. §2810 restraints as the rationale. In discussions with representatives from the Phoenix Police Department, they indicated that although ADHS may notify them when uncovering suspicious activities during inspections, due to confidentiality concerns the information shared often was insufficient to support an investigation.

Of note, one Dispensary to date has forfeited its license as a result of the survey process (pursuant to a mutual consent agreement).

(h) ADHS enforcement options and tools

ADHS does not have criminal enforcement authority. However, both the AMMA and the Program Rules provide multiple tools for ADHS to engage in civil enforcement which ultimately could lead to criminal penalties (involving law enforcement). Additionally, ADHS has authority to issue notices of deficiency or revoke licenses.

ADHS Staff actively uses what they call "provider meetings" to address repeat or egregious offenses by Dispensary licensees. Approximately 10-15% of the licensees have been called to provider meetings due to repeated deficiencies for failure to comply with Program rules and requirements. The Department typically formalizes provider meetings with some form of consent agreement in which violators are held to heightened scrutiny, including agreement that ADHS may conduct unannounced inspections.

To date, ADHS has not revoked any Dispensary licenses. They have agreed, pursuant to a consent agreement to allow one licensee to forfeit their license (short of an actual revocation.)

Members of ADHS staff mentioned that, on a weekly basis, complaints of unlicensed Dispensaries are received from the general public. Investigations of these types of complaints do not fall under Department purview. However, the Department typically notifies law enforcement of the existence of these complaints. The data collected may or may not be sufficient for an investigation to occur.

The following is a listing of some of the express sections in the AMMA in which civil or criminal penalties may be applied for various violations.

A.R.S §36-2816(C) provides a significant disincentive to those considering whether or not to engage in the illegal procurement of medical marijuana on the wholesale market. A knowing violation of this section is a class 2 felony.

A violation of the confidentiality provisions contained in A.R.S. §36-2810 results in a class 1 misdemeanor pursuant to A.R.S. §36-2816(D).

A.R.S. §36-2808 allows for a fine of up to $150 for failure of cardholders to keep ADHS informed of changes in status within certain defined timelines.

A.R.S. §36-2819 confers authority on ADHS to require regular fingerprinting of designated caregivers, a principal officer, dispensary agent or employee of a Dispensary or a medical marijuana dispensary agent. These may then be submitted for a state and federal criminal records check.

Under the Program Rules, and in the event of certain violations, ADHS has authority to either deny or revoke Dispensary certificates (R9-17-322). Some examples of events potentially causing a license denial or revocation are: engaging in diversion of medical marijuana, acquiring medical marijuana from an unlicensed source, failure to follow and comply with ADHS policies and procedures.

Similarly, R9-17-323, provides for denial or revocation of dispensary agents' certificates, in the event of various violations, including engaging in diversion of medical marijuana, conviction of an excluded felony offense, and using medical marijuana without a qualifying patient registry card.

(i) Medical Marijuana packaging, labeling and child proofing

In discussions with counsel for the Department, concerns were raised regarding product labeling and lack of required laboratory testing. In particular, they see the lack of sufficient product labeling as a significant issue, from both an enforcement and a public health perspective. Enforcement officials struggle with the lack of specific product information contained on a processed medical marijuana product making citing for deficiencies much more challenging. There are two major areas of concern from a public health perspective. First, the lack of precise information on dosages and CBD/THC profiles, as well as the effects of the product/strain is concerning given the types of qualifying conditions being treated. Secondly, the lack of child or tamperproof packaging requirements allows for the potential for unintended access to the medical marijuana by children.

The Program Rules regarding product labeling are as follows (R9-17-317):

- the Dispensary's registration number must be listed;
- the amount, strain, and batch number of the medical marijuana used;
- an ADHS warning statement must be placed on any package which includes, among other things, various warnings relating to medical marijuana use and an all caps "KEEP OUT OF THE REACH OF CHILDREN".
- the date of the manufacture, harvest or sale;
- a listing of all chemical additives (including pesticides); and,
- the registry identification number of the qualifying patient.

- If not cultivated by the Dispensary, whether the medical marijuana was obtained from a qualifying patient, a designated caregiver, or another Dispensary.

In the case of an edible product, in addition to the above requirements, the total weight of the edible food product must be stated on the label.

(j) Qualifying condition approval process

ADHS has a rigorous, and well-constructed process for administering requests to add qualifying conditions.

All applications for additional qualifying conditions require supporting clinical research and other key data points for the Department to use in their evaluation. The review process is completed in two stages. During the initial stage, ADHS Bureau Chief reviews the application for conformity and that all required information has been included and filing requirements have been met. The second stage is focused on confirmation that minimum clinical criteria has been met and supports the approval of the qualifying condition for inclusion in the AMMP.

Any application which has complied with the requirements of both stages is submitted to the ADHS Medical Advisory Committee which includes all senior ADHS AMMP personnel and two physicians. The Advisory Committee then completes a thorough analysis including clinical research and evidence review provided by the University of Arizona Schools of Medicine and Public Health. Additionally, a public hearing is scheduled to allow testimony from the community and medical professionals in support of or opposition to of the petition.

Since the inception of the Program 34 applications have been received and processed. In 2014, an application to add PTSD was submitted and approved, thereby adding PTSD to the list of qualifying conditions.

(k) Transferability of licenses or relocation of Dispensaries

The Program Rules prohibit the transfer or assignment of a Dispensary license (R9-17-306). Despite this prohibition, the transfer or assignment of the entities and related assets that effectively control the licensed Dispensaries happens fairly often, according to several attorneys who provide services to Dispensary licensees.

Strictly speaking, it is illegal to sell or transfer a Dispensary license as well as to receive any compensation for doing so. Any transactions in the State of Arizona affecting a nonprofit holding a Dispensary license have been for the sale of some other asset or assets. Individuals have sold equipment, real estate, buildings, management entities etc. Basically anything that effects the ongoing operations relating to a licensed Dispensary has been sold in support of changes in effective control of the licensed Dispensary, without impacting or touching the underlying nonprofit organization that holds the actual Dispensary license.

In conjunction with that sale of assets or whatever the case may be, in some instances a nonprofit will agree to certain terms and provisions affecting the nonprofit itself. In this case, the nonprofit is not a party to the purchase and sale agreement, it merely agrees to certain terms and conditions. Generally, as a condition to closing any change of control transaction, the Arizona Corporation Commission, but more importantly ADHS is required to approve any changes affecting the nonprofit. There are a host of requirements provided by ADHS related to notice and acquisition of approval related to any change in the nonprofit's directors and principal officers. If done correctly there typically is no issue and the change of control transaction occurs, but it's a lengthy, complex and transaction heavy process. This is all done in order to work around the rules prohibiting a technical transferal of the nonprofit's Dispensary license - all of which is perfectly legal.

In Section 3 of this report, a contrasting summary of how certain other states handle transferability of licenses (and related departmental approvals) is provided.

Regarding changes of locations by Dispensaries, this may occur, subject to ADHS approval, and with certain limitations. Pursuant to R9-17-306, a licensed Dispensary may relocate within their CHAA[9] within the first three years of receiving a registration certificate, or outside their CHAA after three years have passed (R9-17-306). Prior to this occurring R9-17-307 outlines a detailed process in which a licensed Dispensary may seek a new location and (if applicable) a location for a new cultivation site.

(l) Reporting and dissemination of information

ADHS has a detailed, well-constructed web site (http://azdhs.gov/licensing/medical-marijuana/index.php). It contains dedicated portals to all of the registrants involved in the Program. The site contains FAQs, general information on the Program (including the Annual Report, quarterly and monthly reports), links to rules and statutes, forms, and historic references, among other things.

The site is easy to navigate, is informative, and can be used as a one-stop shop for news and processes relating to medical marijuana in Arizona.

ADHS public reporting on the Program's status, on a monthly, quarterly, and annual basis, is quite comprehensive, informative and impressive. The forms generated by ADHS are easily accessible and user friendly.

We asked various participants in the industry about ADHS communications. A patient care director at a licensed Dispensary suggested that there be expanded or enhanced communications to the medical community. In particular, that results of scientific studies involving marijuana (both current and as they get issued) should be forwarded to the Arizona Medical Board. She also suggested that ADHS sponsor the creation of additional CME's and pain management seminars, to better inform the medical community about the benefits (and limitations) of medical marijuana.

A qualifying patient recommended that dispensary agents undertake mandatory training in order to better provide more informed guidance to qualifying patients about the effects of various strains, edibles, and tinctures, as well as dosage recommendations. He thought that, objectively, the best type of training would be created and managed by ADHS staff. So that the training wouldn't be a useless "rubber stamp" type of program.

While very positive in general about the AMMP, he did suggest that additional qualifying patient focused literature and updates – likely placed on the ADHS site and provided in hard copy to Dispensaries would be greatly welcomed and helpful. This suggestion was reiterated by a recommending physician who was interviewed.

In discussions with ADHS staff, frustration was expressed with the confidentiality limitations imposed by A.R.S. §36-2816. The staff would like to be able to communicate with the general public, qualifying patients and law enforcement about the locations of licensed Dispensaries, and whether or not a Dispensary has been cited for any deficiencies, and conversely to be able to recommend those that have stellar records. They also felt it would be

[9] ADHS, in setting up the licensing for Dispensaries, determined that up to one license can be issued to each of the 126 designated community health analysis areas ("CHAAs").

helpful to be able to publicly post Dispensary civil violations, as a tool to provide warnings to other Dispensaries and further market self-regulation.

(m) Licensing

The Department's management of the processing of licenses (across all licensing classifications) is exceptional – in terms of processing efficiency and meeting and usually well exceeding all statutory time limits.

The Department's processing is so fast that, in one particular license category, the Department approves licensees prior to receiving the results of background checks involving fingerprinting. When reviewing applications for dispensary agents, ADHS requires the applicant to provide fingerprints and submit to a background check. ADHS policy is to approve the application and provide a provisional dispensary agent card prior to receiving the results from state and federal agencies. Thereby possibly allowing individuals who might otherwise be excluded from acting as a dispensary agent to engage in the handling and distribution of medical marijuana for a period of time. If a dispensary agent application is denied due to negative findings from the fingerprint check the dispensary agent's card is revoked within the system by ADHS.

During our interviews, both law enforcement and ADHS representatives expressed serious concerns with the breadth of authority a dispensary agent card provides. It's commonly considered the "golden ticket", due to the lack of constraints on the amount or storage location of medical marijuana in their possession. If an agent is stopped by law enforcement and presents a valid dispensary agent card, the officers do not investigate further.

ADHS' approach in granting Dispensary licenses is somewhat different from some of the other states studied. The AMMA limits the initial number of Dispensary licenses to one per Community Health Analysis Area ("CHAA"). In the event of multiple applicants competing for the single license with a CHAA, under certain circumstances, ADHS determines the winner via random selection (A.A.C. R9-17-303B4). In Section 3.2.1(m) we will discuss how many other states grant licenses via merit based processes. Additionally, ADHS does not typically review the nature of relationships many (if not most) Dispensary licensees have with affiliated ancillary businesses – either during the application, periodically in the normal course of inspection(s) or during the license renewal processes.

The AMMA and the Program Rules do not require qualifying physicians to apply for certifications to issue qualifying patient recommendations.

(n) Waste Disposal

Regarding the disposal of unused medical marijuana waste, the AMMP has provisions markedly different from those required by the ASBP and DEA regarding controlled substances (further discussed herein in Section 4.1), but largely in line with the requirements found in other states' medical marijuana programs (discussed in Section 3.2.1(n).

A.A.C. R9-17-316 requires all licensed Dispensaries to establish and implement waste destruction plans relating to the disposal of unusable medical marijuana. Furthermore, pursuant to A.A.C. R9-17-320, licensed Dispensaries are required every 24 hours to remove all refuse or waste products from the premises.

ADHS inspectors, regularly confirm with Dispensaries that they (a) have a waste disposal plan on site and (b) that the removal of waste regularly occurs as part of general operating procedures. However, waste disposal is not a point of emphasis or focus typically during ADHS inspections.

Examples of Dispensary waste plans were provided by ADHS for the preparation of this report. Generally, all licensees procedurally contemplate the services of a third party for disposal. It is important to note that the AMMA does not designate a license classification for destruction, therefore any third party who is assuming possession of medical marijuana from a licensee is likely in violation of both state and federal laws relating to controlled substances possession and destruction.

When we spoke with various dispensary owners and dispensary agents, the comments we received regarding waste disposal were limited, with a typical comment being "very little waste is generated. The little amount that is gets destroyed through a chipper after getting doused with bleach."

3.0 COMPARISON OF OTHER STATES' MEDICAL MARIJUANA PROGRAMS

In order to apply as close to an "apples to apples" comparison as possible, we determined that there are currently twenty-three states and the District of Columbia that have legalized medical marijuana programs sharing certain common areas with the AMMP. The states reviewed are: Alaska, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Massachusetts, Maryland, Maine, Michigan, Montana, New Hampshire, New Jersey, New Mexico, Nevada, New York, Oregon, Rhode Island, Vermont, and Washington. The common thread among these states and the AMMP are in each instance:

- cultivation of medical marijuana is allowed;
- medical marijuana is allowed to be dispensed to qualifying patients;
- some form of patient registry involving physician recommendations relating to medical marijuana is in effect;
- distribution of medical marijuana containing THC is allowed.

Of the states used in this assessment, California (1996) was the first state to allow medical marijuana, with New York, Minnesota, Maryland (all in 2014) being the last. In addition to California and the District of Columbia, a number of states studied (AK, CO, HI, ME, MI, MT, NV[10], NJ, NM, OR, RI, VM, DC, WA) allowed medical marijuana prior to passage of Proposition 203 in Arizona. As of October 27, 2014, Arizona had the 6th largest program in the country (in terms of qualifying patients participating a state registry).[11]

Whenever possible, when dealing with locations that have both recreational use and medical marijuana (Washington, Oregon, Colorado, Alaska and Washington, D.C.), we have excluded comments on their respective recreational use regulations. A notable exception relates to our discussion of regulation of processed medical marijuana products in which the same or similar rules apply generally in both the settings.

Our focus in principal in reviewing each respective states' medical marijuana programs was to compare, in each instance, how each state manages the focus areas reviewed in Section 2.14 of this assessment. In particular, the following addresses instances where certain states may exceed Arizona's current requirements.

[10] Nevada first authorized medical marijuana via ballot initiative in 2000, but allowed the actual dispensing of marijuana to occur in 2013, with its first dispensary opening in 2015.
[11] Source: ProCon.org; Arizona's program has grown considerably in 2015, likely surpassing both California and Oregon's registered patient totals.

3.1 Overview of State by State MMJ Programs

Exhibit 2 below entitled "Medical Marijuana Program Overview" is intended in broad strokes to provide the reader with some perspective on how the states studied are addressing key issues including data collection, possession limits, and qualifying patients with out of state medical marijuana cards (defined as "reciprocity").

Exhibit 2 - Medical Marijuana Program Overview

State	Patient Registry	Possession Limit	Centralized Inventory Tracking	Reciprocity
Alaska	Required	1 oz.	No	No
Arizona	Required	2.5 oz.	No	Yes*
California**	Voluntary	8 oz.	Yes**	No
Colorado	Required	2 oz.	Yes	No
Connecticut	Required	1 month supply	No	No
Delaware	Required	6 oz.	No	Yes
District of Columbia	Required	2 oz.	No	No
Hawaii	Required	3 oz.	Yes***	No***
Illinois	Required	2.5 oz.	Yes	No
Maine	Required	2.5 oz.	No	Yes
Maryland	Required	60 day supply	Yes	No
Massachusetts	Required	10 oz.	Yes	No
Michigan	Required	2.5 oz.	No	Yes
Minnesota	Required	30 day supply	No	No
Montana	Required	1 oz.	No	No
Nevada	Required	1 oz.	Yes	Yes
New Hampshire	Required	2 oz.	No	Yes*
New Jersey	Required	2 oz.	No	No
New Mexico	Required	6 oz.	Yes	No
New York	Required	30 day supply	Yes	No
Oregon	Required	24 oz.	Yes	No
Rhode Island	Required	2.5 oz.	No	Yes
Vermont	Required	2 oz.	No	No
Washington	Voluntary****	24 oz.	Yes ****	No

*Subject to certain limitations
**California recently passed legislation which establish a state wide voluntary registry and require centralized data management. The underlying rules aren't likely to be completed until late 2016 or early 2017.
***Rules effective December, 2015 will require implementation of a centralized data system by August, 2016
**** Washington recently passed legislation establishing a regulatory structure for the medical marijuana program to include a voluntary registry, data management system and tiered possession limits. Effective July 1, 2016 qualifying patients entered into the registry database may possess 8 oz. of useable marijuana. Qualifying patients not entered into the registry database may possess up to 6 oz.

3.2 Summary of How Various States Address the Focus Areas in 2.1.4

3.2.1 Focus areas:

(a) Regulation and controls of MIPs, concentrates, and edibles

In Section 2.1.4(a), the dearth of regulations governing the manufacture of products containing processed medical marijuana in Arizona was discussed. Arizona Dispensaries currently offer a wide range of manufactured medical marijuana products, with very little oversight by ADHS or any other state agency. And yet, the market for these processed or non-leaf based medical marijuana products is exploding.

An example of this expanding market can be found in Colorado. "The proliferation of marijuana edibles stunned state and industry leaders, making it one of the biggest surprises during the first year of legal recreational marijuana sales. Potent cookies, candies and drinks — once considered a niche market — now account for roughly 45 percent of the legal marijuana marketplace and led to the most high-profile marijuana controversies in 2014."[12]

Some states, like California, currently have no process in place to regulate the wide variety of MIPs and related products. But California will be drafting safety and potency related regulations in 2016 to place controls over the types of marijuana products allowable in the state.

Many of the states studied have been carefully implementing comprehensive new rules or amending current laws specifically to deal with the burgeoning market for these processed medical marijuana products including MIPs, concentrates, edibles and many others. The focus on more fulsome oversight is not just due to the expanding market size, there's a considerable public health issue. Smoking raw or usable marijuana is very different from ingesting edibles or otherwise using concentrated medical marijuana products. A recent NBC News report commented as follows, "Today, THC in "flower" — meaning the raw "bud" form of weed — is anywhere between 12 and 25 percent, Dispensary manager Huestis said. But there's no comparison when it comes to edibles. A potent edible uses a concentrate that has anywhere from 50 to 90 percent THC."[13]

Nevada, Washington and Colorado's respective regulations relating to the production of MIPs, concentrates and extracts are all very good examples of how medical marijuana compliance has evolved subsequent to passage of AMMA and the Program Rules in Arizona.

Washington and Colorado each recently adopted substantial new regulations relating to processed medical marijuana products. Washington enacted emergency rules in June 2014 to deal specifically with "medibles" or edible medical marijuana products. While Colorado passed a broader set of regulations in February 2015 dealing not just with edible products but also other medical marijuana infused products.

In Nevada's case, regulations were codified in April 2014 in which considerable focus was placed on all facets of medical marijuana product creation, including[14]:

- definitions of potentially hazardous medical marijuana products and ingredients;

[12] The Denver Post, December 26, 2014
[13] www.nbcnews.com, August 19, 2015
[14] Excerpts taken from Nevada Administrative Code 453A, Sections 550-626.

- designation of a "person in charge" having demonstrable knowledge of disease prevention and compliance with all of the requirements of NAC 550 et seq.;
- hand washing and hygiene requirements;
- approved sources of non-marijuana ingredients;
- methods for preventing contamination;
- requirements for preparing, cooking and cooling medical marijuana products;
- materials used in construction of utensils and contact surfaces of equipment;
- ventilation hood systems and devices;
- temperature of hot water sanitizing rinse; chemical sanitizers;
- cooking and baking equipment and microwave ovens: cleaning frequency;
- light intensity;
- mechanical ventilation;
- filters used to manufacture, process or package medical marijuana products;
- authorized methods, equipment, solvents, gases and mediums;
- minimum good manufacturing practices;
- physical facilities requirements, including lighting, ventilation and filtration, potable water and drains;
- requirements for components, product containers and closures.

Additionally, Nevada tacks on rigorous testing of all medical marijuana related products via state licensed independent laboratories (better described in Section 3.2.1(b) Laboratory Testing).

The rules regulating edibles and other infused products in Washington were issued in June 2014 on an emergency basis by the State Liquor Control Board. They were promulgated due to worries about children ingesting candy like products and individuals ingesting too much cannabis from their edibles.

Among the many new requirements placed on product manufacturers, the most prominent was that, "A medical marijuana processor licensee must obtain approval from the liquor control board for all medical marijuana-infused products, labeling, and packaging prior to offering these items for sale to a medical marijuana retailer. The medical marijuana processor licensee must submit a picture of the product, labeling, and packaging to the liquor control board for approval." [15]

Washington also passed comprehensive requirements limiting solid form products to individual servings and specific serving sizes (and related prominent product labeling). The rules also require that all "Marijuana-infused products must be homogenized to ensure uniform disbursement of cannabinoids throughout the product."[16] Additionally, the Liquor Control Board placed greater scrutiny on inspections relating to MIPs, as follows:

> "A marijuana processor producing a marijuana-infused solid or liquid product meant to be ingested orally in a processing facility as required in WAC 314-55-015(10) must pass a processing facility inspection. Ongoing annual processing facility compliance inspections may be required. The liquor board will contract with the department of agriculture to conduct required processing facility inspections. All costs of inspections are borne by the licensee and the hourly rate for inspection is sixty dollars. A licensee must allow the liquor control board or their designee to conduct physical visits and inspect the processing facility, recipes and required records per WAC 314-55-087 during normal business hours without advance notice."

[15] WAC 314-55-077
[16] WAC 314-55-077

In Colorado, new definitions and rules were developed regarding the various products to be regulated and controlled including:

"Medical Marijuana Concentrate" means a specific subset of Medical Marijuana that was produced by extracting cannabinoids from Medical Marijuana. Categories of Medical Marijuana Concentrate include Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate and Solvent-Based Medical Marijuana Concentrate. (Code of Colorado Regulations, 1 CCR 212-1 (M-103).

"Medical Marijuana-Infused Product" means a product infused with Medical Marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures. Such products shall not be considered a food or drug for purposes of the "Colorado Food and Drug Act," part 4 of Article 5 of Title 25, C.R.S. (Code of Colorado Regulations, 1 CCR 212-1 (M-103).

For each licensed facility producing these products, each owner is required to take food safety courses. Specific rules are outlined for each of the various products. An example is solvent based medical marijuana concentrates are expected to be produced, the licensee must obtain a report from an industrial hygienist or professional engineer that certifies all equipment used and that all standard operating procedures are compliant. The report (if applicable) must also include flammable solvent determinations and exhaust system determinations. Selected Colorado regulations (including lab testing) is included in this report as **Appendix I**.

Most of the other states reviewed have adopted some level of oversight of MIPs and related products. This includes Alaska which also requires a marijuana product facility license in order to extract medical marijuana concentrate for sale, or formulate or manufacture any medical marijuana product for sale. (3. A.A.C. 306.500). additionally, any licensed medical marijuana concentrate or product manufacturer must receive board approval prior to manufacturing or selling any product it's seeking to manufacture or produce. (3 A.A.C. 306.525). Alaska also places potency limits on manufactured medical marijuana products and concentrates. (3 A.A.C. 560).

Of note, New Jersey only allows children (qualifying patients) to consume a very limited selection of edible products, and in a strictly controlled fashion.

While in Connecticut, the types of MIPs allowed are very limited. "In general, the edible products have to be baked items, and the market demand is largely for cookies, brownies, and granola. Confections (candies) are banned, as the concern is that their appeal to children is too great, and thus presents a risk."[17]

"The edible products are placed in heat sealed, opaque bags, complete with childproof packaging. The packages are clearly labeled with details about THC potency, a product description, ingredient list, and state required drug codes. The packaging can also contain the logo of the company—the size of which is state regulated."[18]

Medical marijuana industry demographics are shifting considerably from predominantly selling usable or leaf based medical marijuana to manufactured products. In fact, states like Minnesota, New York, and likely Pennsylvania (when it enables medical marijuana) are outright banning smoking of medical marijuana. The shift

[17] Brookings.edu, 420 Series. April 24, 2105.
[18] Brookings.edu, 420 Series. April 24, 2015.

in the method of consumption has made the need for comprehensive controls regarding the potency and safety of non-smokable products even more crucial.

(b) Laboratory testing

Arizona's lack of requirements regarding third party testing of are shared by Rhode Island, Montana, Michigan, Maine and California. However, all of the other states studied have some form of third party testing. Exhibit 3 on the following page illustrates how the various states studied address medical marijuana testing:

Exhibit 3 - Laboratory Testing of Marijuana

State	Lab Type	Products Tested	Type of Testing
Alaska	Independent laboratory	Infused ingestibles / Extracts / Leaf	Potency / Homogeneity Contaminants
Arizona	No testing is required.	None	N/A
California	No testing is required.	None	N/A
Colorado	Independent laboratory	Infused ingestibles / Extracts / Leaf	Potency / Homogeneity Contaminants
Connecticut	Independent laboratory	Leaf	Homogeneity Contaminants
District of Columbia	Independent laboratory	Infused ingestibles / Extracts Leaf	Required testing is undefined.
Delaware	Independent laboratory State laboratory	Infused ingestibles / Extracts Leaf	DHHS may select a random sample during an inspection and test for potency and homogeneity.
Hawaii	Independent laboratory	Infused ingestibles /Extracts / Leaf	Potency / Contaminants DOH may establish provisions
Illinois	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency /Homogeneity Contaminants
Massachusetts	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency /Homogeneity Contaminants
Maryland	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency / Homogeneity Contaminants
Maine	No testing is required. *	None	Type of testing is undefined
Michigan	No testing required.	None	None
Minnesota	Independent laboratory	Extracts	Potency/ Homogeneity Contaminants
Montana	No testing is required.	None	None
New Hampshire	Independent laboratory	Extracts / Leaf	Potency / Contaminants
New Jersey	State laboratory	Infused ingestibles / Extracts Leaf	Potency / Homogeneity Contaminants
New Mexico	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency / Homogeneity Contaminants
Nevada	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency / Homogeneity Contaminants
New York	Independent laboratory State laboratory	Extracts / Leaf	Potency / Homogeneity Contaminants
Oregon	Independent laboratory or Internal Lab if certified compliant	Leaf	Potency / Homogeneity Contaminants
Rhode Island	No testing is required	None	None
Vermont	Independent laboratory	Infused ingestibles /Extracts Leaf	Potency /Homogeneity Contaminants
Washington	Independent laboratory	Infused ingestibles / Extracts Leaf	Potency / Homogeneity Contaminants

*The Maine Department of Health and Human Services, Division of Licensing and Regulatory Services reserves the right to obtain, possess and perform laboratory testing on medical marijuana. (10-144 CMR Ch. 122 R 2.14)

Oregon requires batch testing of usable medical marijuana either via third party laboratory or a Dispensary's internal laboratory. In either case, the veracity of the testing must be attested by a laboratory official regarding the accuracy, and include the levels of pesticides, mold, mildew, THC and CBD. Additionally, if pre-packaged medical marijuana is received from another Dispensary, in lieu of testing, the receiving Dispensary must obtain testing results from the originating Dispensary (OHA 333-008-1190).

In New Mexico, all dried medical marijuana and all concentrated medical marijuana derived products must be tested by an approved laboratory, prior to sale or distribution. The forms of testing required are microbiological, mycotoxin, solvent residue, heavy metals, and quantities of THC and CBD (NMAC 7.34.4.9).

New York requires that all medical marijuana products be examined by a laboratory licensed by the DEA as well as by the New York Department of Health. The testing must be for the following analytes: E.coli, Klebsiella, Pseudomonas (for vaporized products), Salmonella, Streptococcus, Bile tolerant gram negative bacteria, Aspergillus, Mucor species, Penicillum species, Thermophilic Actinomycetes species, Aflatoxin, Antimony, Arsenic, Cadmium, Chromium, Copper, Lead, Nickel, Zinc, Mercury (PHL Section 3369-a, Title 10, Ch. XIII, Part 1004.14).

New Jersey worked carefully to construct rigorous medical marijuana testing requirements, initially seeking input from several other state agencies, "to develop marijuana sampling and testing protocols that ensure compliance with labeling standards and the quality of the product."[19]

New Jersey, using the knowledge gleaned from other states, then added additional product sampling and testing protocols as follows:

> "The PHEL (the Department's Public Health Environmental Laboratory) worked with the Department of Agriculture to develop protocols related to testing for molds and pesticides. The MMP sampling and testing process was developed after researching medical marijuana testing protocols in the United States, Canada, and Europe. Product testing is necessary to establish cannabinoid profiles and screen the product for mold and other contaminants that can be dangerous for qualifying patients with compromised immune systems. The PHEL has developed a testing protocol for the detection of pesticides. Additionally, ATCs have provided the MMP with certification that no chemical pesticides are used in the cultivation of medicinal marijuana.
>
> As of December 31, 2014, the MMP has conducted laboratory testing on 36 distinct strains of medicinal marijuana cultivated by operating ATCs."[20]

Nevada, Maryland and Colorado each require that independent labs test for both potency and homogeneity testing.[21] In all three states, the labs used must be licensed and certified by the state.

In the case of Colorado, the testing labs are licensed to conduct research and analyze all forms of medical marijuana including MIPs and concentrates relating to contaminants and potency. (1 CCR 212-1 M-103). The

[19] The Department of Health Medicinal Marijuana Program 2014 Annual Report (New Jersey).
[20] Ibid.
[21] NRS Ch. 453A, 368 (NV); COMAR 10.62.10 (MD); 1 CCR 212-1 M703 (CO).

testing these certified labs may conduct include testing for microbials, residual solvents, chemical contaminants, biological contaminants; and THC and other cannabinoid potency.

Prior to initiating any testing, each licensed laboratory in Colorado must go through a testing facility certification program administered by the Marijuana Enforcement Division (MED). This includes on-site inspections, successful participation in proficiency testing, and exceeding education and experience thresholds.

Colorado actively tracks the results of testing and publishes the results:

> "In May 2014, MED implemented required potency testing for retail marijuana products to ensure retail marijuana products did not contain more than 100 mg of THC in one unit of edibles. During 2014, licensees reported into METRC™ 3,893 potency test results. Retail marijuana testing facilities reported into METRC™ 72 failed tests for a pass rate of 98.2 percent.
>
> In July 2014, MED implemented additional required testing to ensure that THC infused into retail marijuana products was homogenous throughout the unit of retail marijuana product for sale to a consumer. During 2014, licensees reported into METRC™ 2,261 homogeneity tests. Retail marijuana testing facilities reported in METRC™ 18 failed test for a pass rate of 99.2 percent."[22]

In the cases of Colorado and Nevada, licensed marijuana testing facilities must incorporate all test results into inventory tracking systems (and in Colorado's case, the state operated METRC™ system, as better described later in this document in Section 3.2.1(c) Inventory reporting and related tracking).

(c) Inventory reporting and tracking

As described in Section 2.1.4 (c), Arizona has detailed rules and requirements regarding tracking of inventory by licensed Dispensaries including mandatory record keeping requirements for wholesale and retail transactions, and the transportation of medical marijuana. However, those records are not uploaded to ADHS on a real time basis. They are maintained by the licensee at their place of business, subject to periodic review by ADHS.

Many of the states studied have similar requirements involving internal tracking of inventory and related record keeping. As in Arizona, they also have periodic requirements to undertake some form of internal audit or financial review. These include New Jersey, Vermont, Alaska, New Mexico, Connecticut, and Maryland.

Currently, inventory control requirements in California and Michigan are left to municipal or county determination. However, passage of legislation in California in September 2015 the subsequent rulemaking planned for 2016 will require a comprehensive state operated centralized inventory control system. This system is anticipated to encompass all licensed cultivation facilities, transportation agents, testing labs and Dispensaries. Michigan similarly is considering adoption of legislation that would establish a statewide licensing scheme for dispensaries and cultivators and establish a broad compliance infrastructure including introduction of an inventory tracking system.

Until very recently, Hawaii's laws did not contemplate licensed Dispensaries. All cultivation currently occurs solely at the designated caregiver/qualifying patient level. However, in July of 2015, legislation was enacted establishing a robust regulatory framework including licensed Dispensaries as well as the creation of a state run

[22] Colorado Department of Revenue, Enforcement Division – Marijuana, February 27, 2015 Annual Update

centralized seed to sale tracking system. An interim set of regulations governing this legislation was approved in December 2015 and shall require all licensees to electronically track all wholesale and retail transactions via a state run centralized inventory tracking system.

A number of states layer on additional inventory tracking requirements including such things as seed to sale tracking, use of radio frequency identification to track plants, and real-time centralized (state run) closed loop inventory tracking.

In Massachusetts, licensees are required to implement a comprehensive inventory tracking system which meets the following requirements (105 CMR 725.105):

(1) A Dispensary must limit its inventory of seeds, plants, and usable medical marijuana to reflect the projected needs of registered qualifying patients;

(2) Real-time inventory shall be maintained as specified by the Department and, including, at a minimum, an inventory of medical marijuana plants; medical marijuana plant-clones in any phase of development such as propagation, vegetation, and flowering; medical marijuana ready for dispensing; all MIPs; and all damaged, defective, expired, or contaminated medical marijuana and MIPs awaiting disposal.

(3) A Dispensary shall: (a) Establish inventory controls and procedures for the conduct of inventory reviews, and comprehensive inventories of medical marijuana and MIPs in the process of cultivation, and finished, stored medical marijuana; (b) Conduct a monthly inventory of medical marijuana in the process of cultivation and finished, stored medical marijuana; (c) Conduct a comprehensive annual inventory at least once every year after the date of the previous comprehensive inventory; and (d) Promptly transcribe inventories if taken by use of an oral recording device.

(4) The record of each inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the names, signatures, and titles of the individuals who conducted the inventory.

(5) A Dispensary shall tag and track all medical marijuana seeds, plants, and products, using a seed-to-sale methodology.

In Nevada, Illinois, Washington, New York, Hawaii and Colorado, systems are in place or under development in which closed loop centralized inventory tracking occurs and is managed directly by the state oversight agency.

Colorado uses the Medical Marijuana Enforcement Tracking Reporting Compliance or "METRC™" system. This system was developed in conjunction with a third party vendor and is operated by the Marijuana Enforcement Division (MED). All commercial licensees handling marijuana are required to register with the METRC™ system and all marijuana is tracked using RFID technology. The system is intended to track medical marijuana from the seed or immature plant stage until the Medical Marijuana or Medical Marijuana Infused-Product is sold to a customer at a Medical Marijuana Center or is destroyed. Some highlights of the system are as follows[23]:

- creates a vertically integrated "closed-loop" medical marijuana regulatory scheme which stems, in

[23] www.metrc.com

part, from the landmark 2005 California case, Gonzales vs. Raich (If you can demonstrate a closed loop, in which no marijuana crosses state borders, it strengthens against federal intervention);

- by the use of RFID (Radio Frequency Identification) technology combined with serialized item tracking, the system creates an "end to end" surveillance system where the municipality has real-time visibility at any given time into the "inventory" at all the locations (does not rely on audits for tracking);
- central control of security through RFID secure tag ID;
- captures perpetual inventory quantities for each entity;
- provides an inspection process with the tools necessary to complete onsite validation of inventory with audit capability and anti-piracy safeguards;
- supports the auditing process from a series of exception reports;
- the system maintains a secure reporting environment for each industry participant. Each participant can access their own data but no other participants' data. The regulator has access to all industry participants' data;
- the system provides for a real time digital transport manifest giving access to law enforcement enabling them to quickly discover illegal activity during transportation;
- tracks transfers between licensed premises;
- allows regulatory users to view all licensee activities captured in the system;
- creates audit trails and tools for assessing risk and channeling resources more efficiently (e.g. system notifications and reporting);
- creates an industry database of analytical information to establish trends and benchmarks for marijuana production;
- allows criminal investigators to streamline field enforcement and compliance activities associated with licensees;
- provides aggregate data regarding cultivation, production, transportation and sales of marijuana within the regulated model.

Medical marijuana businesses in Colorado are required to attend and complete training on the system (1 CCR 212-1 M-103). Additionally, medical marijuana businesses in Colorado are required to use the Inventory Tracking System as the primary inventory tracking system of record (1 CCR 212-1 M-309).

Washington also employs "seed to sale" inventory tracking, through a data management system run by the state. The difference with Colorado's system is that the Washington inventory tracking system is not mandatory. The Washington State Liquor and Cannabis Board ("WSLCB") partnered with a third party to implement a software program to track marijuana through the supply chain. However, licensed marijuana producers, processors, and retailers are not required to utilize the state system and may utilize their own inventory tracking software solutions. The only requirement for licensees is that the licensee's system allow for the collection and submission of the specific information and reports required by the WSLCB's seed-to-sale inventory tracking rules for licensees. Furthermore, licensees are required to submit specific information and reports to the Board. To ensure compliance with Washington State regulations, each licensee's system must provide functionality to assist with the analysis of information, auditing operations, and enforcement by the WSLCB.

The rules in Nevada relating to inventory tracking at the Dispensary level are comprehensive and similar to those in Arizona and elsewhere. Although not expressly defined as a requirement in Nevada's rules, the State Division of Public and Behavioral Health is actively seeking 3rd party support in developing a closed loop inventory tracking and patient registry data management system. Judging by the RFP, the state run system will likely require all dispensaries (and registrants) to input all medical marijuana related transactions, on a real time basis. This

system is likely to be implemented during late 2016 (pursuant to an RFP issued by the Division in the summer of 2015.)

(d) Patient registry

In addition to Arizona, every state studied has some form of patient registry, in some instances voluntary (California, Washington and Maine). All of the states studied (as in Arizona) use some form of patient registry managed by the agency having oversight over medical marijuana compliance.

Connecticut is unique in that it has, at a state level, rescheduled marijuana from a Schedule 1 to a Schedule 2 controlled substance. This action in effect causes marijuana to be treated very similarly to any other regularly prescribed Schedule 2-5 substance. And for the purposes of this Section, allows medical marijuana prescriptions to be tracked via the state prescription monitoring and reporting program, a statewide database updated weekly containing all patient level prescription drug related transactions.

All of the other states (including Arizona) have patient registries that are separate from each respective state's prescription drug monitoring programs. (In Arizona's case, the ASBP does provide confirmation that recommending physicians have accessed the Arizona's PMP in order to review a prospective patients' prior prescription drug usage history.)

Several other states actively include recommending physicians in the registry process, including requiring the physician to be a certified registrant. (In Arizona, recommending physicians do not get certified by ADHS, nor do physicians register with the system, other than to confirm a qualifying patient recommendation request and enter the request into the system run by ASBP.)

New York restricts physician recommendations unless and until the recommending physician has applied to the department for a registration to issue qualifying patient certifications and has completed a four-hour course approved by the department. "The educational content of the course shall include: the pharmacology of marihuana; contraindications; side effects; adverse reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; abuse and dependence; and such other components as determined by the commissioner." (PHL Section 3369-a, Title 10, Chapter XIII, Part 1004.1)

In Maryland, all certifying physicians are required to submit an annual report including:

(1) The number of qualifying patients issued written certification by the certifying physician categorized by gender and by county of residence or Baltimore City;
(2) The medical conditions for which certification was issued;
(3) A summary of the clinical outcomes of the qualifying patients' use of medical marijuana by age, gender and other relevant criteria as specified by the Commission;

The patient registry in New Jersey actively tracks qualifying physician statistics and publishes regular information regarding which physicians are certified to issue recommendations and for what types of qualifying conditions. "(s)ince inception of the program, 371 physicians have registered with the program; of those physicians registered, 325 are active, 42 requested to be inactivated, and four were disapproved. From January 1, 2014 through December 31, 2014, 77 new physicians registered with the program. Of active physicians, 70 percent are currently authorizing qualifying patients for the program. All registered physicians are listed on the MMP

website. Patients may ask their primary physician to register with the MMP or they may locate a participating physician on the website by count and/or medical specialty." (DOH 2014 Annual Report).

"Participating physicians must hold an active New Jersey medical license in good standing issued by the NJ Board of Medical Examiners, possess an active dangerous substances registration issued by the NJ Division of Consumer Affairs that is not subject to limitation, and practice within the State of New Jersey." (DOH 2014 Annual Report)

In Delaware, a written certification shall be made only in the course of a bona fide physician-patient relationship where the qualifying patient is under the physician's care for her or his primary care or for her or his debilitating medical condition after the physician has completed an assessment of the qualifying patient's medical history and current medical condition. The bona fide physician-patient relationship may not be limited to authorization for the qualifying patient to use medical marijuana or consultation for that purpose. The written certification shall specify the qualifying patient's debilitating medical condition (78 Del. Laws, c. 23, §1).

Illinois has a very robust and inclusive patient registry, involving multiple state agencies having interest in medical marijuana compliance. Their registry, "is a web-based system established and maintained by the Department of Public Health that is available to the Department of Agriculture, the Department of Financial and Professional Regulation, law enforcement personnel, and registered medical cannabis dispensing organization agents on a 24-hour basis for the verification of registry identification cards, the tracking of delivery of medical cannabis to medical cannabis dispensing organizations, and the tracking of the date of sale, amount, and price of medical cannabis purchased by a registered qualifying patient." (410 ILCS 130/10(x)).

Of particular interest in comparing Arizona's registry to Illinois' is the access law enforcement has in Illinois. Law enforcement's confirmation of an individual's registration with the medical cannabis program is integrated through the Illinois Secretary of State database system for all residents. If a medical marijuana cardholder is pulled over by state or local law enforcement, they can run the qualifying patient's driver's license through the Secretary of State database (for valid registration, warrants, etc.), and that search (by using name/DOB/driver's license number, etc.) would indicate that the qualifying patient is an active cardholder (even if the qualifying patient doesn't have his/her card). That information is not otherwise available to law enforcement (i.e. in theory state police can't do a wholesale search for a comprehensive list of every medical marijuana cardholder in the state).

It should be noted that many of the states' offering medical marijuana are struggling with physician participation, which in turn has severely limited qualifying patient access. In certain states (including Minnesota and Illinois) there are requirements that a physician and qualifying patient have an established relationship with a qualifying patient prior to issuing a certification. In many cases this has been problematic for qualifying patients seeking authorization to obtain a medical marijuana card when their long term physician chooses not to participate in a medical marijuana program. For many physicians, the decision not to participate in the program may be driven by a corporate policy, rather than a philosophical objection.

(e) Use of medical marijuana program proceeds

The majority of agencies studied apply all proceeds generated to cover their respective medical marijuana program costs and expenses. In many states, this includes costs for state run centralized inventory tracking systems, more robust qualifying patient registries, more comprehensive inspections (including financial reviews and due diligence related to all licensees and participants) and additional staffing.

(f) Wholesale medical marijuana market

The regulation and management of wholesale medical marijuana cultivation and personal cultivation is handled in wide variety of ways, depending upon the state. Unlike Arizona, where personal cultivation is allowed under certain circumstances, as well as wholesale donations of medical marijuana to qualifying patients, a number of states have a flat prohibition on personal cultivation. They include Connecticut, Delaware, Illinois, Maryland, Minnesota, New Hampshire, New Jersey and New York. Massachusetts generally prohibits personal cultivation, however they may issue a cultivation registration to a qualifying patient whose access to a medical treatment center is limited by verified financial hardship, a physical incapacity to access reasonable transportation, or the lack of a treatment center within a reasonable distance of the qualifying patient's residence.

Other states have much less restrictive policies than Arizona's. In Maine, a state having roughly 1/5 the population of Arizona, in 2014 there were 4,550 designated caregivers (roughly 8 times greater than Arizona).[24] In each instance, the designated caregivers may cultivate medical marijuana and provide medical marijuana (for compensation) to up to 5 qualifying patients (10 CMR 122 R 5.8.3). Maine also allows collectives, in which groups of designated caregivers cultivate and provide medical marijuana to qualifying patients for reasonable monetary consideration, without going through a similar level of compliance scrutiny placed on licensed dispensaries in the state. Each designated caregiver may possess up to 8 pounds of marijuana per qualifying patient (10 CMR 122 R 5.8.1.2.1) additionally, qualifying patients may grow up to 6 mature plants each (10 CMR 122 R 4.9.1). None of the transactions between designated caregivers and qualifying patients are captured in Maine's patient registry.

In 2014 Michigan, reported 22,966 designated caregivers[25] each of whom may grow up to 12 medical marijuana plants per qualifying patient and assist as many as 5 qualifying patients (MMA R333.103 Rule 3). As in Maine, designated caregivers may charge qualifying patients for services and expenses, and none of the transactions are recorded in a patient registry. A qualifying patient who does not elect a designated caregiver, may grow up to 12 medical marijuana plants (MMA R333.103 Rule 3).[26]

Certain states also limit the amounts of medical marijuana that licensed Dispensaries may acquire from other licensed dispensaries/cultivators. In Colorado, pursuant to section 12-43.3-402(4), C.R.S., a medical marijuana center may purchase not more than thirty percent of its total on-hand medical marijuana inventory from another licensed medical marijuana center. A medical marijuana center may sell no more than thirty percent of its total on-hand medical marijuana inventory to another medical marijuana center. Colorado also has in place its

[24] Maine 2014 MMMP Annual Report, Page 11.
[25] Michigan 2014 MMMP Annual Report, Page 6.

[26] The Michigan legislature is considering new legislation which will (if passed as expected) allow for licensing of commercial cultivators and create a centralized data base and patient registry, managed by the state oversight agency. The centralized data base is expected to track, on a real-time basis, all wholesale medical marijuana transactions and it's anticipated that these reforms would significantly impact the level of designated caregivers and patient cultivation.

"METRC™" system, a seed to sale closed loop tracking system, run by the Marijuana Enforcement Division, which tracks all wholesale medical marijuana transactions between Dispensaries/cultivators on a real time basis.

In addition to Massachusetts' prohibition on qualifying patient cultivation and/or designated caregiver cultivation, limits are placed on the amount of wholesale medical marijuana one Dispensary may acquire from another Dispensary. Dispensaries may not acquire medical marijuana from another Dispensary unless there's (a) a documented emergency (act of God situation) and approval is given by the oversight agency, or (b) a specific qualifying patient's needs cannot be otherwise met by the Dispensary. In either event, no more than 30% of the Dispensary's total annual medical marijuana inventory may be from other dispensaries.

In meeting with the various agencies referenced in this section, a common theme emerges. The states placing controls on wholesale cultivation and/or qualifying patient/designated caregiver cultivation typically have more rigorous data management systems and information reporting requirements in place. The states allowing more liberal forms of cultivation generally struggle with diversion issues, quality assurance oversight, as well as gaps in enforcement protocols. Arizona falls in the middle in terms of controls and regulation of the wholesale medical marijuana market.

(g) Inspections, surveys and financial audits

Exhibit 4 illustrates at a high level how the various states address inspections of medical marijuana Dispensaries. Of note, a number of states go beyond current ADHS policy on inspections by engaging in periodic financial audits as well as inspecting processes relating to extract and concentrate production.

Exhibit 4 - Inspection Requirements

State	Inspections Required	Notice Requirements	Frequency	Enforcement Authority
Alaska	Financial audit Kitchen/extraction review	None	Not defined by statute.	MJ Control Board
Arizona	Kitchen and facility	5 days*	2X per year	ADHS
California	Beginning in 2016, oversight will be transferred to the state.	N/A	N/A	N/A
Colorado	Financial audit Kitchen/extraction review	None	Not defined by statute.	DOR/MED
Connecticut	Kitchen/extraction review; law does not define other required inspections.	None	Not defined by statute.	DCP
District of Columbia	Financial audit DOH may request data from patients and caregivers.	None	Not defined by statute.	DOH
Delaware	Facility Financial Records	None	Not defined by statute.	DHS – Office of MMJ
Hawaii	Financial audit Kitchen/extraction review	None	At least annually	DOH
Illinois	Kitchen/extraction reviews conducted at cultivation facilities. Other required inspections remain undefined by statute.	None	Not defined by statute.	DOH – State Police
Massachusetts	Financial audit Kitchen/extraction review	None	Not less than once per year.	DPH
Maryland	Financial audit Kitchen/extraction review	None	Not defined by statute.	DHMH
Maine	Facility	None	Not defined by statute.	DHHS
Michigan	State police conduct inspections in response to citizen complaints.	N/A	N/A	Oversight is at the county level.
Minnesota	Financial audit Kitchen/extraction review	None	Defined as "reasonable".	DOH
Montana	Not defined by statute.	N/A	N/A	PHHS
New Hampshire	Not defined by statute.	None	Random	DHHS
New Jersey	Financial audit Kitchen/extraction review	None	Not defined by statute.	DHSS
New Mexico	Financial audit Kitchen/extraction review	None	Not defined by statute.	DOH
Nevada	Financial audit Kitchen/extraction review	None	At least annually	DOH
New York	Financial audit Kitchen/extraction review	None	Not defined by statute.	DOH
Oregon	Kitchen/extraction review	None	6 mos./1 per year	OHA
Rhode Island	Not defined by statute.	N/A	N/A	N/A
Vermont	Financial audit Kitchen/extraction review	None	Not defined by statute.	DPS
Washington	Kitchen/extraction review; additional rulemaking in development.	None	Defined as "reasonable".	LCB & law enforcement

*In the event of complaints, the notice requirement is two days.

Many states do unannounced inspections, including Nevada, where "the Division may enter and inspect any building or premises at any time, with or without notice, to: secure compliance with any provision of this chapter, prevent a violation of any provision of this chapter, or conduct an unannounced inspection…in response to an allegation of non-compliance." (NAC 453A.322)

In New Hampshire, "For the purposes of determining compliance……The ATC shall admit and allow any authorized department representative at any time to inspect the facility." (He-C 402.28)

Similarly, New Mexico's regulations state that on site assessments to determine compliance may occur "at any time to assess or monitor". (NM 7.34.4.23).

Massachusetts takes one further step by giving its Department of Public Health authority to conduct unannounced inspections AND require Dispensaries during inspections to test medical marijuana on site for contaminants, "including but not limited to, mold, mildew, heavy metals, plant-growth regulators, and the presence of organic pesticides." (MA 725.300(A-E).

Maryland applies a similar process as Massachusetts with unannounced inspections including the ability to enter any place, including vehicles, "in which medical marijuana is held, dispensed, sold, produced, delivered, transported, manufactured, or otherwise disposed of" (MD 10.62.63(.04)). Additionally, inspectors reserve the right to obtain samples for "testing of any medical marijuana, medical marijuana concentrate, medical marijuana infused product, media used to grow medical marijuana, chemicals or solvents used to process medical marijuana concentrate, any labels or containers for medical marijuana, paraphernalia, any waste material, and of any raw or processed material." (MD 10.62.63(.05)).

Continuing with Maryland, should an inspection result in actionable issue(s), considerable enforcement tools are given to the inspector as follows[27]:

1. In the event that an inspector has reasonable suspicion of an operational failure or of conditions that create a likelihood of diversion, contamination, or a risk to the public health:

   A. An inspector may:

   (1) Suspend the distribution of some or all medical marijuana from the licensed premises;

   (2) Order immediate evacuation of the premises and seal the entry door; or

   (3) Quarantine some or all medical marijuana.

   B. The Commission shall undertake a review of the inspection findings and may:
   (1) Request a recall of the medical marijuana;

   (2) Request independent testing of affected medical marijuana;

[27] MD 10.62.23(.06)

(3) Approve a procedure to reprocess the medical marijuana;

(4) Notify the Maryland State Police if diversion is suspected; or

(5) Order the destruction of contaminated or substandard medical marijuana.

Colorado takes an inter-agency approach in addressing inspections. The State Licensing Authority, including the Marijuana Enforcement Division has authority to direct that independent consultants conduct health and sanitary audits (1CCR 212-1 R M407) when necessary, as well as independent financial audits, as appropriate (1CCR 212-1 R M903). In both instances, the costs for these audits are borne by the Dispensary.

Independent financial audits are triggered typically when: (1) a Dispensary does not provide requested records; (2) the Division has reason to believe that the Dispensary has properly maintained its records; (3) the Dispensary has a prior violation related to record keeping; and (4) the Dispensary has a prior violation related to diversion (1 CCR 212-1 R M903).

Licensees also can expect local inspection requirements from fire, building inspectors, or code enforcement officers to confirm that no health or safety concerns exist (1 CCR 212-1 R M407).

The City of Denver provides a good example of local inspections in Colorado. In Denver, there are 1019 marijuana related licenses involving 451 unique locations (including both recreational use and medical marijuana). Five city agencies are involved with the inspections process relating to dispensaries including: Excises and Licenses, Fire, Public Safety, Environmental Health, and Building Safety.

In the case of the Department of Excises, inspections occur at least annually at each of the unique locations, with an emphasis on:

- floor plan review
- security plan to include cameras
- proximity measurements
- the zoning use

The Department utilizes a unique checklist for each type of license, each including the following common criteria:

- confirmation of building diagram (floor plan) being the same as the one submitted for the initial license;
- Review of the security camera locations and the DVR lockbox;
- overall security protocols to include security guards;
- confirm that all employees are wearing Marijuana Enforcement Division issued badges.

No notice is given for inspections of any license type and unfettered access is required by law. When use of illegal contaminants or pesticides is suspected, the Environmental Health Department is notified.

(h) Enforcement options and tools

Regarding enforcement tools in instances of Dispensary misconduct, ADHS has license revocation authority (See Section 2.1.4(h)). But ADHS is somewhat limited in terms of penalty authority for actions falling short of license

revocation. The Department has implemented a "provider meetings" process which allows for heightened scrutiny on Dispensaries with repeat offenses. However, ADHS enforcement authority remains somewhat limited in comparison to other states.

The following is a sampling of what other forms of enforcement tools are available in certain states above and beyond ADHS' current enforcement authority.

In New Hampshire, the Department of Health and Human Services, depending upon the type of misconduct, may: (1) suspend all or a portion of operations; (2) impose administrative fines; (3) deny an application for a Dispensary registration; or (4) revoke a license (He-C 402.30 (NH)). In terms of impositions of fines, the Department may elect the following[28]:

- $2000 for violating advertising restrictions;
- $1000 for failure to timely submit a license renewal application;
- $2000 per instance, in the event of use or possession of certain prohibited chemicals;
- $2000 per day for failure to notice the Department of a change of location;
- $3000 for exceeding inventory capacity;
- $5000 per offense for providing false or misleading information to the Department;
- $10,000 for failure to allow access by the Department to a Dispensary;
- $1000 for employing personnel who do not meet qualifications for a positon;
- $3000 for engaging an employee who has a felony conviction;
- $1000 for making false or misleading statements to the public;
- $5000 for failure to maintain effective controls against diversion, theft or loss of marijuana;
- $5000 for failure to keep accurate records of all marijuana dispensed to qualifying patients, or designated caregivers, transported or disposed of;
- up to $10,000 in the event of violations determined to jeopardize the health, safety, or well-being of a qualifying patient, designated caregiver, dispensary agent, or the public.

Alaska has authority, in certain instances, to suspend licenses, short of revocation or issue civil fines (Alaska: 3 AAC 306.810).

In Oregon, the Health Authority, Public Health Division, may assess civil fines of up to $500 per incident, per day (ORS 431.262; 333-008-1270), in addition to having authority to revoke licenses.

New Mexico's Department of Health has the authority to issue fines of up to $1000 per penalty, as well as suspend or revoke Dispensary licenses (NMAC 7.34.4.24).

Colorado's Marijuana Enforcement Division has a wide variety of enforcement options including:

- suspension of licenses (1 CCR 212-1 M 1303);
- issuing administrative holds on sales of medical marijuana products ((1 CCR 212-1 M 1202);
- issuing fines of up to $100,000 for public safety violations (1 CCR 212-1 M 1307);
- issuing fines of up to $50,000 for license violations (1 CCR 212-1 M 1307);

[28] He-C 402.30 (NH). The list of fines described herein is not inclusive of all fines the Department of Health and Human Services may impose.

- fines of up to $10,000 for license infractions (1 CCR 212-1 M 1307);
- as well as the option to revoke licenses in each of the instances referenced above, depending upon various factors.

Additionally, Colorado's Marijuana Enforcement Division inspectors have the authority of any peace officer to (among other things), make arrests (with or without warrants), serve warrants, summonses, subpoenas, administrative citations or notices, require inspections, and assist or aid any law enforcement officer in the performance of his or her duties (1 CCR 212-1 M 1201).

(i) Medical marijuana packaging, labeling, and child proofing

Arizona has fairly rigorous requirements relating to packaging and labeling of medical marijuana products. However, a number of states have implemented more comprehensive standards, particularly relating to information about MIPs, concentrates and extracts, the results of lab testing and potency and additional rigor regarding childproofing.

Here is a general sampling of what some states are doing above and beyond Arizona's packaging and labeling requirements:

- In Colorado, Oregon and elsewhere, all medical marijuana packages must be opaque so that the product cannot be seen without opening the packaging material.
- Connecticut requires that any product containing medical marijuana shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1 (b) (4). Also in Connecticut (and several other states) all packaging must list the levels of THC and CBD (a potency statement).
- Alaska's rules stipulate that all packaging state, "Marijuana should not be used by women who are pregnant or breast feeding."
- Qualifying patient focused messaging on recommended dosing and instructions on administering the individual product must be placed on all packages in New York State.

- In Oregon (and elsewhere) all medical marijuana products must be packaged in a manner that's not attractive to minors. In other words, no use of cartoons, packaging that resembles candy or soda based products, etc.
- Colorado, Connecticut, and Illinois among others, all require that results from independent laboratory testing be affixed to all products including (typically): THC and CBD levels.

Nevada's labeling rules are extensive and include variable requirements depending upon the type of medical marijuana and where the medical marijuana is getting distributed. For sales of medical marijuana at a wholesale level, the following form must be followed and includes the results of independent lab testing[29]:

[29] Nevada Administrative Code 453A.508

JT'S NURSERY
Certificate Number: 123 456 789 001 0001

Lot Number:
1234

Harvested On:
01/01/2013

Final Testing Date: 01/15/2013
Packaged On: 01/17/2013
Best if used by: March 17, 2013

16.7% THC 1.5% CBD 0.3% CBN
Myrcene 5.6 mg/g Limonene 5.1 mg/g Valencene 3.5 mg/g

Net Weight: 2 lbs

Regarding the sale of usable medical marijuana at the retail level, the required label form has added requirements, including the qualifying patient name and registry number, a warning about the effects of medical marijuana, and a reminder that the product may be unlawful outside of Nevada[30]:

Joe's Plant Emporium Cert.# 123 456 789 001 0001
Lot #: 1234 Harvested: 01/01/2013

Dispensed to: John J. Smith #1234987 on 11/27/2013
by
We Care Dispensary
123 Main Street, Carson City, NV 89701

WARNING:
This product may have intoxicating effects and may be habit forming

16.7% THC 1.5% CBD 0.3% CBN
Myrcene 5.6 mg/g Limonene 5.1 mg/g Valencene 3.5 mg/g

Net Weight: .25 ounces (7grams)

<u>This product may be unlawful outside the State of Nevada.</u>

[30] Nevada Administrative Code 453A.510

For edible products or medical marijuana infused products sold at retail locations, the front and back of the labels required for containers or packages are as detailed below and include additional information on ingredients and allergens (if any), and cautionary information on intoxicating effects and time delays[31]:

We Care Dispensary, 123 Main Street, Carson City, NV 89701

Date Dispensed: 3/27/2014 **To:** John J. Smith #1234987

Cookie
Net Weight: 6oz (168 grams)

Serving Size: 10mg THC
Contains 10 servings and a total of 100 mg of THC
Use by: 6/3/2014
Myrcene 5.6 mg/g Limonene 5.1 mg/g Valencene 3.5 mg/g

CAUTION: When eaten or swallowed the intoxicating effects of this product can be delayed 2 or more hours.

This product may be unlawful outside the State of Nevada.

Manufactured at: Joe's Kitchen **Cert.#** : 321654987101 0401
123 Main Street, Las Vegas, NV on 2/1/14

Lot#: 1234 Batch # 5463

INGREDIENTS: Flour, Butter, Canola Oil, Sugar, Chocolate, Marijuana, Strawberries

CONTAINS ALLERGENS: Milk, Wheat

Contains marijuana extract processed with butane.

WARNING: This product may have intoxicating effects and may be habit forming.

Many of the states with more comprehensive labeling provisions also require laboratory testing of medical marijuana, in order to provide more comprehensive, verifiable information on packages to qualifying patients about dosage composition. Which helps ensure patient health and public safety.

(j) Qualifying condition approvals

Arizona's process on adding or removing qualifying conditions is among the best in the nation. Most of

[31] Nevada Administrative Code 453A.512

the peer states reviewed have a process to add a qualifying condition. But few exceed the breadth and scope of Arizona's review and approval process. Here are some examples of the qualifying condition approval process in several other states:

In Alaska, the Department of Health and Social Services will consider physician or physician initiated qualifying conditions and then, within 180 days of submission, will provide a determination. (7 A.A.C. 34.200).

Maryland's La Prade Commission allows reviews of qualifying conditions to occur at least once per year if needed. These reviews are conducted via public hearing to evaluate any petition to consider other medical conditions, medical treatments, or diseases that may be treated by using medical marijuana and included in certifying physician applications. The types of petitions to be heard may include the severity of the condition and its treatment, the degree to which other treatments have been unable to alleviate pain, any supportive research or studies, and supportive documentation from the medical community.
(10.62.04)

New Jersey only allows additional qualifying conditions upon action by the state legislature.

Connecticut may have the most detailed approval process of all the states reviewed. After a layered series of evidentiary hurdles are overcome, a petition for an additional qualifying condition goes before a three-member board, which convenes at least twice per year for public hearings. The board then issues recommendations to the commissioner of the medical marijuana program, who then proceeds to adopt regulations.

In Nevada a petition requesting that a particular disease or condition be included among the diseases and conditions that qualify as chronic or debilitating medical conditions may be submitted to the Division of Public and Behavioral Health. Once received, the Division approves or denies a petition within 180 days after receiving the petition (NRS 453A.710).

Illinois residents may petition the Department of Public Health bi-annually to add debilitating medical conditions (77 IAC 946.20). Upon receiving a valid petition, the Department then convenes a Medical Cannabis Advisory Board composed of 16 members, including a cross section of medical professionals and industry stakeholders. The Advisory Board convenes at least twice per year to meet and review petitions and recommend to the Department additional debilitating conditions or diseases that would benefit from the medical use of cannabis.

Continuing with Illinois, during each meeting, a public hearing is conducted to review the petitions received. Following the meeting the Board recommends the approval or denial of each petitioner's request by submitting a written report to the Director within 60 days after conducting the public hearing. The written report includes a medical justification for the recommendation based upon the individual or collective expertise of the members of the advisory board. The medical justification shall delineate between the findings of fact made by the Advisory Board and the scientific conclusions of evidence-based medical research.

Upon review of the Advisory Board's recommendations, the Director renders a final decision regarding the acceptance or denial of the proposed debilitating medical conditions or diseases. The Department will approve or deny a petition within 180 days after its submission during the biannual petition period (77 IAC 946.30).

(k) Transferability of licenses or relocation of Dispensaries

Unlike Arizona, several other states have processes in place to allow for the transfer or assignment of Dispensaries. Typically, these states allow for profit entities to own dispensaries (unlike Arizona's requirement that a state non-profit entity own a Dispensary license).

Colorado's approval process relating to the transferability of Dispensary licenses is detailed and involves considerable advance scrutiny from the Marijuana Enforcement Division prior to approving any transfers. Some highlights of Colorado's regulations relating to license transfers are as follows[32]:

- Each applicant for a transfer of ownership shall provide suitable evidence of a person's proof of lawful presence, residence and good character and reputation that the Division may request.
- Each applicant shall also provide all requested information concerning financial and management associations and interests of other persons in the business, Department of Revenue tax payment information, proof of good and sufficient surety bond and the deed, lease, contract, or other document governing the terms and conditions of occupancy of the licensed premises.
- The Division will not approve a transfer of ownership application without first receiving written notification that the applicant disclosed the transfer of ownership to the relevant local licensing authority.
- Transfers of ownership are not allowed if the entity selling an interest is involved in an administrative investigation or administrative disciplinary action.
- If the applicant is a corporation or limited liability company, it shall submit with the application the names, mailing addresses, and owner's background forms of all of its officers, directors, and owners; a copy of its articles of incorporation or articles of organization; and evidence of its authorization to do business within Colorado. In addition, each applicant shall submit the names, mailing addresses of all persons owning any of the outstanding or issued capital stock, or of any persons holding a membership interest.
- Any proposed transfer of capital stock, regardless of the number of shares of capital stock transferred, shall be reported and approved.
- If the applicant is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, it shall submit with the application the names, mailing addresses, and owner's background forms of all of its partners and a copy of its partnership agreement.

Alaska allows for transfer of medical marijuana establishment licenses, subject to board approval in advance, and subject to certain conditions being met. (3 A.A.C. 306.045)

In Illinois, transfers or assignments of Dispensary licenses are prohibited (68 IAC 1290 R1290.120). But dispensaries may request a change of location (68 IAC 1290.120).

The requirements for organizational or service changes for dispensaries in New Hampshire are quite stringent. These include the following provisions:

- The Dispensary shall provide the department with written notice at least 30 days prior to changes in mailing address or name.

[32] 1 CCR 212-1 R M205

- In the case of a change in physical location, at least 90 days prior to the move, a Dispensary shall submit detailed information required by the Department including site plans, security protocols and local permit requirement for the new location, and a new registration certificate shall be issued by the department A Dispensary shall not open at the new location until final approval is provided by the department. The current registration certificate shall expire and a new registration certificate shall be issued for the new location by the department which shall be valid until the expiration date of the prior registration certificate.
- When there is a change in the name, the Dispensary shall submit to the department a copy of the certificate of amendment from the New Hampshire secretary of state, if applicable.
- A change of ownership of the Dispensary shall not be allowed.
- The Dispensary shall notify the department whenever there is a proposed change in corporate officers, board members, or executive employees. Additionally, the results of a federal and NH state criminal records check shall be submitted to the department for any change in corporate officers, board members, or executive employees of a Dispensary.
- The Dispensary shall inform the department in writing with 30 days advance notice or as soon as practicable when there is a change in administrator and provide the department with a resume identifying the name and qualifications of the new administrator.
- The Dispensary shall notify the department at least 90 days in advance of any renovations or new construction that alter the floor plan of the registered premises.
- An inspection by the department shall be conducted prior to operation for all renovations and new construction at the Dispensary. (He-C 402.07)

New Mexico prohibits the transfer of a license by assignment or otherwise to other persons or locations. Unless the licensed producer applies for and receives an amended license, the license shall be void and returned to the department when any one of the following situations occurs: ownership of the facility changes; location change; change in licensed producer; the discontinuance of operation; or the removal of all medical cannabis from the facility by lawful state authority. (NMAC 7.34.4.8.S)

(l) Reporting and dissemination of information

Most of the states studied use similar communications tools as those offered by ADHS. They typically have dedicated websites, offering program statistics, annual reports, rules and regulations as well as downloadable forms for things like license renewals, required processes, and FAQs.

Several states offer additional information beyond that currently provided by ADHS. A good example is New Jersey in which the names of licensed Dispensaries are listed (including the date of license approvals) as well as information on other Dispensaries seeking licensure. New Jersey also posts information identifying recommending physicians, which county they work from, and their respective medical specialty. New Jersey also offers a Customer Service Unit (CSU) for physicians, qualifying patients, designated caregivers, Dispensaries and the public. The CSU has responded to 25,091 public inquiries via telephone and e-mail. The CSU has also taken a hands-on approach with qualifying patients and designated caregivers to provide assistance through the registration process.[33]

In Maine, the Department of Health and Human Services created and implemented an online program in which statewide law enforcement receives training on issues and information relating Maine's medical marijuana

[33] The Department of Health (NJ) Medicinal Marijuana Program 2014 Annual Report.

program. Administered on behalf of the Department by the Maine Chiefs of Police Association, this training provides consistent education to law enforcement officers. The training is available 24 hours per day through an existing delivery system in use by the Maine Criminal Justice Academy.[34]

Several states require that recommending physicians' undergo annual training on the benefits and risks associated with medical marijuana. While other states publish regular information on required laboratory testing and restrictions relating to the forms and types of manufactured medical marijuana products that may be offered.

Many states require periodic reporting (as is the case in Arizona). In several instances, the data presented (specifically related to physician activities and licensing deficiencies) is more comprehensive than ADHS reports. (This is due to the confidentiality constraints placed on ADHS by A.R.S. 36-2816.)

(m) Licensing

Exhibit 5 on the following page, entitled "Licensing Renewal Requirements" seeks to portray the various fees, renewal licenses required and background scrutiny deployed in certain states. Of note, Arizona does not have a separate licensing category for testing laboratories or processing of medical marijuana products.

[34] Source DHHS Annual Report, Revised June 30, 2015.

Exhibit 5 - Licensing Renewal Requirements Table

State	Cultivation Facility Owner & Agents	Dispensary Owner & Agents	Laboratory Facility	Processor Facility
Arizona	Not applicable*	Submit fingerprints FBI background check Owner - $1,000 fee Agent - $500 fee	Not applicable	Not applicable
Colorado	Submit fingerprints FBI background check Owner - $3,000 - $11,000 fee Agent - $300 - $1,000 fee	Submit fingerprints FBI background check Owner - $3,000 - $11,000 fee Agent - $300 - $1,000 fee	$500	Submit fingerprints FBI background check $2,200 fee.
Illinois	Submit fingerprints FBI background check Owner - $100,000 fee Agent - $100 fee	Submit fingerprints FBI background check Owner - $30,000 fee Agent - $100 fee	None specified.	None specified.
Massachusetts	Submit fingerprints FBI background check Owner - $30,000 fee Agent - $500 fee	Submit fingerprints FBI background check Owner - $30,000 fee Agent - $500 fee	Testing regulations are being revised, delaying lab approvals	Submit fingerprints FBI background check $30,000 fee.
New Jersey	Submit fingerprints State background check Owner - $5,000 fee	Submit fingerprints State background check Owner - $5,000 fee	State run facility	Not Applicable
New Mexico	Submit fingerprints FBI background check Owner - $10,000 - $30,000 fee	Submit fingerprints FBI background check Owner - $10,000 fee	Submit fingerprints FBI background check $2,200 fee.	Submit fingerprints FBI background check $2,200 fee
Nevada	Submit fingerprints Owner - FBI background check Agent – state background check Owner - $1,000 fee Agent - $75 fee	Submit fingerprints Owner - FBI background check Agent – state background check Owner - $5,000 fee Agent - $75 fee	Submit fingerprints State background check Owner - $3,000 fee	Submit fingerprints State background check Owner - $1,000 fee
Washington	Submit fingerprints FBI background check Owner & Agent fees TBD	Submit fingerprints FBI background check Owner & Agent fees TBD	Fingerprints may need to be submitted. FBI background check Fees TBD	Submit fingerprints FBI background check Fees TBD

* The AMMA establishes one license category for both dispensing and cultivating medical marijuana

In Section 2.1.4(m) we certain limitations to ADHS' licensing processes relating to dispensary agent licensing, Dispensary licensing and requirements placed on recommending physicians.

Regarding licensing of Dispensaries, many of the states we studied have very rigorous requirements prior to granting licenses. In Massachusetts, Maryland, and New York, and Illinois (among others) 100's of groups submitted substantial application fees and engaged in competitive processes (effectively RFP processes) in order to win limited Dispensary licenses. In each of these states, fairly exhaustive financial and personal background reviews were performed (and continue to be performed) on prospective owners, and, in each instance, competitive groups had to provide substantial financial guarantees in order to qualify for licensing scoring.

In Massachusetts, a state using a nonprofit model similar to Arizona's, significant disclosures are required regarding all affiliated entities involved with the nonprofit seeking a Dispensary award.

New Jersey also has a rigorous permitting process to thoroughly review the financial and personal backgrounds of the principals associated with prospective dispensaries. The permitting process is modeled after protocols and procedures for reviewing the background and finances of casino operators undertaken by the Division of Gaming Enforcement.

In addition to the licensing types detailed in Exhibit 5, many states have established licensing or certification requirements and criteria for transportation agents, and processors of medical marijuana products. Many of these licenses require similar background checks and scrutiny to those ADHS applies to dispensary agent licenses. Some examples include:

In Maryland, a transportation agent is a registered grower or dispensary agent, authorized by the licensee and registered with the Department to transport products containing medical marijuana, or a licensed and bonded courier of a secure transportation company. M.M.C 10.62.01

Colorado requires licensing of medical marijuana infused product manufacturers which produce medical marijuana infused products such as: edibles, concentrates, tinctures or beverages. These facilities are only authorized to wholesale their products to licensed medical marijuana centers. A sampling of the criteria applicants are required to meet includes:

- resident of the state for two years prior to application;
- have no any delinquent public or child support obligations;
- may not have any Controlled Substance felony convictions;
- may not have any other felony convictions that have not been fully discharged for five years prior to applying for your business license;
- may not have a criminal history that indicates that he or she is not of good moral character;
- may not employ, be assisted by or financed in whole in in part by any other person whose criminal history indicates he or she is not of good character and reputation;
- may not be a licensed physician making qualifying patient recommendations, a sheriff, deputy sheriff, police office, prosecuting officer or be an employee of a local or State Licensing Authority,
- may not employ any person at the Medical Marijuana business that has not passed a criminal history record check (obtained an MED Occupational License). (C.R.S. § 12-43.3-307)

(n) Waste disposal

While the AMMP has limited specifics regarding waste disposal, a number of the states studied provide considerably more detail on required storage and destruction practices.

In Massachusetts, variable rules apply to the storage and destruction of liquid and solid waste composed of or containing medical marijuana, including processed medical marijuana products. Solid waste must be destroyed by an entity permitted by the Department of Environmental Protection. At least two dispensary agents must witness the destruction. Also, Dispensaries are required, at no charge, to accept unused, excess or contaminated medical

marijuana from patients.[35] And records of all medical marijuana disposal or destruction must be kept for at least two years. Massachusetts rules closely mimic the requirements of a DEA licensed reverse distributors acquisition and disposal requirements.

Illinois requires that notifications be given to the Department of Agriculture, the State Police, and the Department of Financial and Professional Regulation prior to any waste disposal (Ill. Section 180).

Washington's waste disposal protocols are very similar to Massachusetts' in that variable rules apply to the destruction of wastes, solids, and leaf and processed medical marijuana products (WA 173-303).

Of all the states reviewed, Colorado has the most detail and rigor established for rules relating to the disposal of medical marijuana related waste. In addition to variable disposal requirements and procedures depending upon the nature of the waste, Colorado requires that waste (in certain instances) be destroyed pursuant to a certificate of designation from the Department of Public Health and Environment. Furthermore, all waste must be recorded in the states' METRC™ system and comprehensive destruction records must be maintained (1 CCR 212-1 M-307).

4.0 COMPARISON TO DEA AND BOARD OF PHARMACY PROTOCOLS

The explosion of medical marijuana programs around the country in recent years has been both surprising and challenging to state agencies charged with building a regulatory framework for a plant based product. Suddenly, a state like Arizona (and ADHS) is left to determine how to regulate this organic plant and its multiple products, in both raw and processed form.

With a typical new drug, the following process is followed:

- A Food and Drug Administration ("FDA") new drug application is submitted by the manufacturer;
- A National Drug Code ("NDC") is issued by the FDA after successful clinical trials are conducted;
- The Department of Health and Human Services ("HHS") & National Institute on Drug Abuse ("NIDA") reviews the drug and its purpose to determine if it is to be deemed a controlled substance;
- The DEA then determines the disposition of the drug within the Controlled Substance Act ("CSA") for scheduling and begins the appropriate rulemaking process.

NDC Example and explanation:

- Each listed drug product is assigned a unique 11-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular labeler. The third segment, the package code,

[35] 105 CMR 725

identifies package sizes and types. Both the product and package codes are assigned by the labeler. The NDC will be in the following configurations: 5-4-2. Some labelers choose to remove leading zeros.

[36]

For example, the NDC for a 100-count bottle of Prozac® 20 mg is 0777-3105-02. The first segment of numbers identifies the labeler. In this case, the labeler code "00777" is for Dista Products Company, the labeler of Prozac®. The second segment, the product code, identifies the specific strength, dosage form (i.e., capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. In this case, "3105" identifies that this dosage form is a capsule. The third segment is the package code, and it identifies package sizes and types. Our example shows that the package code "02" for this bottle of Prozac® identifies that 100 capsules are in the bottle. The FDA maintains a searchable database of all NDC codes on their website.[37]

Once final determination and scheduling occurs (Schedule I-V), the drug may now be ready for commercial use, whether pursuant to a prescription (RX only) or over the counter (OTC). Schedule I drugs uniformly are not available for public consumption in any fashion. According to the DEA, "Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence,"[38] [39]

Each state has a board of pharmacy or controlled substance department which can, by their choosing reclassify a drug into a different schedule or not recognize a federal schedule. In 2011, Carisoprodol (brand name SOMA®), a common muscle relaxer, was not scheduled under the Federal Controlled Substances Act ("CSA). However,

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[36] www.drugs.com; National Drug Codes
[37] www.drugs.com National Drug Codes.
[38] www.dea.gov, January 15, 2015

[39] The DEA position on marijuana (as of April 2013) is as follows: "Marijuana is properly categorized under Schedule I of the Controlled Substances Act (CSA), 21 U.S.C. § 801, et seq. The clear weight of the currently available evidence supports this classification, including evidence that smoked marijuana has a high potential for abuse, has no accepted medicinal value in treatment in the United States, and evidence that there is a general lack of accepted safety for its use even under medical supervision."

due to its high potential for abuse, 21 states classified Carisoprodol as a schedule IV controlled substance within their respective state. Effective January 11, 2012, the DEA placed all forms of Carisoprodol into schedule IV of the Controlled Substances Act. (South Med J. 2012;105(11):619-623.) Regardless of each state board of pharmacy or controlled substance department's determination, the more stringent classification for proper storage and dispensation should typically be followed.

In the United States, with the exception of Missouri, prescription monitoring programs ("PMPs") or prescription drug monitoring programs ("PDMPs") are state-run programs that collect and distribute data about the prescription and dispensation of federally controlled substances and, as the individual states deem appropriate, other potentially addictive or abusable prescription drugs. PMPs are intended to assist physicians, physician assistants, nurse practitioners, dentists and other prescribers, as well as law-enforcement agencies, and to support the legitimate medical use of controlled substances while limiting the abuse and diversion of these agents. Pharmacies that dispense controlled substances and providers who prescribe them are typically required to register with their respective state PMPs and (for pharmacies and providers who dispense controlled substances from their offices) to report the dispensation of such prescriptions to an electronic online database.

NDC's as assigned by the FDA, are entered into the state prescription drug monitoring program (or PMP in Arizona) whenever a prescription is issued. The PMP is most commonly managed by the State Board of Pharmacy (in Arizona's case the "ASBP"). All prescriptions for a drug are authored by an individual licensed by the DEA to prescribe scheduled substances. The controlled substance is most commonly sold at a pharmacy licensed by the DEA (and the ASBP). If the controlled substance expires, it typically is sent to a reverse distributor, also registered by the DEA (and the ASBP), for processing, and ultimately destruction. Many, if not all of the employees along the chain of custody, from physicians, to pharmacy, to reverse distributor, are registered by the DEA or licensed by the state board of pharmacy or other applicable agency. Effectively, anyone handling a scheduled substance in a commercial setting must be licensed by the DEA and applicable state authority.

Because marijuana has been federally deemed a Schedule I substance, and therefore illegal as a commercial medicine, any state tasked with regulating marijuana is left with virtually none of the regulatory tools or federal guidance normally available.

- pharmacies can't handle marijuana as doing so would put its DEA registration in jeopardy;
- hysicians can't issue traditional prescriptions for marijuana as doing so could put their licenses /registrations at risk;
- reverse distributors can't handle the storage and destruction of marijuana as doing so would put their DEA registration in jeopardy;[40]
- finally, the PMP should not be used as a patient registry as PMP funds are primarily underpinned by federal or state government grants and failure to conform to the DEA's edict declaring marijuana to be a Schedule I controlled substance could jeopardize PMP funding.

This results in the state regulating medical marijuana left with creating almost a parallel to what the DEA and ASBP normally would regulate. The emerging trend in several states (discussed in Section 3) has been to effectively try and create a near mirror of standard DEA protocols as well as applying FDA type standards (in

[40] The only instance in which a reverse distributor can legally possess marijuana is if (1) they are registered to handle Schedule I controlled substances and (2) the marijuana is being transferred from another DEA registrant utilizing a US official order form DEA Form 222.

determining allowable product types).

Colorado, by example, has a centralized inventory tracking system, including a marijuana specific patient registry very similar to a prescription drug monitoring program. They apply substantial controls on the manufacture and packaging of all products, including processed marijuana. They have advanced standards for the disposal of marijuana waste. They also engage in several layers (both local and state level) of unannounced inspections (similar to what the DEA and ASBP does with various DEA license holders.)

Circling back to Arizona, the AMMP has some parallels to DEA and ASBP protocols. The following describes some of the similarities as well as some of the dissimilarities.

The AMMP has a patient registry, and uses the ASBP to confirm that recommending physicians are querying qualifying patient histories on the PMP prior to writing a recommendation. However, physicians are not registrants in the medical marijuana registry. (They are registrants with the PMP.) **Appendix II** provides a side by side comparison of PMP requirements and ADHS' patient registry.

Regarding inspections, the DEA (and the ASBP) can at any time, for any reason, perform unannounced inspections. These inspections can include forensic level reviews for inventory controls, security controls, and environmental controls, among other things. Investigators review, in detail, all acquisitions, dispositions and destructions up to 3 years prior to the date of inspection. Investigators may check all paperwork and forms for completion and necessary documentation or they may just select a few items to spot check. Investigators may choose to inventory every controlled substance in inventory or may only choose a select few. Once the inventory is complete, they will compare their count to the documented inventory on-hand and determine the percentage of discrepancy. Investigators will also ask to inspect and test (requiring system to be put into test mode) each component of security equipment including each door contact, motion sensor, audible alarm, key pad and security camera to ensure every alarm will create an alarm event – required documentation of these events and how you are notified. Investigators also review policies and procedures.

In comparison, ADHS in regulating medical marijuana, rarely performs unannounced inspections (as discussed in Section 2.1.4(g)). Typically, licensed Dispensaries are given reasonable advance notice that an inspection is imminent. The inspections, absent unusual circumstances, do not include financial reviews, but they do include reviews of inventory controls, security controls, and environmental controls. For a more detailed comparison regarding inspections, please refer to **Appendix II**.

The inventory controls required by the DEA (and to an extent the ASBP), are rigidly defined and strictly enforced. Regulation does not allow for any "grace period" for inventory documentation. If an investigator walks in unannounced, any DEA registrant must be able to show record of all inventory on hand as all documentation must happen in real time. Additionally, all controlled substances on hand must be inventoried annually and reconciled with expected inventory. Any "significant loss" must be reported to DEA within one business day using a DEA Form 106. Significant loss is subjective and many factors must be considered by the registrant to determine if the loss is considered "significant." However, if the business determines the loss is not significant and the DEA does determine the loss significant, it will be considered a failure to report and penalties may result.

Under the AMMP, licensed Dispensaries are required to actively track, record and audit their inventory management systems – at least every 30 days at a minimum (see Section 2.1.4(c)). However, the records of these audits are not regularly submitted to ADHS. Nor are there forensic reviews of these audits, absent extraordinary circumstances. Please note **Appendix II** for a comparison of the inventory control requirements imposed by the various agencies described herein.

Regarding obtaining a license (or in DEA terms a registration), a pharmacy must first obtain any and all state controlled substance licenses and/or permits required before submitting a DEA application.
In Arizona, Pharmacies are required to first obtain an Arizona State Board of Pharmacy Permit pursuant to A.R.S. 32-1929. Additionally, the following must occur:

- Every pharmacy must have one pharmacist who is designated as the pharmacist in charge who shall be responsible to the ASBP for compliance with all state and federal laws and rules in the operation of the pharmacy (R4-23-610.A).
- All pharmacies must meet minimum size requirements for overall floor space and have adequate counter space available for the pharmacist to perform their duties (see R4-23-609.A. & B; re hospital Pharmacies see R4-23-655).
- All pharmacies must have a sink with hot and cold running water within the pharmacy (R4-23-611.H).
- The dispensing counter of the pharmacy area must be protected by a sneeze barrier (at least 66 inches in height) positioned between the public and the dispensing area (see R4-23-609(H).
- The pharmacy shall obtain and maintain current editions of any two or more references books from the approved list (R4-23-612, i.e. Arizona Pharmacy Act, Arizona Controlled Substances Act, Drug Compatibility, Drug Product Equivalency etc.).
- All pharmacies must obtain and maintain the minimum equipment required to operate a pharmacy (R4-23-612. i.e. Refrigeration equipment for the storage of drugs, prescription labels, warning labels, spatulas in assorted sizes and materials etc.).
- All new pharmacies or pharmacies that have changed ownership or location require a final inspection by the Board or its designee before being opened to the public (R4-23-606).
- The pharmacy must have floor plans or blueprints of the pharmacy area, a zoning statement or a copy of the lease, and must designate an Arizona licensed pharmacist as the pharmacist in charge ("PIC"). The PIC must also have a valid Pharmacist Arizona State Board of Pharmacy License.

Once the ASBP permit is issued, the pharmacy can begin its application for the pharmacy's DEA registration, or permit (issued by the Drug Enforcement Administration).

When the pharmacy has submitted the DEA registration application and fee, this is only the first step in obtaining a registration. The pharmacy will also need to provide copies of:

- All current licensures
- Days and hours of operation
- Any subsidiary firms
- Controlled substances the pharmacy will handle
- Type of pharmacy activity (closed door, retail, compounding, veterinary etc.)
- Standard operating policies and procedures as well as
    - Record keeping procedures
    - Security policies and procedures
    - Employee screening policy
- Any powers of attorney that exist
- Number of expected employees
- Floor plan and square footage
- Types of alarms

- All hardware specifications for installed security system
- Copy of security contract
- Detailed specifications for all cages
- Secure cabinets, safes or other storage
- Responding law enforcement agency
- Name of destruction facility or reverse distributor
- Any other additional processes or procedures

The DEA may also request other information during this time. The DEA requires that all security systems, cameras, storage cabinets, cage doors, and any other fixtures or hardware be installed and functional before they will finish processing an application. They also require all utilities, security contracts and any other services to be active before they will finish processing an application. This requires a significant amount of time and monetary commitment from the pharmacy owners and operators just to complete an application – with no guarantee of approval. While these requirements may seem stringent and harsh, it promotes best in class operators.

In the case of a prospective medical marijuana Dispensary in Arizona, the licensing process (and renewal process), although quite rigorous, is much less invasive in comparison to DEA scrutiny. In particular, the application, and approval process typically takes far less time than in the case of a pharmacy, and the background scrutiny on individuals seeking licensure is considerably less involved and invasive. Please note **Appendix II** for a comparison of respective requirements.

Yet, in both the case of a pharmacy, and a medical marijuana Dispensary, licenses / registrations are being sought to deliver controlled substances to the general public. Lining up the facts, side by side, it's quite clear that the requirements and scrutiny placed on a Dispensary do not approach those placed on a pharmacy. (Needless to say, there is no "apples to apples" comparison between pharmacy controls and qualifying patients/personal caregivers' cultivation of and the related creation of medical marijuana products.)

Regarding the storage and destruction of unused controlled substance waste, DEA and ASBP regulation of the treatment of unused controlled substance waste falls under local, state and federal regulations. Most local and state authorities apply Title 21 Code of Federal Regulations, §1317.90 Methods of destruction which require the following:

> (a) All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to §1317.95(c), shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.
>
> (b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.
>
> (c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

The destruction of any controlled substance are in accordance with the following requirements (§1317.95 Destruction procedures.):

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction*. If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

Once the items are transferred to a registered reverse distributor:

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

(4) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

The DEA and ASBP registered reverse distributor then prepares a DEA Form 41 which lists each controlled substance, its NDC, Form, Strength, Original Package Size, Count in Package, and Number of Packages. This form also records the reverse distributor's information, the destruction facility's information, and the date of destruction and the signatures of two employees who witnessed the destruction.

Under the AMMP, the treatment of waste disposal is dramatically less burdensome on a licensed Dispensary. While there is no equivalent version of a reverse distributor for Dispensaries in Arizona, other options do exist for the inevitable waste all Dispensaries create. Dispensaries are required to present on paper a policy for marijuana disposal during the initial license application process. This policy may be reviewed during subsequent ADHS inspections however, witnessed destruction documentation is not provided to the Department each time a destruction occurs. Please see **Appendix II** for a side by side comparison of requirements.

There are significant differences between obtaining a license to be a pharmacy technician, in comparison to getting licensed as a dispensary agent. One particularly striking difference is the amount of time it takes to receive licensure as a pharmacy technician (often greater than a month), versus a dispensary agent (often less than five days). Furthermore, pharmacy technicians do not get licensed until after the result of state and federal background checks are received. With dispensary agents, licenses are processed and confirmed (on a temporary basis) prior to confirmation from state and federal law enforcement that the individual reviewed is suitable. (Please see Section 2.1.4(m). The differences are further outlined in **Appendix II**.

Regarding oversight of all commercial participants or registrants falling under the aegis of the ASBP, an oversight board has governing authority, as defined under A.R.S. § 32-1902:

"There shall be an Arizona state board of pharmacy which shall consist of six pharmacists, at least one of whom shall be a pharmacist employed by a hospital permittee and one of whom shall be engaged in the day-to-day practice of pharmacy in a permitted community pharmacy; one pharmacy technician and two

public members appointed by the governor pursuant to section 38-211. No pharmacist shall be appointed to the board unless they have been licensed as a pharmacist in this state or any other jurisdiction for a period of ten years and licensed as a pharmacist and a resident in this state for a period of at least five years immediately prior to the date of appointment. The public members shall have been residents in this state for a period of at least five years immediately prior to the date of appointment. Each pharmacist member shall serve for a term of five years. The public members may serve for a term of five years unless removed by the governor. Vacancies occurring on the board other than by expiration of term of office shall be filled for the unexpired portion of the term only."

Under the AMMP, there is no equivalent board having oversight. There is the ADHS Medical Advisory Committee which deals with review and approvals of qualifying medical conditions relating to medical marijuana.[41]

As outlined above and throughout this report robust rules and regulations exist on the state and federal levels for the management of controlled substances. Those rules and regulations are a direct result of years of refinement. And as discussed are not applicable to marijuana because it remains a federally illegal Schedule 1 controlled substance. The AMMA and subsequent rules established in Arizona are sufficient for ADHS to provide regulatory oversight of the AMMP. However, further refinement must occur in order to adapt to the expansion of treatment options, safety and efficacy of the products offered and enhanced enforcement requirements.

[41] It is recommended that ADHS consider expanding upon the already established ADHS medical advisory committee to include additional members comprised of an industry representative, law enforcement and a member at large. By broadening the committee ADHS would have the ability to address virtually all the procedural components of the AMMA/AMMP in a committee form.

5.0 Recommendations

This report seeks to illustrate choices facing ADHS, and other state and local agencies relating to medical marijuana compliance oversight. Further confounding any policy or rulemaking decisions is the fog of federal action or inaction regarding current positions on the legality of medical marijuana programs at a state level. That being said, we have a number of recommendations which could buttress ADHS' goals in supporting public safety and streamlining the flow of compliance data.

Here are eleven broad recommendations and the suggested steps necessary to implement (whether available internally, via rule change, legislative change, referenda or citizen initiative):

Recommendation I: Increased licensing requirements

- Dispensary agents need to clear background checks prior to getting a registry card
- Additional scrutiny placed on effective transfers of licenses (although not currently allowed, transfers are occurring.)

As discussed in Section 2.1.4(m) when reviewing applications for dispensary agents, ADHS currently provides dispensary agent cards prior to getting the results back from state and federal background checks. Thereby possibly allowing individuals who should be excluded from acting as a dispensary agent to handle and dispense medical marijuana. This gap can be addressed by amending ADHS protocols to withhold approvals on dispensary agents until after receiving back ground check information. (In order to address any possible timing issues, ADHS could consider using 3rd party background check agencies.)

Relating to A.A.C. R9-17-308 (Renewing a Dispensary Registration Certification) and R9-17-310 (Administration), we suggest a requirement be added involving an annual review of a licensed Dispensary's financial statements by a certified public accountant. With the financial review completed according to generally accepted accounting principles or modified cash basis accounting.

As part of the financial review, particular focus should be directed towards the various contractors that licensed Dispensaries use. This should allow ADHS to better follow the distribution of money, particularly related to wholesale medical marijuana transactions, including "donations" of medical marijuana. Additionally, review of affiliated contractors should give ADHS insight into when effective control of the licensed nonprofits changes, thereby potentially triggering new licensing scrutiny. Towards this end, and in order to create more financial transparency, we recommend that expanded disclosures relating to contractors involved with licensed dispensaries be implemented. Some suggested expanded or enhanced rules relating to the use of contractors could include:

A Dispensary shall ensure that:

1. Contracted services are provided according to the requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter;
2. Documentation of current contracted services is maintained that includes:
   (a) A list that contains the name of each individual providing services required by A.R.S. Title 36, Chapter 28.1 or this Chapter for or at a licensed Dispensary under a contract, and
   (b) A description of contracted services provided

Necessary action to implement: We expect that these recommendations may require legislative changes or

amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation II: Expanded ADHS patient registry – to include increased real time data flow between the various registrants – physicians, qualifying patients, designated caregivers, Dispensaries, ADHS, and other enforcement agencies, to include identity verification prior to issuing a qualifying patient or dispensary agent card

- Require that physicians receive a registry ID and participate in the ADHS registry directly utilizing their DEA number
- Allow law enforcement to query the ADHS registry via name and birth date in the event card isn't available (if allowable pursuant to the confidentiality constraints contained in A.R.S. 36-2816). (In other words, make this consistent with law enforcement access to the state PMP)
- Requirement that all qualifying patients confirm that an address provided is their physical residence;
- All medical marijuana deliveries shall be made by a designated caregiver or Dispensary to a qualifying patient only to the physical address on file with ADHS or a licensed health care facility
- Revise process to prohibit any sale that in an aggregate would exceed the 2.5 oz. limit. (Specifically, this will take revision to the ADHS patient registry to prohibit a qualifying patient from receiving greater than 2.5 ounces in a 14-day period, whether sold in a single transaction or multiple transactions at one or more locations – with real time tracking)

Effectively, we recommend that the current ADHS patient registry be modified so it is more inclusive, like a prescription drug monitoring program, more closely tying physician information with qualifying patient information and the medication dispensed.

Currently, ADHS tracks only the total number of certifications issued by a physician and ASBP confirms that the physician accessed the PMP at least that many times in a month. To further enhance the AMMP, the information provided by ADHS for ASBP to review should specifically correlate to the qualifying patient for whom the certification was written. This would allow ASBP to reconcile a physician's PMP access to each specific qualifying patient.

We recommend that additional requirements be placed on the physician's written certification recommending marijuana (R9-17-202). These include:

1. A "yes" or "no" confirmation by the physician that the qualifying patient provided his/her medical records from other physicians who treated the qualifying patient for the prior 12 months
   (a) If "yes" a confirmation by the physician that the physician reviewed the qualifying patient's medical records from other physicians for the prior 12 months

2. A statement, initialed by the physician, that:
   (a) The physician reviewed the qualifying patients profile on the AZBOP Controlled Substances Prescription Monitoring Program database;
   (b) The qualifying patient's profile on the AZBOP Controlled Substances Prescription Monitoring Program database is consistent with the medical record information provided to the physician by the qualifying patient

3. If the qualifying patient did not provide the physician with the qualifying patient's medical records from other physicians who treated the qualifying patient during the previous 12 months,

either:
(a) A statement signed and dated by the qualifying patient that the qualifying patient was not treated by another physician during the previous 12 months, or
(b) A copy of documentation, dated at least 30 calendar days before the date of the written certification, of the qualifying patient's request for the qualifying patient's medical records from other physicians who treated the qualifying patient during the previous 12 months

Regarding the transportation of medical marijuana to either (a) a qualifying patient, or (b) a designated caregiver, we suggest that R9-17-315 be amended to provide a requirement that marijuana be delivered only to either the qualifying patient's residence address or the designated caregiver's (as the case may be).

A means of adding considerable rigor to the medical marijuana electronic verification system, and to better confirm qualifying patient medical marijuana limits, would include the following amendments to R9-17-315 (specifically involving medical marijuana dispensed to a qualifying patient by a designated caregiver):

> Enter the following information into the medical marijuana electronic verification system for the qualifying patient or designated caregiver:
>
> (a) If the medical marijuana was dispensed:
> i. in the form of usable medical marijuana, the amount of medical marijuana dispensed;
> ii. in the form of a concentrate, the amount of usable medical marijuana used to produce the concentrate;
> iii. contained in an edible food product or a non-edible product:
> - In the form of usable medical marijuana, the amount of usable medical marijuana
> - In the edible food product or non-edible product; or
> - In the form of concentrate, the amount of usable medical marijuana used to produce the concentrate in the edible food product or non-edible product;

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation III: Authorize the creation of a centralized (ADHS managed) inventory tracking system – directly interfacing with each of the licensed Dispensaries - with an eye towards better recording and capturing information on the wholesale medical marijuana market

- Establish Inventory limits, additional inventory controls
- Close the "donations gap" in which consideration is currently being given to designated caregivers (and qualifying patients) who are cultivating
- Enhance law enforcement access

In Section 3.2.1(c) examples were given of how other states have authorized the creation of centralized inventory tracking systems. The key benefits are that agencies like ADHS can have real-time access to the web of transactions involving medical marijuana, while creating a closed loop system. In particular, these systems are a great compliance tool used to flag anomalies and trigger audits or inspections, and ultimately limit diversion and fraudulent conduct among the commercial participants. When properly constructed, they can reduce the need for

licensed dispensaries to keep double books as a centralized data system removes the reporting dispensaries make first to their internal system and secondarily to the state run system.

Currently, ADHS uses a patient registry to capture (with some limitations) the majority of retail medical marijuana transactions. For inventory tracking ADHS relies on licensed Dispensaries to have robust internal inventory tracking with (effectively) monthly inventory reporting to ADHS.

Based on the examples set in Colorado, Nevada, Washington, New York, Hawaii and elsewhere, ADHS should consider allocating appropriate resources to develop and construct a centralized, ADHS managed inventory tracking system. An expanded medical marijuana data monitoring system should be capable of tracking each commercial transaction involving medical marijuana.

At a minimum the system should track:

- each wholesale and retail transaction – by strain of medical marijuana, form of payment and payment amount, amount of medical marijuana sold, and from which Dispensary cultivation site or qualified individual;
- each shipment of medical marijuana from cultivator to Dispensary;
- each registrant involved in the chain of medical marijuana development and use including qualifying patients, dispensary agents, and designated caregivers;
- medical marijuana Label data;
- global Unique Identifiers (GUIDs);
- disposal data;
- generation of audit forms;
- trip and transportation data;
- laboratory testing data.

The information compiled by the system should be HIPAA compliant and generate secure and streamlined data to limit diversion and provide real time analytics to support the Department, public safety and industry compliance. The overall system solution should be able to be used in whole or in part. It should be easy to use and understand throughout the user experience. Each user should be able to manage their account online. Password changes, reporting lost or stolen cards, changing of email addresses or requesting duplicate medical marijuana cards should all be able to be completed online within the system.

The system should operate on a widely available hosting solution. This would allow for scalable growth and expansion without restriction to the hosting environments. The system should be designed with "defense in depth" in mind. This means that it should have multiple layers of security that start at the platform and go to the point where a user accesses the system. The system should be constantly monitored by third party providers providing a level of security that meets or exceeds current bank grade standards.

The systems' qualifying patient and designated caregiver registry app should provide a simplified user interface for the initiation, processing and approval of qualifying patient applications. The qualifying patients and designated caregivers should have an intuitive, HIPAA compliant dashboard that provides a detailed snapshot of their current status as well as their recent transaction history. The registry should also provide real-time tracking of purchases and automatically limit the qualifying patient or designated caregiver from exceeding the limits set forth in law. At the point of sale, the identification cards should be swiped by both the purchaser (qualifying

patient or designated caregiver) and the dispensary agent. The transaction amount should be able to be validated in real time to ensure that the dispensable medical marijuana limits are not exceeded.

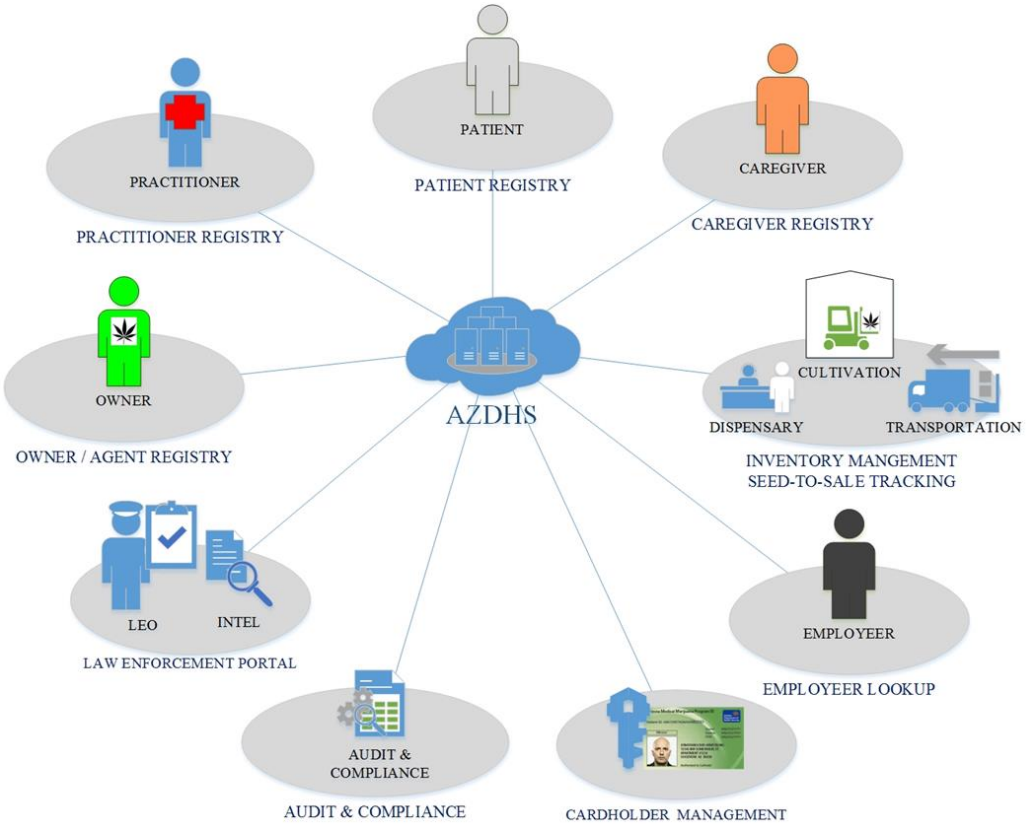
The ADHS registry should streamline the Dispensary application process to make the process paperless. Medical directors, owners and dispensary agents should be loaded into the system with a secure document management upload process. The application fees should continue to be collected electronically before being forwarded to ADHS for review.

The system should provide a dashboard for systems administrators to use that quickly identifies the workload and allows one click access to most tasks. The system should provide real time reporting on all aspects of the Program. All reports should be exportable for use in other tools like Microsoft Excel®.

In addition to creation of a centralized inventory tracking system, there are other opportunities to enhance ADHS compliance relating to tracking of medical marijuana transactions. Considerable modifications can be made to certain parts of R9-17-316 (Inventory Control System). The current methodology allows for considerable gaps in ADHS' method of tracking medical marijuana inventory, in particular regarding wholesale medical marijuana transactions. This includes weaknesses in tracking of "donated" medical marijuana as well as confirming that wholesale acquired medical marijuana actually was acquired from one of three legitimate sources: (1) another licensed Dispensary, (2) a qualifying patient authorized by the Department to cultivate medical marijuana, or (3) a designated caregiver authorized by the Department to cultivate medical marijuana.

Exhibit 6, as follows represents a visual description of what a centralized data management system could include.

Exhibit 6 - Enhanced Patient Registry & Inventory Management



As such, in order to better control the wholesale market, we recommended the following modifications to R9-17-316:

A licensed Dispensary may not acquire from a qualifying patient or designated caregiver:

1. More than two and one-half ounces of usable marijuana during any 14 calendar day period, or
2. If the qualifying patient or designated caregiver is authorized to cultivate, more than twelve marijuana plants during any 60 calendar day period

When a licensed Dispensary acquires usable marijuana from:

1. A qualifying patient or designated caregiver, the Dispensary shall enter the following information into the medical marijuana electronic verification system:
   a. The name and Dispensary registry identification number of the qualifying patient or designated caregiver providing the usable marijuana; and
   b. The amount of usable marijuana acquired; or
2. Another licensed Dispensary, the licensed Dispensary acquiring the medical marijuana shall enter the following information into the medical marijuana electronic verification system:
   a. The name and Dispensary registration certificate number of the providing Dispensary;
   b. If the medical marijuana was acquired in the form of usable marijuana, the amount of usable marijuana acquired;
   c. If the medical marijuana was acquired in the form of a concentrate, the amount of usable marijuana used to produce the concentrate;

d. If the medical marijuana was acquired as part of an edible food product or a non-edible product and the medical marijuana contained in the edible food product or the non-edible product is in the form of:
    i. Usable marijuana, the amount of usable marijuana contained in the edible food product or non-edible product; or
    ii. A concentrate, the amount of usable marijuana used to produce the concentrate; and
e. The date the Dispensary acquired the medical marijuana

When a licensed Dispensary provides medical marijuana to another licensed Dispensary, the Dispensary providing the medical marijuana shall enter the following information into the medical marijuana electronic verification system:

1. The name and Dispensary registration certificate number of the Dispensary acquiring the medical marijuana;
2. If the medical marijuana is provided in the form of usable marijuana, the amount of usable marijuana provided;
3. If the medical marijuana is provided in the form of a concentrate:
    a. The amount of the concentrate, and
    b. The amount of usable marijuana used to produce the concentrate;
4. If the medical marijuana is provided as part of an edible food product or a non-edible product and the medical marijuana contained in the edible food product or the non-edible product is in the form of:
    a. Usable marijuana, the amount of usable marijuana contained in the edible food product or non-edible product; or
    b. A concentrate, the amount of usable marijuana used to produce the concentrate; and
5. The date the medical marijuana was provided to the Dispensary acquiring the medical marijuana.
6. For receiving non-edible products containing medical marijuana from another Dispensary:
    a. A description of the non-edible products received from the other Dispensary, including the total weight of each non-edible product and the strain or strains, batch number or numbers, and estimated amount of usable marijuana contained in each non-edible product;
    b. The strain or strains, batch number or numbers, and estimated amount of usable marijuana contained in all the non-edible products received by the Dispensary;
    c. The name and registry identification number of the:
        i. Other Dispensary and the dispensary agent providing the non-edible products to the receiving Dispensary,
        ii. Individual or individuals acting in accordance with R9-17-301(C) authorizing the Dispensary to receive the non-edible products from the other Dispensary, and
        iii. Dispensary agent receiving the non-edible products on behalf of the receiving Dispensary;
    d. The date and time the name and registry identification number of the dispensary agent providing the non-edible products was verified; and
    e. The date the non-edible products were provided to the Dispensary;
7. For providing edible food products containing medical marijuana to another Dispensary:
    a. A description of the edible food products provided to the other Dispensary, including the total weight of each edible food product and the strain or strains, batch number or

numbers, and estimated amount of usable marijuana contained in each edible food product;

b. The strain or strains, batch number or numbers, and estimated amount of usable marijuana contained in all the edible food products;

c. The name and registry identification number of the:

i. Providing Dispensary and the dispensary agent receiving the edible food products on behalf of the other Dispensary,

ii. Individual or individuals acting in accordance with R9-17-301(C) authorizing the Dispensary to provide the edible food products to the other Dispensary, and

iii. Dispensary agent providing the edible food products on behalf of the Dispensary;

d. The date and time the name and registry identification number of the dispensary agent receiving the edible food products was verified; and

e. The date the edible food products were provided to the other Dispensary; and

8. For providing non-edible products containing medical marijuana to another Dispensary:

a. A description of the non-edible products provided to the other Dispensary, including the total weight of each non-edible product and the strain or strains, batch number or numbers, and estimated amount of usable marijuana contained in each non-edible product;

b. The strain or strains, batch number or numbers, and estimated amount of usable contained in all the non-edible products;

c. The name and registry identification number of the:

i. Providing Dispensary and the dispensary agent receiving the non-edible products on behalf of the other Dispensary,

ii. Individual or individuals acting in accordance with R9-17-301(C) authorizing the Dispensary to provide the non-edible products to the other Dispensary, and

iii. Dispensary agent providing the non-edible products on behalf of the Dispensary;

d. The date and time the name and registry identification number of the dispensary agent receiving the non-edible products was verified; and

e. The date the non-edible products were provided to the Dispensary.

Additionally, any transportation of medical marijuana (or any type or processed medical marijuana product), pursuant to R9-17-318 must be entered into the licensed Dispensary's inventory tracking system as well as the medical marijuana electronic verification system. Here are some suggested modifications to R9-17-318:

For transportation of medical marijuana, edible food products containing marijuana, processed medical marijuana products containing medical marijuana, and medical marijuana paraphernalia with the intent to dispense to a qualifying patient or the qualifying patient's designated caregiver, the following information for each qualifying patient or designated caregiver must be included in the transportation plan and entered into the inventory tracking system and concurrently the medical marijuana electronic verification system:

i. Name and registry identification number of the qualifying patient;

ii. If the intent is to dispense to the qualifying patient's designated caregiver, the name and registry identification number of the qualifying patient's designated caregiver;

iii. The location, including the address, requested by the qualifying patient or the qualifying patient's designated caregiver,

iv. The anticipated date and time of dispensing;

v. The amount of each of the following intended to be dispensed to the qualifying patient or the qualifying patient's designated caregiver;
   (1) medical marijuana,
   (2) edible food products containing marijuana,
   (3) non-edible products containing marijuana,
   (4) medical marijuana plants, and
   (5) medical marijuana paraphernalia; and

For transportation of medical marijuana, edible food products containing marijuana, medical plants, or medical marijuana paraphernalia being transported to another Dispensary or cultivation site:

i. for a Dispensary, the name of the Dispensary and the Dispensary's registration certificate number;
ii. for a cultivation site, the name of the cultivation site's Dispensary and the Dispensary's registration certificate number;
iii. the location of the Dispensary or cultivation site;
iv. the anticipated date and time of the receiving Dispensary's acceptance;
v. the amount of each of the following transported to the receiving Dispensary or cultivation site:
   (1) Medical marijuana,
   (2) Edible food products containing medical marijuana,
   (3) Non-edible products containing medical marijuana,
   (4) Medical marijuana plants, and
   (5) Medical marijuana paraphernalia; and

If a dispensary agent is unable to dispense or a receiving Dispensary or cultivation site does not accept the medical marijuana, edible food products containing medical marijuana, medical marijuana plants, or medical marijuana paraphernalia listed on a trip plan, the Dispensary agent shall return the medical marijuana, edible food products containing marijuana, medical marijuana plants, or marijuana paraphernalia to the originating Dispensary.

After transportation, a dispensary agent shall enter the end time of the trip and any changes to the trip plan, including the return of medical marijuana (if applicable), on the trip plan.

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation IV: Establish licensing and standards for independent laboratory testing of medical marijuana: including testing of the leaf as well as processed medical marijuana products, including extracts and concentrates for potency, homogeneity, contaminants, including pesticides and confirmation of THC/CBD levels

The regulation of the potency (THC) and contaminant levels in both raw and processed medical marijuana products is a material public health and safety issue, faced not just in Arizona but in every other state allowing medical marijuana. Exhibit 3 "Laboratory Testing" provides a stark contrast between Arizona's testing of medical marijuana (none) and the many states which have adopted testing procedures, typically using licensed third party testing laboratories.

Currently, A.A.C. R9-17-317D allows ADHS to "conduct analysis" upon request of medical marijuana samples. However, current ADHS practice (subject to current restrictions under AMMA and the Program Rules) restricts all ADHS staff from conducting analysis, and from medical marijuana being housed onsite at ADHS. While this "testing" option could (if allowed by law) provide some relief to those concerned about the content and potency of medical marijuana, it doesn't go far enough.

We recommend that legislative changes be made and/or the Program Rules amended to create a new licensing category for third party testing labs. Furthermore, samples of all medical marijuana products (in raw or processed form) offered by a licensed Dispensary should be tested by a licensed testing laboratory for potency, contaminants and homogeneity. The results of the testing should also be provided to ADHS via input into a centralized inventory tracking system (discussed in Recommendation III herein).

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation V: Expanded requirements for packaging, labeling, child proofing to include points of origin for all medical marijuana products, including donations

Arizona's rules regarding packaging and labeling of medical marijuana and products containing medical marijuana could be amended to include some of the requirements found in other states. Our recommendation includes adding the following requirements:

- from Colorado: all packaging must be opaque so that the product cannot be seen without opening the packaging material;
- from Connecticut: all packaging list the levels of THC and CBD (a potency statement);
- from Alaska: all packaging must state, "Marijuana should not be used by women who are pregnant or breast feeding";
- from Connecticut: any product containing marijuana shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1 (b)(4);
- from New York: dosing and administration instructions shall be placed on all packages;
- from Oregon: all marijuana products shall be packaged in a manner that's not attractive to minors. In other words, no use of cartoons, packaging that resembles candy or soda based products, etc.;
- from Colorado: (Assuming Arizona adopts some form of required laboratory testing) all packages must list the form of independent testing and results of that testing;

We also are providing some sample language amending A.A.C. R9-17-317 in order to address products involving processed medical marijuana products including extracts or concentrates to current Arizona law relating to packaging and labeling:

Edited into R9-17-317……

3. The form in which the medical marijuana is being provided;

4. If the medical marijuana is in the form of:
   a. Usable marijuana, the amount of usable marijuana provided;
   b. A concentrate:
      i. The amount of concentrate provided,

ii. The type of extraction method used to produce the concentrate,
iii. The name of any substance used to remove the active ingredients from the cannabis plant during the extraction process, and
iv. The amount of usable marijuana used during the extraction process to produce the concentrate being dispensed;

c. An edible food product or non-edible product:
i. The total weight of the edible food product or non-edible product;
ii. If the medical marijuana contained in the edible food product or non-edible product is usable marijuana, the amount of usable marijuana in the edible food product or non-edible product; and
iii. If the medical marijuana contained in the edible food product or non-edible product is a concentrate:
(1) The amount of concentrate in the edible food product or non-edible product,
(2) The type of extraction method used to produce the concentrate,
(3) The name of any substance used to remove the active ingredients from the cannabis plant during the extraction process, and
(4) The amount of usable marijuana used during the extraction process to produce the concentrate contained in the edible food product or non-edible product being dispensed;

Finally, regarding donated medical marijuana, we recommend that the rules be amended to require that all applicable packages contain a statement indicating the source of the donation to include the donors' unique identifier, and confirmation that the source was not a licensed Dispensary.

Necessary action to implement: we expect that this recommendation in large measure can be implemented via amendment to the Arizona Administrative Code (the Program Rules).

Recommendation VI: Enforce Inspection protocols including use of unannounced Inspections and expanded inspections protocols. Move away from "surveys" and educate to enforce

Various members of ADHS staff suggested that the inspection/survey process become more closely aligned with other ADHS Bureau of Special Licensing protocols and programs. And that the advance and reasonable notice requirements contained in the Program Rules be revised when possible to allow for random, unannounced inspections. This would also cause the AMMP to more closely resemble ASBP and DEA protocols in which unannounced inspections are a matter of course for all commercial registrants. In order to accomplish this, modifications to the Program Rules are necessary (in most instances).

We suggest that R9-17-309 be amended to include a requirement that ADHS periodically review each licensed Dispensary's entries into the medical marijuana electronic verification system. And, as warranted, depending upon the results of this periodic review, engage the support of certified public accountants to delve more deeply into the financial records of the subject licensed Dispensary to confirm the veracity of financial records (Also discussed above in Recommendation I). This can be a particularly useful tool in curtailing possible malfeasance relating to wholesale medical marijuana transactions.

We also recommend that ADHS adopt protocols similar to those required in Massachusetts. Their Department of Public Health has authority to conduct unannounced inspections AND require Dispensaries during inspections to

test medical marijuana on site for contaminants, "including but not limited to, mold, mildew, heavy metals, plant-growth regulators, and the presence of organic pesticides." (MA 725.300(A-E)).

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation VII: Increased inspection protocols and compliance oversight to qualify for having a kitchen and manufacturing MIPS, extracts, concentrates, etc.

As discussed earlier in this report, in comparison to several other states, ADHS has very limited controls over the manufacturing of processed medical marijuana products. To address this gap, in addition to the laboratory testing protocols described in Recommendation IV, we suggest the following:

In order for a licensed Dispensary to engage in the creation of processed medical marijuana products, the Dispensary must get written kitchen approval from ADHS. We recommend that additional compliance requirements be layered on to the kitchen approval process, including:

- require licensed Dispensaries to first obtain a county food establishment operating permit, prior to applying for kitchen approval from ADHS[42];
- upon receipt of a county food establishment operating permit from the Dispensary, ADHS should then be required to complete a separate kitchen inspection to validate compliance with AMMP requirements, prior to issuance of a license or kitchen certification;
- thereafter, as a pre-condition to a Dispensary license renewal, should the Dispensary operate a kitchen, the Dispensary must provide all required county inspection and permitting documentation with the renewal application, then ADHS will conduct a separate inspection. If all is in order ADHS will issue a kitchen certification in conjunction with the license renewal;
- ongoing inspections will be completed by county officials, and then by ADHS personnel (subject to receipt of the county permit);
- finally, ADHS should look to the examples set in other states (like Colorado) and adopt expanded internal policies on the form, scope and breadth of facility and kitchen inspections.

Necessary action to implement: we expect that this recommendation in large measure can be implemented via amendment to the Arizona Administrative Code (the Program Rules), as well as ADHS internal policy relating to form of inspections.

Recommendation VIII: Provide additional enforcement tools to ADHS to allow for civil monetary penalties, additional license restrictions (i.e. suspensions)

Currently, ADHS has authority to revoke licenses for instances of misconduct by licensees. But there are very few intermediary penalties ADHS could benefit from having when dealing with policy or process violations. Many of the states we studied give multiple tools to the oversight agencies to curb misconduct, short of using the ultimate hammer – license revocation. At a minimum, giving ADHS the option to suspend a license until corrective action(s) occur would provide a strong message to the market that there is enforcement "teeth" in the AMMP. If used appropriately, having summary suspension authority could be a great deterrent.

[42] To our knowledge, Coconino County is the only county currently requiring Dispensaries to have food safety inspections.

We recommend the adoption of rule changes allowing ADHS summary suspension authority. Additionally, we recommend that civil monetary penalties be added, good examples of which can be found in New Hampshire's regulations.

In New Hampshire, the Department of Health and Human Services, depending upon the type of misconduct, may: (1) suspend all or a portion of operations; (2) impose administrative fines; (3) deny an application for a Dispensary registration; or (4) revoke a license (He-C 402.30 (NH)). In terms of impositions of fines, the Department may elect the following[43]:

- $2000 for violating advertising restrictions;
- $1000 for failure to timely submit a license renewal application;
- $2000 per instance, in the event of use or possession of certain prohibited chemicals;
- $2000 per day for failure to notice the Department of a change of location;
- $3000 for exceeding inventory capacity;
- $5000 per offense for providing false or misleading information to the Department;
- $10,000 for failure to allow access by the Department to a Dispensary;
- $1000 for employing personnel who do not meet qualifications for a positon;
- $3000 for engaging an employee who has a felony conviction;
- $1000 for making false or misleading statements to the public;
- $5000 for failure to maintain effective controls against diversion, theft or loss of marijuana;
- $5000 for failure to keep accurate records of all marijuana dispensed to qualifying patients, or designated caregivers, transported or disposed of;
- Up to $10,000 in the event of violations determined to jeopardize the health, safety, or well-being of a qualifying patient, designated caregiver, Dispensary agent, or the public.

We suggest considering expanding the role for the ADHS Medical Advisory Committee or alternatively creating a new committee or board. This is similar to that found with the ASBP, with power to address licensing issues, complaints, suspensions, new applications, change to existing licenses, and fines.

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation IX: Expanded education and training – requirements to have dispensary owners, dispensary agents (including medical directors), designated caregivers and physicians undergo periodic training (continuing education), enhanced qualifying patient communication requirements

We recommend that ADHS increase the dissemination of medical marijuana efficacy studies (federal, academic or otherwise) to licensed Dispensaries and their patient care directors, as well as to qualifying patients (via email or other notices).

We also recommend that ADHS consider sponsoring additional approved courses to include information on medical marijuana doses, qualifying patient counseling and substance abuse education.

[43] He-C 402.30 (NH). The list of fines described herein is not inclusive of all fines the Department of Health and Human Services may impose.

In addition to current training requirements placed on a licensed Dispensary's medical directors pursuant to A.A.C. R9-17-313, we suggest that all required Dispensary training with dispensary agents be:

> (a) Based on a defined curriculum, with confirmatory documentation added to the list of items ADHS inspectors review;
>
> (b) Training shall occur at least every 6 months (currently annual). And require that all training curriculum shall be available for ADHS review as well as a documented list of attendees.

We recommend that medical directors be required to attend at least 1 hour of CME or CME equivalent training on the emerging science of medical marijuana, the palliative benefits, and/or the types of doses and treatment available for the various approved qualified medical conditions.

Similar requirements could be required of dispensary agents involved with the management or oversight of medical recommendations and dosages at the Dispensary level including patient health directors or their equivalent management level dispensary agents, as the case may be.

Finally, following Maine's lead, we recommend that ADHS sponsor courses designed to train law enforcement in the nuances of the AMMP, including the patient registry, regulation of the wholesale and commercial medical marijuana market, dispensary agent transportation of medical marijuana and inventory tracking requirements.

Necessary action to implement: We expect that these recommendations may require legislative changes or amendments to the Administrative Code (the Program Rules) as well as changes to ADHS internal policy.

Recommendation X: Expanded public communications to allow for broad dissemination of information relating to disaster communications, standing of licensees and public awareness messaging

As the proliferation of medical marijuana increases, along with wide varieties of untested, high potency processed medical marijuana products, public safety issues will likely continue to emerge. As such, we recommend that ADHS dedicate time and resources to the development of a disaster communications plan with well defined communications channels and messaging protocol with designated spokespeople for situations demanding immediate responses. This should include complete media training for key ADHS employees and appropriate state officials.

In the interests of public safety, we recommend that current ADHS practice of limiting public information on the disclosure of where Dispensaries are located, and which are in good (or bad) standing be amended. Implementation of public communications should then occur to provide information on locations of licensed dispensaries, publishing instances of violations by licensed Dispensaries, and whether or not they are in good standing.[44]

We also recommend that ADHS launch a wide spread public awareness campaign to inform the public about the AMMP, issues relating to the ingestion or smoking of medical marijuana, and information about the uses and effects of processed medical marijuana products.

[44] Current ADHS policy is that the confidentiality provisions of A.R.S. 36-2810 preclude ADHS from offering this information to 3rd parties.

Necessary action to implement: we expect that this recommendation in large measure can be implemented by modifications to current ADHS policy and practices. In the case of the limitations imposed by A.R.S. 36-2810, we suggest seeking an attorney general opinion in order to seek clarification on the limits of the regulation.

Recommendation XI – Use of proceeds

ADHS staff specifically asked the authors to explore additional uses for proceeds from the AMMP. The following suggestions are portrayed in broad strokes based on interviews with ADHS, law enforcement and industry participants.[45]

- Development, implementation and management of a comprehensive inventory management system.
- Additional enforcement resources to allow for more thorough and complex inspections, greater support for local law enforcement agencies to investigate complaints and cursory financial reviews. As well as the ability for the department to contract with 3rd party agencies for background checks
- Creation of training curriculum for certifying physicians, dispensary owners and dispensary agents, similar to CEU requirements for other professional licensees in the state of Arizona.
- Launch a state wide public awareness campaign aimed at improving citizen awareness on the AMMP and guidelines for storage and usage of medical marijuana
- Support of substance abuse programs
- Establishment of a medical marijuana research grant program to document qualifying patient results using medical marijuana for various qualifying conditions

All enrichments should be aligned with the ADHS mission to promote, protect and improve the health and wellness of individuals and communities in Arizona.

Necessary action to implement: we expect that these recommendations may require legislative changes or amendments to the Program Rules as well as changes to ADHS internal policy.

[45] We have not reviewed current ADHS Program financial statements and related expenditure summaries.

6.0 CONCLUSIONS

The AMMP in certain respects sets a positive example for other states initiating sensible regulations for medical marijuana compliance. The Program is efficiently managed with a relatively small dedicated staff (in comparison to other states) and is notable for:

- Only a handful of states have more qualifying patients in their patient registry
- The process for adding or subtracting qualified conditions is rigorous and well publicized
- Response times to requests for patient registry and dispensary agent cards are best in class
- Customer service levels in terms of efficient licensing processing (across all license categories) are without peer

With this being said, there are significant areas for improvement in the system including:

- No state sanctioned testing of medical marijuana products (either via licensed independent labs or state controlled labs).
- Lack of controls relating to the manufacture and packaging of all forms of processed medical marijuana products
- Lack of a centralized data management system (in comparison to several other states that have adopted state run seed to sale inventory tracking systems to limit diversion and flag compliance anomalies)
- Limited ADHS enforcement tools (other than, effectively, license revocation).
- Inspections should more closely resemble DEA/ASBP standards – currently there's a lack of unannounced inspections, limited financial reviews/audits, and limited investigation and related permitting of medical marijuana kitchens producing processed medical marijuana products
- Limited controls over the wholesale medical marijuana market (in particular "donations" and unlicensed "hubs")
- Limited data and reporting transparency between various enforcement agencies
- The registry could be more like a prescription drug monitoring program, tying physician information with qualifying patient information and medication (and related doses) dispensed

Many of the recommendations contained in this assessment will require legislative changes (as well as changes to current ADHS policy). Amendments to current law, policy and related protocols, particularly those relating to medical marijuana, are often very difficult given the uncertainties and procedural impediments. It is informative to see what neighboring states are doing, most prominently Colorado and Nevada to get a sense of how others are addressing many, if not all, of the concerns raised within this report.

It is quite impressive what ADHS has accomplished given the substantial constraints under which they were placed by virtue of Proposition 203, the AMMA and the Program Rules.

While we are indeed grateful for the assistance of the department as well as the many others who assisted us with the creation of this report, Beacon Information Designs, with support from Elliott D. Pollack & Co., took great care in preparing the statements, opinions, evaluations and analysis contained herein. We have worked diligently to provide a fact based analysis. However, should there be factual inaccuracies; we will issue corrective statements if necessary.

Much of the information reviewed regarding the policies and procedures of medical marijuana programs in various states was obtained through readily available public resources and assumed to be accurate at the time of review.

APPENDIX I – SELECTED COLORADO REGULATIONS REGARDING OVERSIGHT OF MEDICAL MARIJUANA INFUSED PRODUCTS

Code of Colorado Regulations
Marijuana Enforcement Division, Adopted 11.1.2015

Basis and Purpose – M 604

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV),12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana-Infused Products Manufacturers. It requires all Owners and Occupational Licensees to attend a food handler training course prior to manufacturing any Edible Medical Marijuana Product. This rule also authorizes the State Licensing Authority to require that an independent consultant conduct an independent food safety audit of a Medical Marijuana Infused-Products Manufacturing Facility. This rule explains when an independent food safety audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana-Infused Products Manufacture's refusal to cooperate or pay for the audit. It sets forth general standards and basic sanitary requirements for Medical Marijuana-Infused Products Manufacturers. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public. Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public outside of packaging as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine portions for its products or to provide a mechanism with the product for accurately measuring a portion.

M 604 – Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations

A. Training

1. Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational Licensee must:

a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or

b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:

i. Causes of foodborne illness, highly susceptible populations and worker illness;
ii. Personal hygiene and food handling practices;
iii. Approved sources of food;
iv. Potentially hazardous foods and food temperatures;

v. Sanitization and chemical use; and
vi. Emergency procedures (fire, flood, sewer backup).

2. A Medical Marijuana-Infused Products Manufacturer must obtain documentation evidencing that each Owner or Occupational Licensee has successfully completed the examination or course required by this rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner or Occupational Licensee is engaged in the manufacturing of an Edible Medical Marijuana-Infused Product.

B. General Standards

1. A Medical Marijuana-Infused Products Manufacturer may be subject to inspection by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

2. A Medical Marijuana-Infused Products Manufacturer that manufacturers Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

C. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Medical Marijuana or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in Medical Marijuana-Infused Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

3. That all persons working in direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:

a. Maintaining adequate personal cleanliness;

b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and

c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

4. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Medical Marijuana or Medical Marijuana-Infused Product;

5. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana or Medical Marijuana-Infused Product are exposed;

6. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

7. That there is adequate safety-type lighting in all areas where Medical Marijuana or Medical Marijuana-Infused Product are processed or stored and where equipment or utensils are cleaned;

8. That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

9. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

10. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Medical Marijuana-Infused Products Manufacturer and used in accordance with labeled instructions;

11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Medical Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;

12. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;

13. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines;

14. That each Medical Marijuana-Infused Products Manufacturer shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;

15. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;

16. That Medical Marijuana or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and

17. That storage and transport of finished Medical Marijuana-Infused Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.

C.5. Product Safety.

Paragraph (C.5) is effective beginning October 1, 2016.

1. A Medical Marijuana-Infused Products Manufacturer that manufactures Edible Medical Marijuana-Infused Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana-Infused Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.

2. A Medical Marijuana-Infused Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana-Infused Product it manufactures. If a Medical Marijuana-Infused Products Manufacturer determines a standard portion for an Edible Medical Marijuana-Infused Product, that information must be documented in the product's standard production procedure.

3. For each Edible Medical Marijuana-Infused Product, the total amount of active THC contained within the product must be documented in the standard production procedures.

4. Universal Symbol Marking Requirements.

a. The following categories of Edible Medical Marijuana-Infused Products shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Medical Marijuana-Infused Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable.

i. Chocolate
ii. Soft confections
iii. Hard confections or lozenges
iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar)
v. Pressed pills and capsules

b. The Universal Symbol marking shall:

i. Be marked, stamped, or otherwise imprinted on at least one side of the Edible Medical Marijuana-Infused Product;

ii. Be centered either horizontally or vertically on the Edible Medical Marijuana-Infused Product; and

iii. If centered horizontally on the Edible Medical Marijuana-Infused Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's width, but not less than ¼ inch by ¼ inch; or

iv. If centered vertically on the Edible Medical Marijuana-Infused Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.

c. If a Medical Marijuana-Infused Products Manufacturer elects to determine portions for an Edible Medical Marijuana-Infused Product, then the Universal Symbol shall be applied to each portion in accordance with the requirements of subsubparagraph (C.5)(4)(b) of this rule M 604. Except that the size of the Universal Symbol marking shall be determined by the size of the portion instead of the overall product size, and shall not be less than ¼" by ¼".

d. Edible Medical Marijuana-Infused Products that are liquids, loose bulk goods (e.g. granola, cereals, popcorn), or powders, are exempt from the Universal Symbol marking requirements provided that they comply with the labeling and Child-Resistant Container packaging requirements of rule M 1004.5.

5. Remanufactured Products Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not utilize a commercially manufactured food product as its Edible Medical Marijuana-Infused Product. The following exceptions to this prohibition apply:

a. A food product that was commercially manufactured specifically for use by the Medical Marijuana-Infused Products Manufacturer Licensee to infuse with marijuana shall be allowed. The Licensee shall have a written agreement with the commercial food product manufacturer that declares the food product's exclusive use by the Medical Marijuana-Infused Products Manufacturer.

b. Commercially manufactured food products may be used as ingredients in a Medical Marijuana-Infused Products Manufacturer's Edible Medical Marijuana-Infused Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana-Infused Product, and (2) the Medical Marijuana-Infused Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana-Infused Product contains the commercially manufactured food product.

6. Trademarked Food Products. Nothing in this rule alters or eliminates a Medical Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.

D. Standard Operating Procedures

1. A Medical Marijuana-Infused Products Manufacturer must have written standard operating procedures for each category of Medical Marijuana Concentrate and type of Medical Marijuana-Infused Product that it produces.

a. All standard operating procedures for the production of a Medical Marijuana Concentrate must follow the requirements in Rule M 605.

b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana-Infused Products Manufacturer.

2. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its standard Medical Marijuana Concentrate or Medical Marijuana-Infused Product production process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

E. Independent Health and Sanitary Audit

1. State Licensing Authority May Require an Independent Health and Sanitary Audit

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Medical Marijuana-Infused Products Manufacturer to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana-Infused Products Manufacturer is in compliance with the requirements set forth in this rule or other applicable food handling laws, rules or regulations and in compliance with the concentrate production rules in Rule M 605 or other applicable laws, rules and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Medical Marijuana-Infused Products Manufacturer. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Medical Marijuana-Infused Products Manufacturer will be responsible for all direct costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the food handling training required for Owners and Occupational Licensees engaged in the production of Edible Medical Marijuana-Infused Products to the Division;

b. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the production of Medical Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or employees, or Production Batch specific records;

c. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer is in violation of one or more of the requirements set forth in this rule or Rule M 605; or

d. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product; or

e. Multiple Production Batches of Medical Marijuana Concentrate or Medical Marijuana-Infused Product produced by the Medical Marijuana-Infused Products Manufacturer failed contaminant testing.

3. Compliance Required. A Medical Marijuana-Infused Products Manufacturer must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this rule.

4. Suspension of Operations

a. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Medical Marijuana-Infused Products Manufacturer's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, the Medical Marijuana-Infused Products Manufacturer may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

ii. If an agreement to suspend operations is reached, then the Medical Marijuana-Infused Products Manufacturer may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to another Medical Marijuana Business during the period of time specified in the agreement. Depending on the condition of the Licensed Premises and required remedial measures, the Division may permit a Medical Marijuana-Infused Products Manufacturer to produce Medical Marijuana Concentrate or manufacture Medical Marijuana-Infused Product while operations have been suspended.

F. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Code of Colorado Regulations

Marijuana Enforcement Division, Adopted 11.1.2015

Basis and Purpose – M 605

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana-Infused Products Manufacturer and establish standards for the production of those concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S.

M 605 – Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

A. Permitted Categories of Medical Marijuana Concentrate Production

1. A Medical Marijuana-Infused Products Manufacturer may produce Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate.

2. A Medical Marijuana-Infused Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO2, ethanol, isopropanol, acetone, and heptane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.

3. Beginning on July 1, 2014, a Medical Marijuana-Infused Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this rule during the next formal rulemaking.

B. General Applicability. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

1. Ensure that the space in which any Medical Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required.

2. Ensure that all applicable sanitary rules are followed. See M 604.

3. Ensure that the standard operating procedure for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:

a. Conduct all necessary safety checks prior to commencing production;
b. Prepare Medical Marijuana for processing;
c. Extract cannabinoids and other essential components of Medical Marijuana;
d. Purge any solvent or other unwanted components from a Medical Marijuana Concentrate,
e. Clean all equipment, counters and surfaces thoroughly; and
f. Dispose of any waste produced during the processing of Medical Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule M 307 – Waste Disposal.

4. Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination.

5. Establish written emergency procedures to be followed by Owners or Occupational Licensees in case of a fire, chemical spill or other emergency.

6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises. The training manual must include, but need not be limited to, the following topics:

a. All standard operating procedures for each method of concentrate production used at that Licensed Premises;
b. The Medical Marijuana-Infused Products Manufacturer's quality control procedures;
c. The emergency procedures for that Licensed Premises;
d. The appropriate use of any necessary safety or sanitary equipment;
e. The hazards presented by all solvents used within the Licensed Premises as described in the material safety data sheet for each solvent;
f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
g. Any additional periodic cleaning required to comply with all applicable sanitary rules.

7. Provide adequate training to every Owner or Occupational Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate.

a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.

b. The individual training an Owner or Occupational Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner or Occupational Licensee can safely produce a Medical Marijuana Concentrate. See Rule M 901- Business Records Required.

c. The Owner or Occupational Licensee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules. See Rule M 901- Business Records Required.

8. Maintain clear and comprehensive records of the name, signature and Owner or Occupational License number of every individual who engaged in any step related to the creation of a Production Batch of Medical Marijuana Concentrate and the step that

C. Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate. Medical Marijuana-Infused Products Manufacturer that engages in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate must:

1. Ensure that all equipment, counters and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.

2. Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.

3. Ensure that any room in which dry ice is stored or used in processing Medical Marijuana into a Medical Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO2.

4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Water-Based Medical Marijuana Concentrate or Food-Based Medical Marijuana Concentrate.

5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-Based Medical Marijuana Concentrate.

6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Medical Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade. Individual performed. See Rule M 901- Business Records Required.

7. Follow all of the rules related to the production of a Solvent-Based Medical Marijuana Concentrate if a pressurized system is used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate.

D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana-Infused Products Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate must:

1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and standard operating procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a local jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (http://www.iccsafe.org), the International Fire Code of 2012 (http://www.iccsafe.org) or the National Electric Code of 2014 (http://www.nfpa.org), as appropriate. Note that this rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, which are available to the public;

a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Medical Marijuana into a Medical Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:

i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations.

ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights, junction boxes, must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations.

iii. Determine whether a gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

iv. Determine whether fire suppression system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

b. CO2 Solvent Determination. If CO2 is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO2 gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO2 is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Medical Marijuana Concentrate are to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.

d. Material Change. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its Licensed Premises, equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its standard operating procedures and, if changed, its Licensed Premises and equipment as well.

e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana-Infused Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Medical Marijuana into a Medical Marijuana Concentrate.

f. Records Retention. A Medical Marijuana-Infused Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule or regulation, compliance with this rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Medical Marijuana Concentrate on the Licensed Premises.

2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Medical Marijuana Concentrate must be food-grade and must not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;

3. Ensure that the room in which Solvent-Based Medical Marijuana Concentrate shall be produced must contain an emergency eye-wash station;

4. Ensure that a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Medical Marijuana Concentrate;

a. UL or ETL Listing

i. If the system is UL or ETL listed, then a Medical Marijuana-Infused Products Manufacturer may use the system in accordance with the manufacturer's instructions.

ii. If the system is UL or ETL listed but the Medical Marijuana-Infused Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Medical Marijuana-Infused Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

b. Ethanol or Isopropanol. A Medical Marijuana-Infused Products Manufacturer Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Medical Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.

5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;

a. A Medical Marijuana-Infused Products Manufacturer must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana-Infused Products Manufacturer must maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule M 901- Business Records Required.

b. A Medical Marijuana-Infused Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate.

6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Medical Marijuana-Infused Products Manufacturer store more Flammable Solvent on its Licensed Premises than the

maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;

7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner or Occupational Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and

8. Ensure that a trained Owner or Occupational Licensee is present at all times during the production of a Solvent-Based Medical Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.

E. Ethanol and Isopropanol. If a Medical Marijuana-Infused Products Manufacturer only produces Solvent-Based Medical Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from the requirements in paragraph D of this rule and instead must follow the requirements in paragraph C of this rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used.

F. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affection public safety.

APPENDIX II – SELECTED FEDERAL / STATE REQUIREMENTS IN COMPARISON TO EQUIVALENT ADHS REQUIREMENTS

Recordkeeping and Inventory	
FEDERAL & STATE	**ADHS**
Title 21 CFR Part 1304.04 Maintenance of records and inventories. (a)…every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration **Title 21 CFR Part 1304.11 Inventory requirements** (a) *General requirements*. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the	**Title 9, Chapter 17 Arizona Administrative Code R9-17-316 Inventory Control System** A Dispensary shall designate in writing a dispensary agent who has oversight of the Dispensary's medical marijuana inventory control system. A Dispensary shall only acquire marijuana from: The Dispensary's cultivation site, Another Dispensary or another Dispensary's cultivation site, A qualifying patient authorized by the Department to cultivate marijuana, or A designated caregiver authorized by the Department to cultivate marijuana. A Dispensary shall establish and implement an inventory control system for the Dispensary's medical marijuana that documents: Each day's beginning inventory, acquisitions, harvests, sales, disbursements, disposal of unusable marijuana, and ending inventory; For acquiring medical marijuana from a qualifying patient or designated caregiver: A description of the medical marijuana acquired including the amount and strain, The name and registry identification number of the qualifying patient or designated caregiver who provided the medical marijuana, The name and registry identification number of the dispensary agent receiving the medical marijuana on behalf of the Dispensary, and The date of acquisition; For acquiring medical marijuana from another Dispensary: A description of the medical marijuana acquired including the amount, strain, and batch number; The name and registry identification number of the Dispensary providing the medical marijuana; The name and registry identification number of the dispensary agent providing the medical marijuana;

Recordkeeping and Inventory	
FEDERAL & STATE	**ADHS**
inventory date and it shall be indicated on the inventory. (b) *Initial inventory date*. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. (c) *Biennial inventory date*. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. (d) *Inventory date for newly controlled substances*. On the effective date of a rule by the Administrator pursuant to§§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section. Title 21 CFR Part 1304.21 General requirements for continuing records. (a) Every registrant required to keep records pursuant to §1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory. (b) Separate records shall be maintained by a registrant for each registered location except as provided in Sec. 1304.04(a). In the event	The name and registry identification number of the dispensary agent receiving the medical marijuana on behalf of the Dispensary; and The date of acquisition; For each batch of marijuana cultivated: The batch number; Whether the batch originated from marijuana seeds or marijuana cuttings; The origin and strain of the marijuana seeds or marijuana cuttings planted; The number of marijuana seeds or marijuana cuttings planted; The date the marijuana seeds or cuttings were planted; A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers used in the cultivation; The number of plants grown to maturity; Harvest information including: Date of harvest, Final processed usable marijuana yield weight, and Name and registry identification number of the dispensary agent responsible for the harvest, and i. The disposal of medical marijuana that is not usable marijuana including the: Description of and reason for the marijuana being disposed of including, if applicable, the number of failed or other unusable plants; Date of disposal; Method of disposal; and Name and registry identification number of the dispensary agent responsible for the disposal; For providing medical marijuana to another Dispensary: The amount, strain, and batch number of medical marijuana provided; The name and registry identification number of the other Dispensary; The name and registry identification number of the Dispensary agent who received the medical marijuana on behalf of the other Dispensary; and The date the medical marijuana was provided; and For receiving edible food products infused with medical marijuana from another Dispensary:

Recordkeeping and Inventory	
FEDERAL & STATE	**ADHS**
controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible. (c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in §1304.22(d). (d) In recording dates of receipt, importation, distribution, exportation, other transfers, or destruction, the date on which the controlled substances are actually received, imported, distributed, exported, otherwise transferred, or destroyed shall be used as the date of receipt, importation, distribution, exportation, transfer, or destruction (e.g., invoices, packing slips, or DEA Form 41). (e) *Record of destruction*. In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to §1317.95(d), or causes the destruction of a controlled substance pursuant to §1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with §1304.22(c), and such record need not be maintained on a DEA Form 41.	A description of the edible food products received from the Dispensary including total weight of each edible food product and estimated amount and batch number of the medical marijuana infused in each edible food product, Total estimated amount and batch number of medical marijuana infused in the edible food products, The name and registry identification number of the: Dispensary and the dispensary agent providing the edible food products to the receiving Dispensary, and Dispensary agent receiving the edible food products on behalf of the receiving Dispensary, and The date the edible food products were provided to the Dispensary. The individual designated in subsection (A) shall conduct and document an audit of the Dispensary's inventory that is accounted for according to generally accepted accounting principles at least once every 30 calendar days. If the audit identifies a reduction in the amount of medical marijuana in the Dispensary's inventory not due to documented causes, the Dispensary shall determine where the loss has occurred and take and document corrective action. If the reduction in the amount of medical marijuana in the Dispensary's inventory is due to suspected criminal activity by a Dispensary agent, the Dispensary shall report the Dispensary agent to the Department and to the local law enforcement authorities. E. A Dispensary shall: Maintain the documentation required in subsections (C) and (D) at the Dispensary for five years from the date on the document, and Provide the documentation required in subsections (C) and (D) to the Department for review upon request.

Security and Reverse Distribution	
FEDERAL & STATE	**ADHS**
Title 21 CFR Part 1301.75 Physical security controls for practitioners (a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. (c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by §1317.80(d). (d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration. (e) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container. **Title 21 CFR Part 1317.05 Registrant disposal** (a) *Practitioner inventory*. Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways: (1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction; (2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location; (3) For the purpose of return or recall, promptly deliver that controlled substance by common or	**Title 9, Chapter 17 Arizona Administrative Code R9-17-318 Security** Except as provided in R9-17-310(A)(7), a Dispensary shall ensure that access to the enclosed, locked facility where marijuana is cultivated is limited to the dispensary's principal officers, board members, and authorized dispensary agents. A dispensary agent may transport marijuana, marijuana plants, and marijuana paraphernalia between the Dispensary and: The Dispensary's cultivation site, 2. A qualifying patient, and 3. Another Dispensary. Before transportation, a Dispensary agent shall: Complete a trip plan that includes: The name of the Dispensary agent in charge of transporting the marijuana; The date and start time of the trip; A description of the marijuana, marijuana plants, or marijuana paraphernalia being transported; and The anticipated route of transportation; and Provide a copy of the trip plan in subsection (C)(1) to the Dispensary. During transportation, a Dispensary agent shall: Carry a copy of the trip plan in subsection (C)(1) with the Dispensary agent for the duration of the trip; Use a vehicle without any medical marijuana identification; Have a means of communication with the Dispensary; and Ensure that the marijuana, marijuana plants, or marijuana paraphernalia are not visible. After transportation, a dispensary agent shall enter the end time of the trip and any changes to the trip plan on the trip plan required in subsection (C)(1). F. A Dispensary shall: Maintain the documents required in subsection (C)(2) and (E), and

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contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or (4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located. (i) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose. (ii) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners: (A) By transfer to a registrant authorized to transport or destroy the substance; (B) By delivery to an agent of the Administration or to the nearest office of the Administration; or (C) By destruction in the presence of an agent of the Administration or other authorized person. (5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances. **Title 21 CFR Part 1317.90 Methods of destruction** (a) All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to §1317.95(c), shall be destroyed in compliance with applicable Federal,	Provide a copy of the documents required in subsection (C)(2) and (E) to the Department for review upon request. G. To prevent unauthorized access to medical marijuana at the Dispensary and, if applicable, the Dispensary's cultivation site, the Dispensary shall have the following: 1. Security equipment to deter and prevent unauthorized entrance into limited access areas that include: Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic device; Exterior lighting to facilitate surveillance; Electronic monitoring including: i. At least one 19-inch or greater call-up monitor, ii. A video printer capable of immediately producing a clear still photo from any video camera image, iii. Video cameras: Providing coverage of all entrances to and exits from limited access areas and all entrances to and exits from the building, capable of identifying any activity occurring in or adjacent to the building; and Having a recording resolution of at least 704 x 480 or the equivalent; iv. A video camera at each point of sale location allowing for the identification of any qualifying patient or designated caregiver purchasing medical marijuana, A video camera in each grow room capable of identifying any activity occurring within the grow room in low light conditions, Storage of video recordings from the video cameras for at least 30 calendar days, A failure notification system that provides anaudible and visual notification of any failure in the electronic monitoring system, and Sufficient battery backup for video cameras and recording equipment to support at least five minutes of recording in the event of a power outage; and

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State, tribal, and local laws and regulations and shall be rendered non-retrievable. (b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present. (c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety. **Title 21 CFR Part 1317.95 Destruction procedures** **The destruction of any controlled substance shall be in accordance with the following requirements:** (a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction*. If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete. (b) *Transport to a registered location*. If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed: (1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);	Panic buttons in the interior of each building; and 2. Policies and procedures: a. That restrict access to the areas of the Dispensary that contain marijuana and if applicable, the Dispensary's cultivation site to authorized individuals only; b. That provide for the identification of authorized individuals; That prevent loitering; For conducting electronic monitoring; and For the use of a panic button. **Destruction** ***There are no specific destruction requirements outlined with Title 9 Chapter 17.***

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(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location; (3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete; (c) *Transport to a non-registered location*. If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed: (1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur); (2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location; (3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances; (4) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and (5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable. (d) *On-site destruction*. If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed: (1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and (2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.	

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Title 21 CFR Part 1316.03 Authority to make inspections In carrying out his functions under the Act, the Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of: (a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to part 1304 of this chapter, order form records required to be kept pursuant to part 1305 of this chapter, prescription and distribution records required to be kept pursuant to part 1306 of this chapter, records of listed chemicals, tableting machines, and encapsulating machines required to be kept pursuant to part 1310 of this chapter, import/export records of listed chemicals required to be kept pursuant to part 1313 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage. (b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to this Act; (c) Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises; (d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises);	**Title 9, Chapter 17 Arizona Administrative Code R9-17-309 Inspections** Submission of an application for a Dispensary registration certificate constitutes permission for entry to and inspection of the Dispensary and, if applicable, the Dispensary's cultivation site. Except as provided in subsection (D), an onsite inspection of a Dispensary or the Dispensary's cultivation site shall occur at a date and time agreed to by the Dispensary and the Department that is no later than five working days after the date the Department submits a written request to the Dispensary to schedule the certification or compliance inspection, unless the Department agrees to a later date and time. The Department shall not accept allegations of a Dispensary's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter from an anonymous source. If the Department receives an allegation of a Dispensary's or a Dispensary's cultivation site's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter, the Department may conduct an unannounced inspection of the Dispensary or the Dispensary's cultivation site. If the Department identifies a violation of A.R.S. Title 36, Chapter 28.1 or this Chapter during an inspection of a Dispensary or the Dispensary's cultivation site: The Department shall provide the Dispensary with a written notice that includes the specific rule or statute that was violated; and The Dispensary shall notify the Department in writing, with a postmark date within 20 working days after the date of the notice of violations, identifying the corrective actions taken and the date of the correction.

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(e) Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person (i.e., has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why); (f) Except as provided in **§1316.04**, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder. **Title 21 CFR Part 1316.05 Entry** **An inspection shall be carried out by an inspector.** Any such inspector, upon (a) stating his purpose and (b) presenting to the owner, operator or agent in charge of the premises to be inspected (1) appropriate credentials, and (2) written notice of his inspection authority under Sec. 1316.06 of this chapter, and (c) receiving informed consent under Sec. 1316.08 or through the use of administrative warrant issued under Secs. 1316.09-1316.13, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner. Title 21 CFR Part 1316.06 Notice of inspection The notice of inspection (DEA (or DNB) Form 82) shall contain: (a) The name and title of the owner, operator, or agent in charge of the controlled premises; (b) The controlled premises name; (c) The address of the controlled premises to be inspected; (d) The date and time of the inspection; (e) A statement that a notice of inspection is given pursuant to section 510 of the Act (**21 U.S.C. 880**); (f) A reproduction of the pertinent parts of section 510 of the Act; and (g) The signature of the inspector.	

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A.R.S. § 36-2602 of House Bill 2136 - requires the ASBP to establish a controlled substances prescription monitoring program that: Includes a computerized central database tracking system to track the prescribing, dispensing and consumption of Schedule II, III, and IV controlled substances in Arizona, Assists law enforcement in identifying illegal activity related to the prescribing, dispensing and consumption of Schedule II, III, and IV controlled substances, Provides information to patients, medical practitioners, and pharmacists to help avoid the inappropriate use of Schedule II, III, and IV controlled substances, and Is designed to minimize inconvenience to patients, prescribing medical practitioners and pharmacies while effectuating the collection and storage of information. The Board awarded a contract to Health Information Designs of Auburn, Alabama on March 31, 2008 to provide data collection, database storage and management, and web hosting services. In December 2013 the contract and system was changed to Optimum of Columbus, Ohio. The law requires anyone who dispenses Schedule II, III, IV controlled substances to report the dispensing of these drugs to the database. Mandatory reporting by pharmacies began on October 17, 2008. The Board began collecting dispensing practitioner's data in October 2009. The purpose of this legislation is to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription controlled substance drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances. The primary function of the ASBP is to provide a central repository of all prescriptions dispensed	**Title 9, Chapter 17 Arizona Administrative Code R9-17-315 Qualifying Patient Records**. A Dispensary shall ensure that: A qualifying patient record is established and maintained for each qualifying patient who obtains medical marijuana from the Dispensary; An entry in a qualifying patient record: Is recorded only by a dispensary agent authorized by Dispensary policies and procedures to make an entry, Is dated and signed by the dispensary agent, Includes the dispensary agent's registry identification number, and Is not changed to make the initial entry illegible; If an electronic signature is used to sign an entry, the dispensary agent whose signature the electronic code represents is accountable for the use of the electronic signature; A qualifying patient record is only accessed by a dispensary agent authorized by Dispensary policies and procedures to access the qualifying patient record; A qualifying patient record is provided to the Department for review upon request; A qualifying patient record is protected from loss, damage, or unauthorized use; and A qualifying patient record is maintained for five years from the date of the qualifying patient's or, if applicable, the qualifying patient's designated caregiver's last request for medical marijuana from the Dispensary. If a Dispensary maintains qualifying patient records electronically, the Dispensary shall ensure that: There are safeguards to prevent unauthorized access, and The date and time of an entry in a qualifying patient record is recorded electronically by an internal clock. A Dispensary shall ensure that the qualifying patient record for a qualifying patient who requests or whose designated caregiver on behalf

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for Schedule II, III, and IV controlled substances in Arizona. Authorized persons may request information from this repository to assist them in treating patients and identifying and deterring drug diversion, consistent with A.R.S. § 36-2604. Assuring confidentiality and the security of the data is a primary consideration for this program for all aspects to include data collection and storage, transmission of requests, and dissemination of reports. ARS 36-2606. Registration; requirements (L07, Ch. 269, sec. 4. Eff. until 1/1/16) A. Beginning November 1, 2007 and pursuant to rules adopted by the board, each medical practitioner who is issued a license pursuant to title 32 and who possesses a registration under the federal controlled substances act must have a current controlled substances prescription monitoring program registration issued by the board. The registration is: 1. Subject to biennial renewal as specified in this article. 2. Not transferable or assignable. 3. Valid only in conjunction with a valid license issued by a professional licensing board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 21, 25 or 29. B. An applicant for registration pursuant to this section must submit an application as prescribed by the board. C. The board shall assign all persons registered under this article to one of two registration renewal groups. The holder of a registration ending in an even number must renew the registration biennially on or before May 1 of the next even-numbered year. The holder of a registration ending in an odd number must renew the registration biennially on or before May 1 of the next odd-numbered year. The board shall automatically suspend the registration of any registrant who fails to renew the registration on or before May 1 of the year in which the renewal is due. The board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing	of the qualifying patient requests medical marijuana from the Dispensary contains: Qualifying patient information that includes: The qualifying patient's name; The qualifying patient's date of birth; and The name of the qualifying patient's designated caregiver, if applicable; Documentation of any patient education and support materials provided to the qualifying patient or the qualifying patient's designated caregiver, including a description of the materials and the date the materials were provided; For each time the qualifying patient requests and does not obtain medical marijuana or, if applicable, the designated caregiver requests on behalf of the qualifying patient and does not obtain medical marijuana from the Dispensary, the following: The date, The name and registry identification number of the individual who requested the medical marijuana, and The Dispensary's reason for refusing to provide the medical marijuana. **36-2804. Registration and certification of nonprofit medical marijuana dispensaries** (Caution: 1998 Prop. 105 applies) A. Nonprofit medical marijuana dispensaries shall register with the department. B. Not later than ninety days after receiving an application for a nonprofit medical marijuana Dispensary, the department shall register the nonprofit medical marijuana Dispensary and issue a registration certificate and a random 20-digit alphanumeric identification number if: 1. The prospective nonprofit medical marijuana Dispensary has submitted the following: (a) The application fee. (b) An application, including: (i) The legal name of the nonprofit medical marijuana Dispensary. (ii) The physical address of the nonprofit medical marijuana Dispensary and the physical address of one additional location, if any, where marijuana

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information in the prescription monitoring program database tracking system. D. A registrant shall not apply for registration renewal more than sixty days before the expiration date of the registration. E. An applicant for registration renewal pursuant to this section must submit a renewal application prescribed by the board by rule. F. Pursuant to a fee prescribed by the board by rule, the board may issue a replacement registration to a registrant who requests a replacement because the original was damaged or destroyed, because of a change of name or for any other good cause as prescribed by the board.	will be cultivated, neither of which may be within five hundred feet of a public or private school existing before the date of the nonprofit medical marijuana Dispensary application. (iii) The name, address and date of birth of each principal officer and board member of the nonprofit medical marijuana Dispensary. (iv) The name, address and date of birth of each nonprofit medical marijuana dispensary agent. (c) Operating procedures consistent with department rules for oversight of the nonprofit medical marijuana Dispensary, including procedures to ensure accurate record-keeping and adequate security measures. (d) If the city, town or county in which the nonprofit medical marijuana Dispensary would be located has enacted zoning restrictions, a sworn statement certifying that the registered nonprofit medical marijuana Dispensary is in compliance with the restrictions. 2. None of the principal officers or board members has been convicted of an excluded felony offense. 3. None of the principal officers or board members has served as a principal officer or board member for a registered nonprofit medical marijuana Dispensary that has had its registration certificate revoked. 4. None of the principal officers or board members is under twenty-one years of age. C. The department may not issue more than one nonprofit medical marijuana Dispensary registration certificate for every ten pharmacies that have registered under section 32-1929, have obtained a pharmacy permit from the Arizona board of pharmacy and operate within the state except that the department may issue nonprofit medical marijuana Dispensary registration certificates in excess of this limit if necessary to ensure that the department issues at least one nonprofit medical marijuana Dispensary registration certificate in each county in which an application has been approved. D. The department may conduct a criminal records check in order to carry out this section.

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	36-2804.01. <u>Registration of nonprofit medical marijuana Dispensary agents; notices; civil penalty; classification</u> (Caution: 1998 Prop. 105 applies) A. A nonprofit medical marijuana dispensary agent shall be registered with the department before volunteering or working at a medical marijuana Dispensary. B. A nonprofit medical marijuana Dispensary may apply to the department for a registry identification card for a nonprofit medical marijuana dispensary agent by submitting: 1. The name, address and date of birth of the nonprofit medical marijuana dispensary agent. 2. A nonprofit medical marijuana dispensary agent application. 3. A statement signed by the prospective nonprofit medical marijuana dispensary agent pledging not to divert marijuana to anyone who is not allowed to possess marijuana pursuant to this chapter. 4. The application fee. C. A registered nonprofit medical marijuana Dispensary shall notify the department within ten days after a nonprofit medical marijuana dispensary agent ceases to be employed by or volunteer at the registered nonprofit medical marijuana Dispensary. D. No person who has been convicted of an excluded felony offense may be a nonprofit medical marijuana dispensary agent. E. The department may conduct a criminal records check in order to carry out this section. **Title 9, Chapter 17 Arizona Administrative Code R9-17-103 Application Submission** An applicant submitting an application for a registry identification card or to amend, change, or replace a registry identification card for a qualifying patient, designated caregiver, or dispensary agent shall submit the application electronically in a Department-provided format. A residence address or mailing address submitted for a qualifying patient or designated caregiver as part of an application for a registry identification card is located in Arizona.

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	A mailing address submitted for a principal officer or board member as part of a Dispensary certificate registration application or as part of an application for a dispensary agent registration identification card is located in Arizona. **R9-17-202. Applying for a Registry Identification Card for a Qualifying Patient or a Designated Caregiver** **A.** Except for a qualifying patient who is under 18 years of age, a qualifying patient is not required to have a designated caregiver. **B.** A qualifying patient may have only one designated caregiver at any given time. **C.** Except for a qualifying patient who is under 18 years of age, if the information submitted for a qualifying patient complies with A.R.S. Title 36, Chapter 28.1 and this Chapter but the information for the qualifying patient's designated caregiver does not comply with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall issue the registry identification card for the qualifying patient separate from issuing a registry identification card for the qualifying patient's designated caregiver. **D.** If the Department issues a registry identification card to a qualifying patient under subsection (C), the Department shall continue the process for issuing or denying the qualifying patient's designated caregiver's registry identification card. **E.** The Department shall not issue a designated caregiver's registry identification card before the Department issues the designated

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	caregiver's qualifying patient's registry identification card. **F.** Except as provided in subsection (G), to apply for a registry identification card, a qualifying patient shall submit to the Department the following: 1. An application in a Department-provided format that includes: a. The qualifying patient's: i. First name; middle initial, if applicable; last name; and suffix, if applicable; ii. Date of birth; and iii. Gender; b. Except as provided in subsection (F)(1)(i), the qualifying patient's residence address and mailing address; c. The county where the qualifying patient resides; d. The qualifying patient's e-mail address; e. The identifying number on the applicable card or document in subsection (F)(2)(a) through (e); f. The name, address, and telephone number of the physician providing the written certification for medical marijuana for the qualifying patient; g. Whether the qualifying patient is requesting authorization for cultivating marijuana plants for the qualifying patient's medical use because the qualifying patient believes that the qualifying patient resides at least 25 miles from the nearest operating Dispensary; h. If the qualifying patient is requesting authorization for cultivating marijuana plants, whether the qualifying patient is designating the qualifying patient's designated caregiver to cultivate marijuana plants for the qualifying patient's medical use;

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	i. If the qualifying patient is homeless, an address where the qualifying patient can receive mail; j. Whether the qualifying patient would like notification of any clinical studies needing human subjects for research on the medical use of marijuana; k. An attestation that the information provided in the application is true and correct; and l. The signature of the qualifying patient and date the qualifying patient signed; 2. A copy of the qualifying patient's: a. Arizona driver's license issued on or after October 1, 1996; b. Arizona identification card issued on or after October 1, 1996; c. Arizona registry identification card; d. Photograph page in the qualifying patient's U.S. passport; or e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the qualifying patient: i. Birth certificate verifying U.S. citizenship, ii. U.S. Certificate of Naturalization, or iii. U.S. Certificate of Citizenship; 3. A current photograph of the qualifying patient; 4. A statement in a Department-provided format signed by the qualifying patient pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; 5. A physician's written certification in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's application that

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	includes: a. The physician's: i. Name, ii. License number including an identification of the physician license type, iii. Office address on file with the physician's licensing board, iv. Telephone number on file with the physician's licensing board, and v. E-mail address; b. The qualifying patient's name and date of birth; c. A statement that the physician has made or confirmed a diagnosis of a debilitating medical condition as defined in A.R.S. § 36-2801 for the qualifying patient; d. An identification, initialed by the physician, of one or more of the debilitating medical conditions in R9- 17-201 as the qualifying patient's specific debilitating medical condition; e. If the debilitating medical condition identified in subsection (F)(5)(d) is a condition in: i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; orii. R9-17-201(14), the debilitating medical condition; f. A statement, initialed by the physician, that the physician: i. Has established a medical record for the qualifying patient, and ii. Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297; g. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90 calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's

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	debilitating medical condition diagnosed or confirmed by the physician; h. The date the physician conducted the in-person physical examination of the qualifying patient; i. A statement, initialed by the physician, that the physician reviewed the qualifying patient's: i. Medical records including medical records from other treating physicians from the previous 12 months, ii. Response to conventional medications and medical therapies, and iii. Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database; j. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient; k. A statement, initialed by the physician, that in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of marijuana to treat or alleviate the qualifying patient's debilitating medical condition; l. A statement, initialed by the physician, that if the physician has referred the qualifying patient to a Dispensary, the physician has disclosed to the qualifying patient any personal or professional relationship the physician has with the Dispensary; m. An attestation that the information provided in the written certification is true and correct; and n. The physician's signature and the date the physician signed; 6. If the qualifying patient is designating a caregiver, the

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	following in a Department-provided format: a. The designated caregiver's first name; middle initial, if applicable; last name; and suffix, if applicable; b. The designated caregiver's date of birth; c. The designated caregiver's residence address and mailing address; d. The county where the designated caregiver resides; e. The identifying number on the applicable card or document in subsection (F)(6)(i)(i) through (v); f. One of the following: i. A statement that the designated caregiver does not currently hold a valid registry identification card, or ii. The assigned registry identification number for the designated caregiver for each valid registry identification card currently held by the designated caregiver; g. An attestation signed and dated by the designated caregiver that the designated caregiver has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; h. A statement signed by the designated caregiver: i. Agreeing to assist the qualifying patient with the medical use of marijuana; and ii. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; i. A copy of the designated caregiver's: i. Arizona driver's license issued on or after October 1, 1996; ii. Arizona identification card issued on or after October 1, 1996; iii. Arizona registry identification card; iv. Photograph page in the designated caregiver's U.S. passport; or v. Arizona driver's license or identification card

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	issued before October 1, 1996 and one of the following for the designated caregiver: (1) Birth certificate verifying U.S. citizenship, (2) U.S. Certificate of Naturalization, or (3) U.S. Certificate of Citizenship; j. A current photograph of the designated caregiver; and k. For the Department's criminal records check authorized in A.R.S. § 36-2804.05: i. The designated caregiver's fingerprints on a fingerprint card that includes: (1) The designated caregiver's first name; middle initial, if applicable; and last name; (2) The designated caregiver's signature; (3) If different from the designated caregiver, the signature of the individual physically rolling the designated caregiver's fingerprints; (4) The designated caregiver's address; (5) If applicable, the designated caregiver's surname before marriage and any names previously used by the designated caregiver; (6) The designated caregiver's date of birth; (7) The designated caregiver's Social Security number; (8) The designated caregiver's citizenship status; (9) The designated caregiver's gender; (10) The designated caregiver's race; (11) The designated caregiver's height; (12) The designated caregiver's weight; (13) The designated caregiver's hair color; (14) The designated caregiver's eye color; and (15) The designated caregiver's place of birth; or ii. If the designated caregiver's fingerprints and information required in subsection (F)(6)(k)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the designated caregiver as a result of the application; and

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	7. The applicable fees in R9-17-102 for applying for: a. A qualifying patient registry identification card; and If applicable, a designated caregiver registry identification card. G. To apply for a registry identification card for a qualifying patient who is under 18 years of age, the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient shall submit to the Department the following: 1. An application in a Department-provided format that includes: a. The qualifying patient's: i. First name; middle initial, if applicable; last name; and suffix, if applicable; ii. Date of birth; and iii. Gender; b. The qualifying patient's residence address and mailing address; c. The county where the qualifying patient resides; d. The qualifying patient's custodial parent's or legal guardian's first name; middle initial, if applicable; last name; and suffix, if applicable; e. The identifying number on the applicable card or document in subsection (G)(5)(a) through (e); f. The qualifying patient's custodial parent's or legal guardian's residence address and mailing address; g. The county where the qualifying patient's custodial parent or legal guardian resides; h. The qualifying patient's custodial parent's or legal guardian's e-mail address;

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	i. The name, address, and telephone number of a physician who has a physician-patient relationship with the qualifying patient and is providing the written certification for medical marijuana for the qualifying patient; j. The name, address, and telephone number of a second physician who has conducted a comprehensive review of the patient's medical record maintained by other treating physicians, and is providing a written certification for medical marijuana for the qualifying patient; k. The qualifying patient's custodial parent's or legal guardian's date of birth; l. Whether the qualifying patient's custodial parent or legal guardian is requesting authorization for cultivating medical marijuana plants for the qualifying patient's medical use because the qualifying patient's custodial parent or legal guardian believes that the qualifying patient resides at least 25 miles from the nearest operating Dispensary; m. Whether the qualifying patient's custodial parent or legal guardian would like notification of any clinical studies needing human subjects for research on the medical use of marijuana; n. Whether the individual submitting the application on behalf of the qualifying patient under 18 years of age is the qualifying patient's custodial parent or legal guardian; o. One of the following:

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	i. A statement that the qualifying patient's custodial parent or legal guardian does not currently hold a valid registry identification card, or ii. The assigned registry identification number for the qualifying patient's custodial parent or legal guardian for each valid registry identification card currently held by the qualifying patient's custodial parent or legal guardian; p. An attestation that the information provided in the application is true and correct; and q. The signature of the qualifying patient's custodial parent or legal guardian and the date the qualifying patient's custodial parent or legal guardian signed; 2. A current photograph of the: a. Qualifying patient, and b. Qualifying patient's custodial parent or legal guardian serving as the qualifying patient's designated caregiver; 3. An attestation in a Department-provided format signed and dated by the qualifying patient's custodial parent or legal guardian that the qualifying patient's custodial parent or legal guardian has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; 4. A statement in a Department-provided format signed by the qualifying patient's custodial parent or legal guardian who is serving as the qualifying patient's designated caregiver: a. Allowing the qualifying patient's medical use of marijuana; b. Agreeing to assist the qualifying patient with the medical use of marijuana; and

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	c. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; 5. A copy of one of the following for the qualifying patient's custodial parent or legal guardian: a. Arizona driver's license issued on or after October 1, 1996; b. Arizona identification card issued on or after October 1, 1996; c. Arizona registry identification card; d. Photograph page in the qualifying patient's custodial parent or legal guardian U.S. passport; or e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the qualifying patient's custodial parent or legal guardian: i. Birth certificate verifying U.S. citizenship, ii. U. S. Certificate of Naturalization, or iii. U. S. Certificate of Citizenship; 6. If the individual submitting the application on behalf of a qualifying patient is the qualifying patient's legal guardian, a copy of documentation establishing the individual as the qualifying patient's legal guardian; 7. For the Department's criminal records check authorized in A.R.S. § 36-2804.05: a. The qualifying patient's custodial parent or legal guardian's fingerprints on a fingerprint card that includes: i. The qualifying patient's custodial parent or legal guardian's first name; middle initial, if applicable; and last name; ii. The qualifying patient's custodial parent or

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	legal guardian's signature; iii. If different from the qualifying patient's custodial parent or legal guardian, the signature of the individual physically rolling the qualifying patient's custodial parent's or legal guardian's fingerprints; iv. The qualifying patient's custodial parent's or legal guardian's address; v. If applicable, the qualifying patient's custodial parent's or legal guardian's surname before marriage and any names previously used by the qualifying patient's custodial parent or legal guardian; vi. The qualifying patient's custodial parent's or legal guardian's date of birth; vii. The qualifying patient's custodial parent's or legal guardian's Social Security number; viii. The qualifying patient's custodial parent's or legal guardian's citizenship status; ix. The qualifying patient's custodial parent's or legal guardian's gender; x. The qualifying patient's custodial parent's or legal guardian's race; xi. The qualifying patient's custodial parent's or legal guardian's height; xii. The qualifying patient's custodial parent's or legal guardian's weight; xiii. The qualifying patient's custodial parent's or legal guardian's hair color; xiv. The qualifying patient's custodial parent's or legal guardian's eye color; and xv. The qualifying patient's custodial parent's or legal guardian's place of birth; or b. If the qualifying patient's custodial parent's or legal guardian's fingerprints and information required in subsection (G)(7)(a) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification

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	card issued to the qualifying patient's custodial parent or legal guardian as a result of the application; 8. A written certification from the physician in subsection (G)(1)(i) and a separate written certification from the physician in (G)(1)(j) in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's application that includes: a. The physician's: i. Name, ii. License number including an identification of the physician license type, iii. Office address on file with the physician's licensing board, iv. Telephone number on file with the physician's licensing board, and v. E-mail address; b. The qualifying patient's name and date of birth; c. An identification of one or more of the debilitating medical conditions in R9-17-201 as the qualifying patient's specific debilitating medical condition; d. If the debilitating medical condition identified in subsection (G)(9)(c) is a condition in: i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; or ii. R9-17-201(14), the debilitating medical condition; e. For the physician listed in subsection (G)(1)(i): i. A statement that the physician has made or confirmed a diagnosis of a debilitating medical condition as defined in A.R.S. § 36-2801 for the qualifying patient; ii. A statement, initialed by the physician, that the physician: (1) Has established a medical record for the qualifying patient, and

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	(2) Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297; iii. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90 calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's debilitating medical condition diagnosed or confirmed by the physician; iv. The date the physician conducted the in-person physical examination of the qualifying patient; v. A statement, initialed by the physician, that the physician reviewed the qualifying patient's: (1) Medical records including medical records from other treating physicians from the previous 12 months, (2) Response to conventional medications and medical therapies, and (3) Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database; and vi. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the use of medical marijuana to the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient; f. For the physician listed in subsection (G)(1)(j), a statement, initialed by the physician, that the physician conducted a comprehensive review of the qualifying patient's medical records from other treating physicians; g. A statement, initialed by the physician, that, in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of marijuana to treat or alleviate the qualifying patient's debilitating medical condition; h. A statement, initialed by the physician, that if the

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	physician has referred the qualifying patient's custodial parent or legal guardian to a Dispensary, the physician has disclosed to the qualifying patient any personal or professional relationship the physician has with the Dispensary; i. An attestation that the information provided in the written certification is true and correct; and j. The physician's signature and the date the physician signed; and 9. The applicable fees in R9-17-102 for applying for a: a. Qualifying patient registry identification card, and b. Designated caregiver registry identification card. H. For purposes of this Article, "25 miles" includes the area contained within a circle that extends for 25 miles in all directions from a specific location. I. For purposes of this Article, "residence address" when used in conjunction with a qualifying patient means: 1. The street address including town or city and zip code assigned by a local jurisdiction; or 2. For property that does not have a street address assigned by a local jurisdiction, the legal description of the property on the title documents recorded by the assessor of the county in which the property is located. Historical Note New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

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Arizona Administrative Code **R4-23-606. Resident Pharmacy Permit:** Community, Hospital, and Limited Service A. Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued pharmacy permit. B. Application. 1. To obtain a permit to operate a pharmacy in Arizona, a person shall submit a completed application form and fee as specified in R4-23-602 that includes: a. Documentation of compliance with local zoning laws, if required by the Board; b. A detailed floor plan showing proposed pharmacy area including size and security; c. A copy of the lease agreement, if applicable; and; d. A disclosure statement indicating whether a medical practitioner will receive compensation, either directly or indirectly, from the pharmacy; 2. Before issuing a pharmacy permit, the Board shall: a. Receive and approve a completed permit application; and b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer. 3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting based on the need for additional information. C. Notification. A pharmacy permittee shall notify the Board office within ten days of changes involving the type of pharmacy operated, telephone number, facsimile number, e-mail address, mailing address, name of business, or staff pharmacist. A pharmacy permittee shall provide the Board of immediate notice of a change of the pharmacist-in-charge. D. If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current, Board-issued nonprescription drug permit as required in Section R4-23-603. E. Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an	**Title 9, Chapter 17 Arizona Administrative Code** **R9-17-304. Applying for a Dispensary:** Registration Certificate A. An individual shall not be an applicant, principal officer, or board member on: 1. More than one Dispensary registration certificate application for a location in a single CHAA, or 2. More than five Dispensary registration certificate applications for locations in different CHAAs. B. If the Department determines that an individual is an applicant, principal officer, or board member on more than one Dispensary registration certificate application for a CHAA or more than five Dispensary registration certificate applications, the Department shall review the applications and provide the applicant on each of the Dispensary registration certificate applications with a written comprehensive request for more information that includes the specific requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter that the Dispensary registration certificate application does not comply with. 1. If an applicant withdraws an application to comply with this Chapter and submits information demonstrating compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall process the applicant's remaining Dispensary registration certificate applications according to this Chapter. 2. If an applicant does not withdraw an application or submit information demonstrating compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall issue a denial to the applicant according to R9-17322. 3. An application fee submitted with a Dispensary registration certificate application in subsection (B) that is withdrawn is not refunded. C. To apply for a Dispensary registration certificate, an entity shall submit to the Department the following: 1. An application in a Department-provided format that includes: a. The legal name of the Dispensary; b. The physical address of the proposed Dispensary; c. The following

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existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B). F. Relocation or remodel. 1. No less than 30 days before the relocation of remodel of an existing pharmacy, the pharmacy permittee shall submit a completed application for remodel or relocation electronically or manually on a form furnished by the Board. a. An application for relocation shall included the documents required by subsections (B)(1)(a) through (d). b. An application for remodel shall included the documents required by subsection (B)(1)(b). 2. The new or remodeled facility shall pass a final inspection by a Board compliance officer before operations begin. G. Permit renewal.	information for the entity applying: i. Name, ii. Type of business organization, iii. Mailing address, iv. Telephone number, and v. E-mail address; d. The name of the individual designated to submit dispensary agent registry identification card applications on behalf of the Dispensary; e. The name and license number of the Dispensary's medical director; f. The name, residence address, and date of birth of each: i. Principal officer, and ii. Board member; g. For each principal officer or board member, whether the principal officer or board member: i. Has served as a principal officer or board member for a Dispensary that had the Dispensary registration certificate revoked; ii. Is a physician currently providing written certifications for qualifying patients; iii. Is a law enforcement officer; or iv. Is employed by or a contractor of the Department; h. Whether the entity agrees to allow the Department to submit supplemental requests for information; i. A statement that, if the Dispensary is issued a Dispensary registration certificate, the Dispensary will not operate until the Dispensary is inspected and obtains an approval to operate from the Department; j. An attestation that the information provided to the Department to apply for a Dispensary registration certificate is true and correct; and k. The signatures of the principal officers of the Dispensary according to R9-17-301(A) and the date the principal officers signed; 2. If the entity applying is one of the business organizations in R9-17-301(A)(2) through (7), a copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents that include: a. The name of the business organization, b. The type of business organization, and c. The names and titles of the individuals in R9-17301(A) and (B); 3. For each principal officer and board member: a. An attestation signed and dated by the principal officer or board member that the principal officer or board member has not been convicted of an excluded felony offense as defined in A.R.S. § 362801; and b. For the Department's criminal

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	records check authorized in A.R.S. § 36-2804.05: i. The principal officer's or board member's fingerprints on a fingerprint card that includes: (1) The principal officer's or board member's first name; middle initial, if applicable; and last name; (2) The principal officer's or board member's signature; (3) If different from the principal officer or board member, the signature of the individual physically rolling the principal officer's or board member's fingerprints; (4) The principal officer's or board member's residence address; (5) If applicable, the principal officer's or board member's surname before marriage and any names previously used by the principal officer or board member; (6) The principal officer's or board member's date of birth; (7) The principal officer's or board member's Social Security number; (8) The principal officer's or board member's citizenship status; (9) The principal officer's or board member's gender; (10) The principal officer's or board member's race; (11) The principal officer's or board member's height; (12) The principal officer's or board member's weight; (13) The principal officer's or board member's hair color; (14) The principal officer's or board member's eye color; and Supp. 12-4 Page 20 December 31, 2012 Title 9, Ch. 17 Arizona Administrative Code Department of Health Services – Medical Marijuana Program (15) The principal officer's or board member's place of birth; or ii. If the fingerprints and information required in subsection (C)(3)(b)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the principal officer or board member as a result of the application; 4. Policies and procedures that comply with the requirements in this Chapter for: a. Inventory control, b. Qualifying patient recordkeeping, c. Security, and d. Patient education and support; 5. As required in A.R.S. § 36-2804(B)(1)(d), a sworn statement

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	signed and dated by the individual or individuals in R9-17-301(A) certifying that the Dispensary is in compliance with any local zoning restrictions; 6. Documentation from the local jurisdiction where the Dispensary's proposed physical address is located that: a. There are no local zoning restrictions for the Dispensary's location, or b. The Dispensary's location is in compliance with any local zoning restrictions; 7. Documentation of: a. Ownership of the physical address of the proposed Dispensary, or b. Permission from the owner of the physical address of the proposed Dispensary for the entity applying for a Dispensary registration certificate to operate a Dispensary at the physical address; 8. The Dispensary's by-laws including: a. The names and titles of individuals designated as principal officers and board members of the Dispensary; b. Whether the Dispensary plans to: i. Cultivate marijuana; ii. Acquire marijuana from qualifying patients, designated caregivers, or other dispensaries; iii. Sell or provide marijuana to other dispensaries; iv. Transport marijuana; v. Prepare, sell, or dispense marijuana-infused edible food products; vi. Prepare, sell, or dispense marijuana-infused non-edible products; vii. Sell or provide marijuana paraphernalia or other supplies related to the administration of marijuana to qualifying patients and designated caregivers; viii. Deliver medical marijuana to qualifying patients; or ix. Provide patient support and related services to qualifying patients; c. Provisions for the disposition of revenues and receipts to ensure that the Dispensary operates on a not-for-profit basis; and d. Provisions for amending the Dispensary's by-laws; 9. A business plan demonstrating the on-going viability of the Dispensary on a not-for-profit basis that includes: a. A description and total dollar amount of expenditures already incurred to establish the Dispensary or to secure a Dispensary registration certificate by the individual or business organization applying for the Dispensary registration certificate, b. A description and total dollar amount of monies or tangible assets received for operating the

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	Dispensary from entities other than the individual applying for the Dispensary registration certificate or a principal officer or board member associated with the Dispensary including the entity's name and the interest in the Dispensary or the benefit the entity obtained, c. Projected expenditures expected before the Dispensary is operational, d. Projected expenditures after the Dispensary is operational, and e. Projected revenue; and 10. The applicable fee in R9-17-102 for applying for a Dispensary registration certificate. D. Before an entity with a Dispensary registration certificate begins operating a Dispensary, the entity shall apply for and obtain an approval to operate a Dispensary from the Department. **Title 9, Chapter 17 Arizona Administrative Code** **R9-17-305. Applying for Approval to Operate a Dispensary** A. To apply for approval to operate a Dispensary, a person holding a Dispensary registration certificate shall submit to the Department, at least 60 calendar days before the expiration of the Dispensary registration certificate, the following: 1. An application in a Department-provided format that includes: a. The name and registry identification number of the Dispensary; b. The physical address of the Dispensary; c. The name, address, and date of birth of each dispensary agent; d. The name and license number of the dispensary's medical director; e. If applicable, the physical address of the Dispensary's cultivation site; f. The Dispensary's Transaction Privilege Tax Number issued by the Arizona Department of Revenue; g. The Dispensary's proposed hours of operation during which the Dispensary plans to be available to dispense medical marijuana to qualifying patients and designated caregivers; h. Whether the Dispensary agrees to allow the Department to submit supplemental requests for information; i. Whether the Dispensary and, if applicable, the Dispensary's cultivation site are ready for an inspection by the Department; j. If the Dispensary and, if applicable, the

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	Dispensary's cultivation site are not ready for an inspection by the Department, the date the Dispensary and, if applicable, the Dispensary's cultivation site will be ready for an inspection by the Department; k. An attestation that the information provided to the Department to apply for approval to operate a Dispensary is true and correct; and Arizona Administrative Code Title 9, Ch. 17 Department of Health Services – Medical Marijuana Program December 31, 2012 Page 21 Supp. 12-4 l. The signatures of the principal officers of the Dispensary according to R9-17-301(A) and the date the principal officers signed; 2. A copy of documentation issued by the local jurisdiction to the Dispensary authorizing occupancy of the building as a Dispensary and, if applicable, as the Dispensary's cultivation site, such as a certificate of occupancy, a special use permit, or a conditional use permit; 3. A sworn statement signed and dated by the individual or individuals in R9-17-301(A) certifying that the Dispensary is in compliance with local zoning restrictions; 4. The distance to the closest private school or public school from: a. The Dispensary; and b. If applicable, the Dispensary's cultivation site; 5. A site plan drawn to scale of the Dispensary location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; 6. A floor plan drawn to scale of the building where the Dispensary is located showing the: a. Layout and dimensions of each room, b. Name and function of each room, c. Location of each hand washing sink, d. Location of each toilet room, e. Means of egress, f. Location of each video camera, g. Location of each panic button, and h. Location of natural and artificial lighting sources; 7. If applicable, a site plan drawn to scale of the Dispensary's cultivation site showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and 8. If applicable, a floor plan

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	drawn to scale of each building at the Dispensary's cultivation site showing the: a. Layout and dimensions of each room, b. Name and function of each room, c. Location of each hand washing sink, d. Location of each toilet room, e. Means of egress, f. Location of each video camera, g. Location of each panic button, and h. Location of natural and artificial lighting sources. B. A Dispensary's cultivation site may be located anywhere in the state where a cultivation site is allowed by the local jurisdiction.

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Arizona Administrative Code **ARTICLE 11. PHARMACY TECHNICIANS** **R4-23-1101.** Licensure and Eligibility A. License required. A person shall not work as a pharmacy technician or pharmacy technician trainee in Arizona, unless the person possesses a pharmacy technician or pharmacy technician trainee license issued by the Board. B. Eligibility. 1. To be eligible for licensure as a pharmacy technician trainee, a person shall: a. Be of good moral character, b. Be at least 18 years of age, and c. Have a high school diploma or the equivalent of a high school diploma. 2. To be eligible for licensure as a pharmacy technician, a person shall: a. Meet the requirements of subsection (B)(1), b. Complete a pharmacy technician training program that meets the standards prescribed in R4-23-1105, and c. Pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination. C. A pharmacy technician delinquent license. Before an Arizona pharmacy technician license will be reinstated, a pharmacy technician whose Arizona pharmacy technician license is delinquent for five or more consecutive years shall furnish to the Board satisfactory proof of fitness to be licensed as a pharmacy technician and pay all past due biennial renewal fees and penalty fees. Satisfactory proof includes: 1. For a person with a delinquent license	**Title 9, Chapter 17 Arizona Administrative Code R9-17-311 Submitting an Application for a Dispensary Agent Registry Identification Card** **Except as provided in R9-17-107(F), to obtain a Dispensary agent registry identification card for an individual serving as a principal officer or board member for the Dispensary, employed by the Dispensary, or providing volunteer services at or on behalf of the Dispensary, the Dispensary shall submit to the Department the following for each Dispensary agent:** An application in a Department-provided format that includes: The dispensary agent's first name; middle initial, if applicable; last name; and suffix, if applicable; The dispensary agent's residence address and mailing address; The county where the dispensary agent resides; The dispensary agent's date of birth; The identifying number on the applicable card or document in subsection (5)(a) through (e); The name and registry identification number of the Dispensary; and The signature of the individual in R9-17-304(C)(1)(d) or R9-17-308(B)(1)(e), as applicable, designated to submit dispensary agent

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who is practicing as a pharmacy technician out-of-state with a pharmacy technician license issued by another jurisdiction: a. Proof of current, unrestricted pharmacy technician licensure in another jurisdiction; and b. Proof of employment as a pharmacy technician during the last 12 months; or 2. For a person with a delinquent license who did not practice as a pharmacy technician within the last 12 months: a. Take and pass a Board-approved pharmacy technician examination, and b. Complete 20 contact hours or two CEUs of continuing education activity sponsored by an approved provider, including at least two contact hours or 0.2 CEUs of continuing education activity in pharmacy law. R4-23-1102. Pharmacy Technician Licensure A. Eligibility. An applicant for licensure as a pharmacy technician shall provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant: 1. Competed a pharmacy technician training program that meets the standards prescribed in R4-23-1105(B)(2); and 2. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination; or 3. Meets the requirements of R4-23-1105(D)(1) or (2). B. Application. 1. An applicant for licensure as a pharmacy technician shall: a. Submit a completed application electronically or manually on a form furnished by the Board, and b. Submit with the application form: i. The documents specified in the application form, ii. The initial licensure fee specified in R4-23-205(A)(3)(a), and iii. The wall license fee specified in R4-23-205(E)(1)(c). 2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form. C. Licensure. 1. If an applicant is found to be ineligible for pharmacy technician licensure under statute and rule, the Board office shall issue written notice of denial to the applicant. 2. If an applicant is found to be eligible for pharmacy technician licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a	applications on the Dispensary's behalf and the date the individual signed; An attestation signed and dated by the dispensary agent that the dispensary agent has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; One of the following: A statement that the dispensary agent does not currently hold a valid registry identification card, or The assigned registry identification number for the dispensary agent for each valid registry identification card currently held by the dispensary agent; A statement in a Department-provided format signed by the dispensary agent pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; A copy of the dispensary agent's: Arizona driver's license issued on or after October 1, 1996; Arizona identification card issued on or after October 1, 1996; Arizona registry identification card; Photograph page in the dispensary agent's U.S. passport; or Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the dispensary agent: Birth certificate verifying U.S. citizenship, ii. U.S. Certificate of Naturalization, or iii. U.S. Certificate of Citizenship; A current photograph of the dispensary agent; For the Department's criminal records check authorized in A.R.S. § 36-2804.05: The dispensary agent's fingerprints on a fingerprint card that includes: The Dispensary agent's first name; middle initial, if applicable; and last name; The dispensary agent's signature; iii. If different from the dispensary agent, the signature of the individual physically rolling the dispensary agent's fingerprints;

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license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy technician prior to receiving the certificate of licensure. 3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy technician until the Board office issues a certificate of licensure as specified in subsection (2). 4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public. D. License renewal. 1. To renew a license, a pharmacy technician shall submit a completed license renewal application electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(A)(3)(b). 2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall not practice as a pharmacy technician. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension. 3. A licensee shall maintain the renewal certificate of licensure in the practice site for inspection by the Board or its designee or review by the public. E. Time-frames for pharmacy technician licensure and license renewal. The Board office shall follow the time-frames established in R4-23-202(F). F. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacy technician until the pharmacy permitee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy technician. R4-23-1106. Continuing Education Requirements A. General. According to A.R.S. § 32-1925(I), the Board shall not renew a pharmacy technician license unless the applicant has during the two years preceding the application for renewal: 1. Participated in 20 contact hours or two CEUs of continuing education activity sponsored by an Approved Provider defined in R4-23-110, and 2.	The dispensary agent's address; If applicable, the dispensary agent's surname before marriage and any names previously used by the dispensary agent; The dispensary agent's date of birth; vii. The dispensary agent's Social Security number; viii. The dispensary agent's citizenship status; ix. The dispensary agent's gender; x. The dispensary agent's race; xi. The dispensary agent's height; xii. The dispensary agent's weight; xiii. The dispensary agent's hair color; xiv. The dispensary agent's eye color; and xv. The dispensary agent's place of birth; or If the dispensary agent's fingerprints and information required in subsection (7)(a) were submitted to the Department within the previous six months as part of an application for a designated caregiver registry identification card or a dispensary agent registry identification card for another Dispensary, the registry identification number on the registry identification card issued to the dispensary agent as a result of the application; and The applicable fee in R9-17-102 for applying for a dispensary agent registry identification card.

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At least two of the contact hours or 0.2 of the CEUs are approved courses in pharmacy law. For a pharmacy technician licensed less than 24 months the continuing education contact hours are calculated by multiplying 0.83 hours times the number of months between the date of initial licensure and the licensee's next license renewal date. B. Valid CEUs. The Board shall: 79 ARIZONA ADMINISTRATIVE CODE (RULES): TITLE 4: PROFESSIONS AND OCCUPATIONS - CHAPTER 23: BOARD OF PHARMACY 7/2014 (TNP) 1. Only accept CEUs for continuing education activities sponsored by an Approved Provider; 2. Only accept CEUs accrued during the two-year period immediately before licensure renewal; 3. Not allow CEUs accrued in a biennial renewal period in excess of the required two CEUs to be carried forward to the succeeding biennial renewal period; 4. Allow a pharmacy technician who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider to receive CEUs for a presentation by following the same attendance procedures as any other attendee of the continuing education activity; and 5. Not accept as a CEU a pharmacy technician's normal teaching duties within a learning institution if the pharmacy technician's primary responsibility is the education of health professionals. C. Continuing education records and reporting CEUs. A pharmacy technician shall: 1. Maintain continuing education records that: a. Verify the continuing education activities the pharmacy technician participated in during the preceding five years; and b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity; 2. At the time of licensure renewal, attest to the number of CEUs the pharmacy technician participated in during the renewal period on the biennial renewal form; and 3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request. D. The Board shall deem a pharmacy	

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technician's failure to comply with the continuing education participation, recording, or reporting requirements of this Section as unprofessional conduct and grounds for disciplinary action by the Board under A.R.S. § 32- 1927.01. E. A pharmacy technician who is aggrieved by any decision of the Board concerning continuing education units may request a hearing before the Board.	

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