



LSU AgCenter

Project Concept

for the

Alison Neustrom Act

R.S. 40:1046

This Project Concept serves as a reference point for each aspect of the AgCenter's proposed medical marijuana production program. This document does not contain legal or tax advice, and is prepared based upon estimated data, industry presumptions, and information that is subject to change. See additional disclaimer in Appendix I.

Alison Neustrom Act Project Concept Outline

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ALISON NEUSTROM ACT PROJECT CONCEPT

I. Genesis of the Louisiana Medical Marijuana Law

While Louisiana has had legislation since 1991 regarding marijuana, the lack of enabling rules and regulations prevented access to the medication until the passage of Senate Bill 143 in 2015. Dr. Alison Neustrom of Lafayette, Louisiana, dedicated her life to research, advocacy, and social work on issues including child abuse, juvenile justice, and anti-poverty programs. At 42, Dr. Neustrom passed away from aggressive pancreatic cancer.¹ During the last phase of her illness, she testified about her condition in front of the House Health and Welfare Committee, on which she once served. Her testimony ultimately compelled the legislature to approve the Alison Neustrom Act (the “Act”) 2015.² The Act sunsets on January 1, 2020.

Background

Senator Fred Mills, a pharmacist and former director of the Louisiana Board of Pharmacy, championed Dr. Neustrom’s cause, working with the Louisiana Sheriff’s Association and the Louisiana District Attorney’s Association to amend the proposed legislation, making it more palatable to law enforcement while reaching the most patients with qualifying medical conditions possible for purposes of passage of the law. Senator Mills stated an ongoing objective of the legislation will be to expand the conditions for which medical marijuana can be researched and utilized in the future.

Medical Conditions

The Act delineates “debilitating medical conditions” whereby “therapeutic marijuana” is allowed for the treatment of conditions, including: Cancer, HIV/AIDS, Cachexia (Wasting Syndrome), Seizure Disorders, Epilepsy, Spasticity, Crohn’s, Multiple Sclerosis, and Muscular Dystrophy. A further review of Medical Conditions is performed at **Article II.b.**

Delivery Methods

The Act specifies that therapeutic marijuana can only be delivered to patients through refined forms of marijuana. The Act prohibits raw or crude marijuana and inhaled or smoked marijuana delivery methods. The Louisiana Department of Agriculture and Forestry defines medical marijuana to include any parts of the plant *Cannabis sativa*, and all derivatives or subspecies of all strains of cannabis, whether growing or not, the seed thereof; the resin extracted from any part of such plant; and any compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), cannabidiol (CBD) and all other naturally occurring cannabinol derivatives, whether produced directly or indirectly by extraction. This term shall not include the mature stalks of

¹ Dr. Neustrom’s obituary is contained in **Appendix A.**

² La. R.S. 40:1046.

such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination. The production of medical marijuana infused products from concentrate includes and is not limited to: edibles, oils, extracts, tinctures, sprays, capsules/pills, topical applications, oils or lotions, trans-dermal patches and suppositories. The Louisiana Pharmacy Board rules and regulations allow for delivery methods of the infused therapeutic marijuana to include: oils, extracts, edibles, tinctures, sprays, capsules, pills, topical applications such as oils or lotions, transdermal patches and suppositories.

State Law and Public Safety

The Act delegates authority to administrative agencies that implement rules to regulate the medical marijuana program in Louisiana. The administrative agencies have created a strict enforcement program to safeguard the public welfare and to ensure that all those involved in the program are above reproach. Once licensed or permitted, those involved in the program must adhere to continuing reporting requirements to guarantee their uncompromised compliance with the medical marijuana program.

The administrative rules and regulations, and the seed to sale system were designed to implement safeguards in every phase of medical marijuana cultivation, production, transportation, and dispensation. Strict tracking systems and reporting requirements prevent diversion from the regulated program. Additionally, the ability to conduct research on marijuana for medical uses is an important program component that will inform medical professionals and patients, and will assist legislators in the continuing efforts to provide a safe research-based system of medical marijuana for Louisiana.

Patients, physicians, and pharmacists fall under a regulatory program that specifies appropriate licensing, medical diagnosis, and treatment of patients who may benefit from the therapeutic use of marijuana. The medical marijuana produced and dispensed to patients must comply with rigorous product safety testing, packaging, labeling, and prohibitions on advertising to ensure only legitimate patients benefit from the therapeutic use of marijuana.

Licensure

The Louisiana Department of Agriculture and Forestry (the Department) can issue only one specialty license to a “Production Facility” for the cultivation and production of medical marijuana, except as provided in the Act for the LSU AgCenter (“the AgCenter”) and Southern University Agricultural Center (“Southern”). Under the Act, the AgCenter and Southern each have a right of first refusal to receive a license for a production facility, either separately or jointly. The AgCenter and Southern have both chosen to exercise their options to become Licensees.

Research

The Act specifically authorizes the AgCenter to conduct research on medical marijuana. The AgCenter will operate a separate research division for independent research. The research division may operate alongside and in the same facility as the Production Entity's commercial operation, which will produce therapeutic medical marijuana products for qualified patients of Louisiana. For a discussion of the anticipated research opportunities the AgCenter intends to pursue, please see **Articles VI and IX**.

Federal versus State Law

The Act cannot preempt federal law. While the administrative rules and regulations provide for a strict regulatory program to protect public health and welfare in the State of Louisiana, they cannot preempt federal law. The federal Controlled Substances Act classifies marijuana as a Schedule I substance. The Louisiana medical marijuana laws and regulations thus conflict with federal law. The State of Louisiana has granted limited criminal immunity to patients, but it has not done so for the physicians, pharmacists, and producers of medical marijuana or their employees and agents. The legislature issued a warning that all persons involved or interested in being involved in these activities remain subject to the full force and effect of federal law and must consult separate legal counsel prior to conducting such activities. Because only patients and caregivers are offered immunity, protections need to be extended to producers, pharmacies, and ancillary service providers.

Compliance with Federal Guidance

As an educational institution with a distinguished record of research and product development, the AgCenter has been granted the right to become licensed by the State of Louisiana for the production of medical marijuana. The legislature specifically granted the AgCenter and Southern a presumption of suitability as Licensees and has exempted them from several administrative rules and regulations related to applications, investigations, eligibility, suitability, financial requirements, license limitations, and fees. Further variances from certain licensing requirements may be granted to the AgCenter and Southern.

Louisiana's medical marijuana legislation follows many other states that have legalized the therapeutic use of marijuana. Throughout the nation, states have enacted rules that follow the principles set out in a United States Department of Justice (DOJ) memorandum of August 2013, known as the "Cole Memo." The Cole Memo advised the states to enact robust rules and regulations to enforce marijuana legislation so as not to run afoul of the DOJ's enforcement priorities. According to the Cole Memo, the following are the priorities that will guide the DOJ's enforcement of the Controlled Substances Act against marijuana related conduct:

- Preventing the distribution of marijuana to minors.

- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs and cartels.
- Preventing diversion of marijuana from states where it is legal under state law in some form to other states.
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana.
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use.
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands.
- Preventing marijuana possession or use on federal property.

A copy of the Cole Memo is attached in **Appendix B**.

Louisiana’s legislation and its administrative rules and regulations appear to have attempted to address the priorities of the Cole Memo to keep its medical marijuana program in line with federal guidelines, even though the DOJ still makes it very clear that marijuana remains an illegal drug under the Controlled Substances Act with no immunity from federal prosecution.

Further, on August 11, 2016, the United States Drug Enforcement Agency (“DEA”) announced that while it would not change the classification of marijuana from Schedule I, it would relax the rules for marijuana research to make it easier for institutions to grow marijuana for scientific study. The DEA’s recent position in conjunction with Louisiana’s legislative and regulatory change encouraging research by the LSU AgCenter presents a positive outlook for its medical marijuana program. See the DEA’s recent decision and Policy Statement for Proposed Rules at **Appendix B**. See additional DEA discussion at the end of **Article III** and **Article VIII.f**.

Effect of DEA’s Recent Scheduling Announcement

The DEA announced that while it would not reschedule marijuana from its Schedule I classification, it would expand the number of entities registered with DEA to grow and distribute marijuana for FDA-authorized research purposes. The DEA currently authorizes just one grow facility in Mississippi. While 25 states have approved the medical use of marijuana for a growing list of conditions, including Parkinson’s, Crohn’s disease, Tourette’s syndrome, Alzheimer’s, lupus and rheumatoid arthritis, the research to support many of those treatments is in its infancy. The new policy could begin to change that. “It will create a supply of research-grade marijuana that is diverse, but more importantly, it will be competitive and

you will have growers motivated to meet the demand of researchers,” said John Hudak, a senior fellow at the Brookings Institution.³

It is unclear how many additional universities may receive licenses to grow marijuana, but the new program does not set a cap on the number who may qualify. Any institution that has an approved research protocol and security measures required to store dangerous drugs can apply. Researchers will still have to receive approval from federal agencies to conduct medical studies of marijuana, including from the DEA, and FDA. Those whose projects are funded by the National Institute on Drug Abuse will also need consent.

a. Louisiana Legislation Summary

While the Act creates the legislative framework, it serves as the mandate for state agencies to implement the law. The Act empowers three agencies to work together to promulgate the rules and regulations governing the administration of Louisiana’s medical marijuana program. The three agencies are: The Louisiana Department of Agriculture and Forestry (the Department), which licenses and regulates the cultivation and production of medical marijuana; the Louisiana Board of Medical Examiners (the Medical Board), which regulates physicians who recommend medical marijuana to patients; and the Louisiana Board of Pharmacy (the Pharmacy Board), which regulates the pharmacies that dispense the medical marijuana to patients.

Links to the current rules and regulations proposed by the three state agencies are provided in **Appendix C**. The below legislation summary outlines the process for operation of the Production Facility, and highlights areas of overlapping jurisdiction by the three agencies.

b. Rules and Regulations

i. Louisiana Department of Agriculture & Forestry

Summary

The Department has issued a “Notice of Intent” to adopt the proposed rules and regulations regarding medical marijuana. The proposed rules and regulations are encompassed in LAC 7:XLIX, Chapters 1-31. Ch. 1 contains Definitions which, among other items, define medical marijuana as any part of the marijuana plant that will be manufactured into extracted medical marijuana concentrates and infused products. Medical marijuana is limited to edible products, ointments and tinctures. Raw or smoked marijuana is prohibited.

Ch. 3 restates the Department’s authority; Ch. 5 contains the application requirements for the producer of medical marijuana (the “Licensee”) and permits for its employees; Ch. 7 states

³Hulak, John, *The DEA’s Decision Is More Important Than Rescheduling*, THE BROOKINGS INSTITUTION, <https://www.brookings.edu/blog/fixgov/2016/08/11/the-deas-marijuana-decision-is-more-important-than-rescheduling/> (August 11, 2016) (last visited September 2, 2016).

the fees; Ch. 9 outlines the licensing, compliance and inspection requirements; Ch. 11 governs the production facility internal controls; Ch. 13 governs the record keeping and reporting requirements; Ch. 15 sets forth the rules for the Production Facility (as defined below), secured areas and use of pesticides; Ch. 17 relates the surveillance and security requirements; Ch. 19 describes the seed to sale tracking system (LMMTS); Ch. 21 mandates quality controls and testing; Ch. 23 lists Laboratory testing requirements for the Laboratory (as defined below); Ch. 25 covers transportation of medical marijuana; Ch. 27 dictates rules for sanitation and waste; Ch. 29 restricts labeling and advertising; and Ch. 31 delineates enforcement.

Background Checks

The application process for a license includes a strict background check of all persons who benefit, directly or indirectly, from obtaining such a license and who must agree to abide by the Department's authority. The applicant must demonstrate by clear and convincing evidence that they are "suitable," defined as a person of good moral character whose prior activities and criminal history do not pose a public threat, who is capable and likely to conduct the activities with strict adherence to the rules and regulations, and a person who is trustworthy and honest. The AgCenter has been deemed suitable by the legislature; however, employees, investors and all subcontractors will be subject to background checks. Definitions of those subject are contained within the Department rules and regulations. They include employees, agents, persons with economic or financial interests, and other beneficiaries.

Production Facility

The Production Facility is the permanent indoor structure that will house the operation for the cultivation and production of the medical marijuana. The applicant for a production facility license must submit its application through forms provided by the Department and must provide detailed plans and design specifications drafted by licensed professionals to be compliant with architectural standards and state/local codes and regulations. The designs must include facility size and a plan for surveillance and equipment; a construction schedule with projected dates of completion and commencement of operations; an explanation and identification of the sources of funds; a proposed management plan; anticipated personnel, employees, and organizational chart. The applicant shall propose internal controls for accounting, job descriptions, personnel systems, inventory control procedures, and security standards for the total operation of the Production Facility.

Permitting

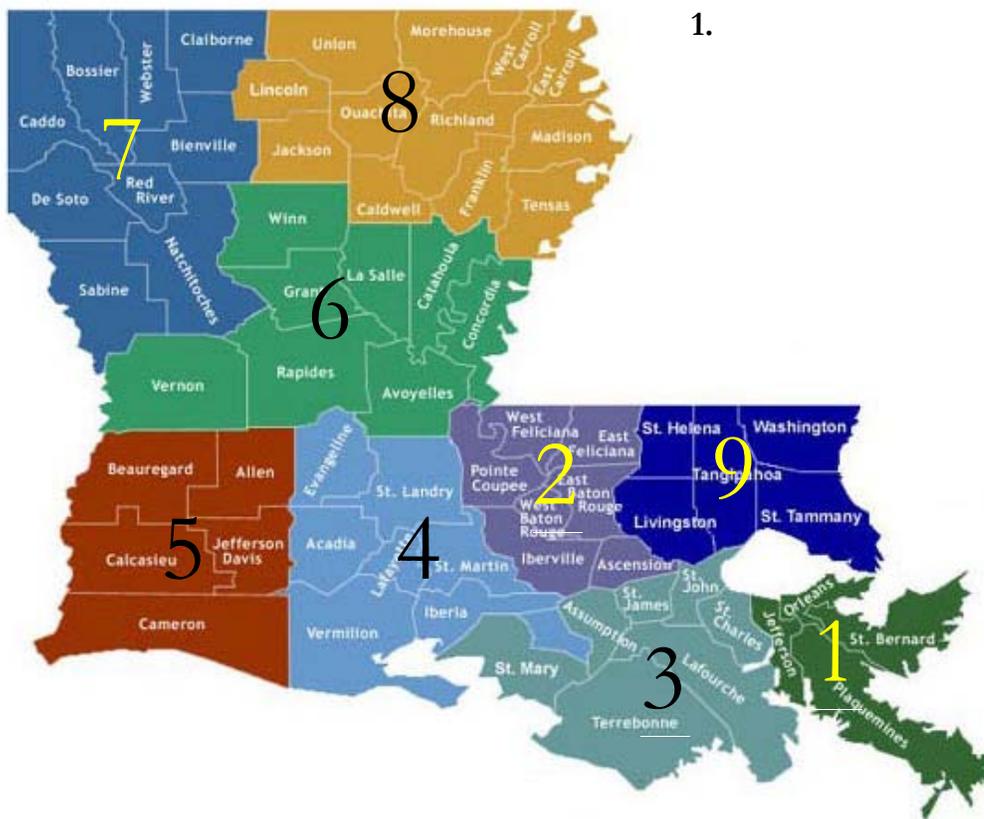
Once licensed, the Licensee must obtain employee permits. Employees will be issued a permittee identification badge, which must be renewed by the Department through annual applications. The AgCenter is exempted from the license fee of \$100,000 under the Act, but must pay a \$100 annual permit application per employee, and a quarterly fee of 7% of gross sales to the Department. Once obtained, the license cannot be transferred or assigned.

For a complete discussion of the Department’s rules and regulations, please see **Appendix C**.

ii. Board of Pharmacy

Summary

Up to 10 pharmacies are permitted under the Act. The Pharmacy Board regulations set forth the parishes included in each of nine regions currently designated to have one pharmacy each. A tenth pharmacy location is reserved for future needs. Below is a map of the pharmacy regions:



The Pharmacy Board drafted regulatory proposals for the 10 licensed dispensary pharmacies and pharmacists who will dispense medical marijuana to patients under the Louisiana Administrative Code at Title 46 Governing Professional and Occupational Standards, Part LIII: Pharmacists, Chapter 24 for Limited Service Providers, Subchapter E Marijuana Pharmacy. The regulations govern: the application process to be determined by an Application Review Committee; the issuance of a Therapeutic Marijuana designation for the officers and persons holding a professional credential from the Pharmacy Board; the issuance of a Pharmacist-in-Charge privilege for pharmacists who will be responsible for the entire pharmacy staff; the operation of the marijuana pharmacies; the establishment of credit and

escrow requirements for the pharmacies; security requirements; and standards of practice for environmental, staffing, operational, recordkeeping, professional, reporting, and disposal aspects.

Regulatory Overlap

Areas of overlapping jurisdiction between the Pharmacy Board regulations and the Department rules and regulations include:

- Transportation. While the Pharmacy Board rules allow for transportation to be conducted by either the pharmacy or the Production Facility, the Department rules only allow the Production Facility to transport medical marijuana and product. New versions of the regulations should clarify either one or the other. By agreement, the Private Entity/LLC will be responsible for all transportation of its products to the pharmacies.
- Testing. Both the Pharmacy Board rules and the Department rules outline testing requirements to be conducted by approved laboratories for medical marijuana and product. However, the Pharmacy Board rules outline a broader testing process, demanding compliance on products under several additional standards including the United States Pharmacopeia standards for dietary supplements and United States Environmental Protection Agency.
- Dosage Forms. The Pharmacy Board rules mandate that medical marijuana products be “pharmaceutical grade” with an attendant definition and specifies the dosage forms to oils, extracts, tinctures, sprays, solid oral dosage forms (e.g. capsules or pills), liquid oral dosage forms (e.g. solutions or suspensions), edible dosage forms, topical applications, oils or lotions, trans-dermal patches, and suppositories. This is further clarification of the Department rules, which merely define “medical marijuana infused products” and “product as 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.” By agreement, the licensee or its subcontractor will maintain the ability to create dosages and products that comply with the Act and regulations adopted by regulatory bodies.

Under a general mandate in the Act, the AgCenter must produce sufficient amounts for patients state-wide on a monthly basis. Packaging limitations are 10 milligram single servings, maximum of 10 servings per package, or 100 milligrams. There is no prohibition as to how many packages a patient can obtain per month. The AgCenter in collaboration with the Medical Board & the Pharmacy Board will have to use the best available data and practices to determine dosing for medical marijuana through research in conjunction with the state agencies.

The areas of overlapping authority between the Department and Pharmacy Board rules and regulations will necessitate further clarification as the adoption process moves forward. In addition, an in-state immunity provision from criminal prosecution beyond patients must be addressed by the Louisiana legislature.

The Pharmacy Board's proposed regulations are contained in **Appendix C**.

iii. Board of Medical Examiners

Summary

The Medical Board has issued a "Notice of Intent" to adopt the proposed rules and regulations regarding medical marijuana. The proposed rules and regulations are encompassed in LAC Title 46 Professional and Occupational Standards, Part XLV Medical Professions, Subpart 3 Practice, Chapter 77 Marijuana for Therapeutic Use by Patients Suffering from Qualifying Medical Condition. The Medical Board will allow physicians who are licensed and in good standing in the state of Louisiana to practice medicine to apply as Registrants with the Medical Board to recommend the use of therapeutic marijuana to patients.

Patient Qualification

Requirements to qualify for therapeutic marijuana include the following:

- The physician will be limited to treating 100 patients. However, approval for more patients may be obtained from the Medical Board.
- The physician may not have any kind of ownership or investment interest in a marijuana pharmacy or producer.
- The physician must diagnose a patient as having a qualifying debilitating medical condition.
- The physician must create an individualized treatment plan to include documentation that other alternative treatments have been considered or attempted without adequate or reasonable success.
- The patients must be re-examined every 90 days.
- The patients must provide informed consent that includes an acknowledgement that marijuana is not approved by the United States Food and Drug Administration, and that it is federally illegal, subject to severe criminal and civil penalties.

Record Keeping

Detailed medical records are to be kept on each and every patient. Patients are required to be reexamined every 90 days, and their records/ files are to be updated. The file for each patient is to include the quantity of marijuana, dosage and route of administration. **Article V** discusses software that has been designed for this type of record keeping.

The Medical Board's proposed regulations are contained in **Appendix C**.

II. Marijuana Industry Statistics.

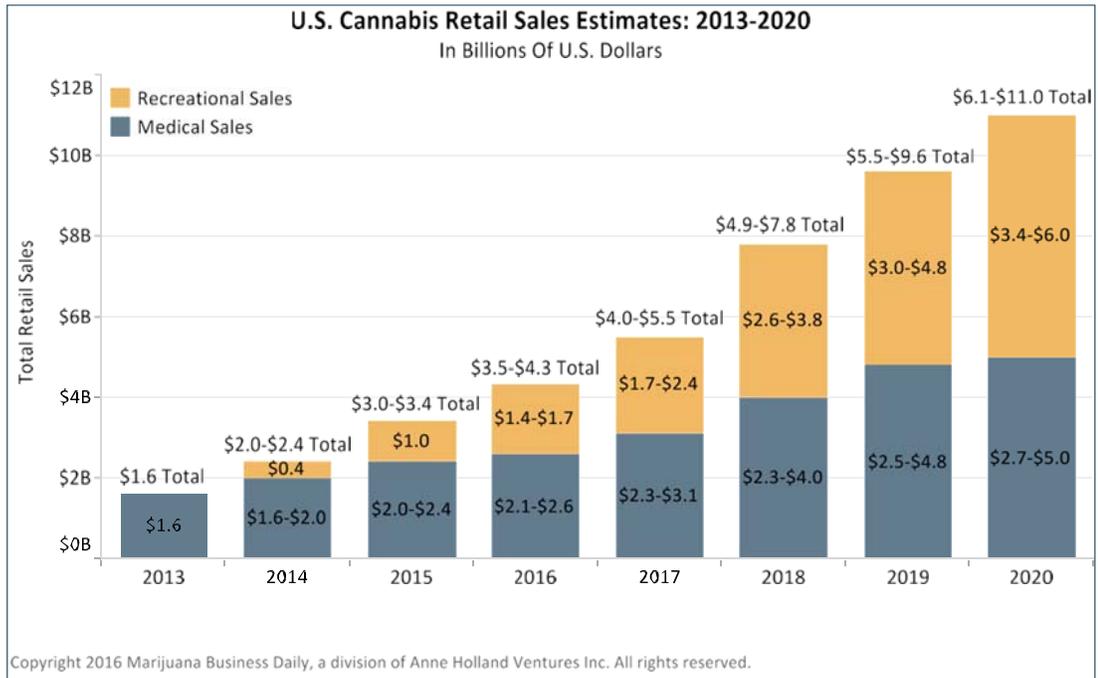
a. National Statistics.

Summary

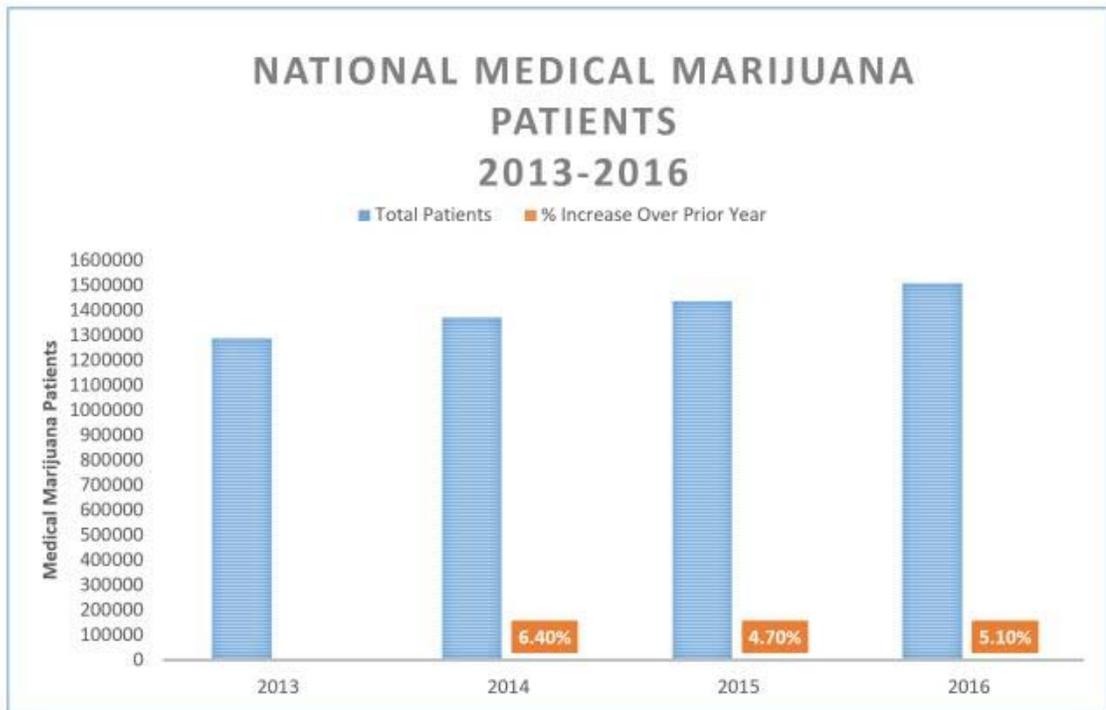
A total of 25 states and the District of Columbia have enacted laws that establish systems for the medical use of marijuana. In each of the 25 states, a medical professional's recommendation or certification is required for a patient to qualify for the respective program. The laws generally include medical marijuana use for cancer, AIDS, multiple sclerosis, severe or debilitating pain, and severe nausea. Their laws also have additional protections for the practitioners who make recommendations and include designated caregivers who may assist patients with retrieval and delivery of medicine.

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The following 2016 chart⁴ reflects the upward climb of medical marijuana sales projected from 2013 to 2020:



The following 2016 chart⁵ depicts the slow but steady rise in medical marijuana use from 2013 through 2016:



⁴ Marijuana Business Daily™, *Marijuana Business Factbook*, Chart 1.01 (4th ed. 2016).

⁵ Adapted from Marijuana Business Daily™, *Marijuana Business Factbook*, Chart 1.11 (4th ed. 2016).

Relevant State-by-State Comparison

A comparison with other states with similar medical marijuana programs is informative for the future of Louisiana’s program. Hypotheses derived from other states’ data and activity for implementation of medical marijuana programs are accounted for within these Project Concept presumptions. A full discussion is included in **Appendix E**.

b. Louisiana Statistics

The following chart quantifies extrapolations of statistics for persons suffering from qualifying conditions in the Louisiana population:⁶

<u>Estimated Number of Potential Patients by Condition</u>	
Debilitating Medical Condition	Patients
HIV/Aids	19,000
Cancer	206,490
Cachexia (Wasting Syndrome)	282,750
Spasticity	15,500
Multiple Sclerosis	3,640
Muscular Dystrophy	120
Crohn’s	9,200
Seizure Disorders (Epilepsy)	39,820
Total	576,520
Estimate of Patients By Condition	1,441 (0.25%)

Assumptions

The above .25% conditions estimate includes possible therapeutic marijuana patients by debilitating medical condition as provided for by the Act. To arrive at an anticipated patient pool number, the estimate of patients who suffer from the above medical conditions is reduced by the percentage of patients who actually seek and receive a recommendation, and then further reduced by those expected to actually use therapeutic marijuana. Louisiana is starting at a point whereby marijuana has been seen as an illicit drug with no beneficial use.

An estimate of initial patient counts is therefore recommended based on 0.25% of all possible patients with qualifying medical condition or based on 0.031% by population in comparison to other states. As seen below, Louisiana’s numbers are reduced due to the limited medical

⁶ Adapted from data contained in **Appendix D**.

conditions (namely no chronic pain or psychological conditions), and refined delivery methods. As research continues to yield evidence-based studies of the beneficial uses of therapeutic marijuana, and as more qualifying conditions are potentially added, the estimated number of patients can be expected to rise.

III. Patient Counts

Because the medical conditions and delivery methods are limited under the Act, the initial estimated patient base is conservative. The following chart represents an extrapolation of patients for Louisiana compared other states with similar populations, qualifying conditions and authorized dosage forms:

Estimated Number of Potential Patients by Population			
State	Population	Medical Patients	Limited Medical Condition
Connecticut	3,590,886	8,685	Y
Massachusetts	6,794,422	19,279	Y
Minnesota	5,489,594	1,041	Y
New York	19,795,791	1,301	Y
Louisiana	4,685,000	1,441	Y
(0.031% of Population)			

A 0.031% patient estimate was realized for Louisiana for the percentage of patients when compared to total population. The chart shows a comparison to Connecticut, Minnesota and New York, which lodge similar limitations on medical conditions and delivery methods as Louisiana. For states that allow medical marijuana for chronic pain, the percentage of medical patients per population increases significantly.

Considering Medical Marijuana in Light of Opioid Crisis

As the United States grapples with a growing opioid epidemic characterized by abuse, addiction, and overdose, researchers have begun to evaluate the effect the availability of medical marijuana has on a variety of issues. The results of numerous studies suggest that the deleterious effects of alcohol and prescription medication appear to be reduced in states with legal medical marijuana. Unfortunately, the studies have been performed under differing assumptions and variables, rendering some of them merely anecdotal.

A recent scientific study focusing on medical marijuana was performed by researchers at the University of Georgia to investigate whether prescription patterns differ for conditions that are treatable with medical marijuana. Although the data pool was small, taken from prescription drugs purchased under Medicare Part D between 2010 and 2013, which

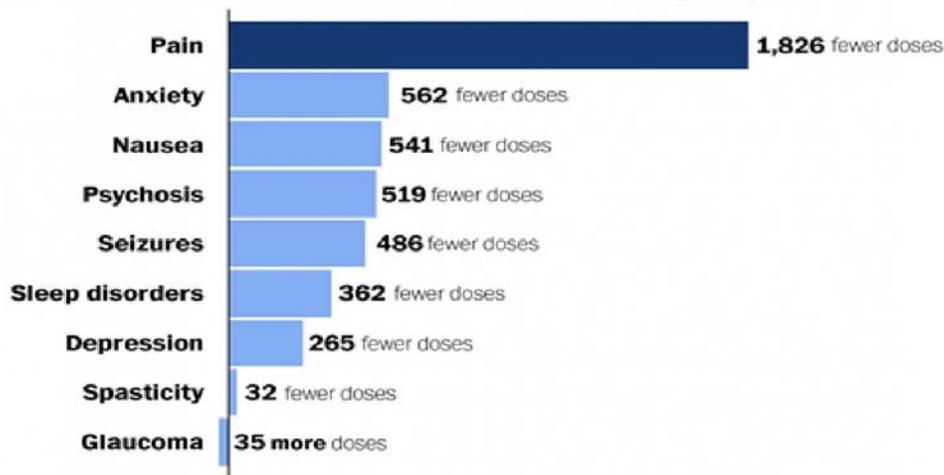
necessarily reflects an older population base less apt to utilize medical marijuana, the data still reflected lower opiate prescription rates for listed conditions in medical marijuana states.

The most significant drop in prescription drugs occurred for chronic pain, followed by anxiety, nausea, and psychosis. Controls implemented in the research included looking at prescription drugs for which there is no counterpart in medical marijuana, such as blood thinners, flu antivirals, and antibiotics. For these products, there was no change in the number of prescriptions in a medical marijuana state. For glaucoma, however, because medical marijuana is effective primarily on a short term basis, prescriptions actually increased, indicating that when prescription drugs can better treat a condition, the availability of medical marijuana does not supersede sound medical judgment.

The University of Georgia researchers analyzed data from 17 medical marijuana states in 2013, and found that, despite the newness of the therapy, pharmaceutical prescriptions had already dropped significantly compared to states prohibiting marijuana. For the time period viewed in medical marijuana states, doctors prescribed 1,826 fewer doses of pain suppressants, 562 fewer doses of anti-anxiety medication, 541 fewer anti-nausea doses, 486 fewer doses of seizure medication, and 265 fewer doses of antidepressants each year. The findings as to eight conditions are reflected in this chart:

Fewer Pills Prescribed in Medical Marijuana States

Difference between annual drug doses prescribed per physician in medical marijuana states, and in states without medical marijuana laws, by drug category



WAPO.ST/WONKBLOG

Source: Bradford and Bradford, Health Affairs, July 2016

The study went on to conclude that roughly \$165,000,000 in Medicare spending was saved in medical marijuana states in 2013. The researchers hypothesized that if all 50 states were to

utilize medical marijuana, the estimated annual Medicare prescription savings would total over \$468,000,000, which represents 0.5% of the current total spending.⁷

IV. Production Facility

The largest start-up cost for the Production Entity’s program is the acquisition and retrofitting of the Production Facility. The Department regulations define “Production Facility” as “a permanent, secured, indoor space designed and located in one geographic location, operated solely for the production of medical marijuana and product by the licensee to perform necessary activities to provide licensed dispensary pharmacies with usable product.” Aside from appropriate location, enhanced security, odor control, and discretion, a properly designed indoor Production Facility also provides maximum control over the growing environment, resulting in reliable and consistent marijuana crops. Further, indoor production facilities are better capable of preventing and containing pest, contaminate, or disease issues in accordance with regulations.

A review of the commercial real estate market has identified multiple locations that may be suitable for a production facility. Retrofitting and improvements will be required, but these location are well-suited to accommodate the added surveillance and access control required by a marijuana cultivation program under Louisiana’s regulations and could be easily expanded in the future to meet projected patient count increases. However, to accommodate the specialized needs of a marijuana production, research, extraction, and warehousing facility, the estimated retrofitting costs are significant.

The information and costs outlined below are estimates for a potential facility buildout and operation costs associated with this project concept.

a. Retrofit and Renovation – Design and Budget

Significant retrofitting and renovation will be required to re-purpose an existing warehouse into a fully functional indoor medical grow operation. HVAC installation, utility infrastructure upgrades and operations costs are expected to be significant. Preliminary estimates total approximately \$4,526,400 for the retrofitting and build-out of 15,000 square feet (initially for Phase 1), including a 10% design and 10% contingency on an expedited basis. An area built out for office space will also be necessary. The budget is as follows:

⁷ Bradford AC, Bradford WD, *Medical Marijuana Laws Reduce Prescription Medication Use in Medicare Part D*, Health Affairs, Vol. 35:7 1230-1336 (July 2016).

Warehouse Production Facility Capital Expenditures Preliminary Program and Budget Estimate for Phase 1 Partial Build-out Phase 1 - 15000 sf Retrofit/Renovation
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Capital Expenditures - Budget Estimate for Retrofit/Renovation			
	Quantity (sq. ft.)	Unit Cost (sq. ft.)	Totals
Construction (Renovation, Retrofit and Equipment Install)			
Utilities Infrastructure (Electrical w/ Emerg Pwr, Water, Gas)	1	\$250,000.00	\$250,000.00
Security System	1	\$400,000.00	\$400,000.00
Environmental Controls (lights, irrig, A/C, exhaust, cir fans)	1	\$125,000.00	\$125,000.00
Grow/Veg Lights (Production and Research)	5000	\$35.00	\$175,000.00
Hydroponic Irrigation Sys (tanks, racks, tables, fertigator)	5000	\$40.00	\$200,000.00
Miscellaneous Equip (fork lift, pallet jack, storage racks, etc)	1	\$100,000.00	\$100,000.00
Space Build-out (util, CO2, HVAC, dehumid, epox flrs, FRP wall)			
Bud/Veg/Mother Rooms	3000	\$225.00	\$675,000.00
Research Grow Space	2000	\$225.00	\$450,000.00
Labs, Vault, Research Lab space (1000 sf)	3100	\$300.00	\$930,000.00
Drying/Storage, Enclose Loading Dock	2420	\$100.00	\$242,000.00
Burden Area	4500	\$50.00	\$225,000.00
Construction Sub-Total			\$3,772,000.00
Design and Contingency (20%)			\$754,400.00
Design/Construction Estimate			\$4,526,400.00
Lab Equipment and Furnishings Estimate			\$1,445,000.00
Design/Construction/Equipment Estimate Total =			\$5,971,400.00

An abstract of the property must be initiated, and a due-diligence period commenced. The current tenant's lease is to terminate imminently. A Phase One environmental assessment will have to be performed, which typically takes up to 90 days.

Acquisition of the site will depend on several contingencies:

- 1) Outcome of Phase One Environmental Assessment.
- 2) Re-Zoning or Variance Request may be required.
- 3) Final State Rules or Regulations. The buyer should subjectively determine whether changes to the rules and regulations render the intended use of the property unfeasible.
- 4) MAI Commercial Appraisal. The appraisal typically takes 4-6 weeks to complete at a cost of \$3500.
- 5) Accurate Survey/Abstract to demonstrate the property comports with representations and disclosures.

Acquisition of the site also involves the following considerations:

i. Design-Build Approach

The design-build delivery method (“Design-Build”) is a shift from the more traditional design-bid-build delivery of construction contracts and may be a good option for this project. Successful design-build projects offer an owner many benefits that add value to a project. Some of these advantages include:

- Single Point of Responsibility.

Earlier Knowledge of Guaranteed Costs.

- Compressed Schedule and Time Savings.

A competitive process can be used to select the Design-Build team. A Request for Proposal (RFP) can be released to potential contractors at an early stage and will identify a response due date. The RFP will clearly and fairly identify requirements for both the building and the design-build team. The RFP should include all programming, project criteria and definitions to allow meaningful, fair competition. The most challenging aspect of preparing an RFP is creating a statement of facility requirements that is comprehensive enough to assure compliance by the design-build teams, but avoids overly restrictive requirements that inhibit creativity. A Design-Build typically consists of a prime contractor, architects, and engineers.

ii. Pre-Construction Assessments

The pre-construction phase of the project is crucial, setting the course for a successful job. It includes business and financial assessments, in which the Design-Builder’s pre-construction staff learns about the business, industry, goals, vision, financial realities, and current and future Production Facility needs. Concurrently, architects and engineers begin architectural, mechanical and electrical system assessments, and review any existing floor plans, fire and smoke preparations, interior room finishes and structural systems. While the Design-Build team gathers critical information, surveyors perform a field assessment of the job site to ready it for construction. These assessments define key parameters like state/local codes, compliance requirements, topography, the area’s weather characteristics and more.

With all the gathered information, the Design-Build team identifies a design and construction program to help achieve budget, goals and time constraints. The scope of the project is set, and creative solutions take shape to help finalize design.

iii. Architectural Design

At this phase, the Design-Build team has a solid understanding of the project scope and schedule, cost, job site, and the Production Facility's architectural, electrical and mechanical requirements. Next, the construction team and project managers partner with the architectural team to value engineer cost savings into the design.

This is where Design-Build differs from other construction methods. Architects can be employed directly by the Design-Builder, or the Design-Builder can subcontract out specialty design to trusted architectural design partners. Architects work on the same team, under the same contract, with the Design-Builder. All key project team members work together to form a design that balances all needs. Architects, engineers, construction professionals, key subcontractors, and vendors can all add value at the inception of a build.

Once the Design-Build team has defined the big picture, preliminary drawings progress into detailed design and schematics. The Design-Build team works in fluid collaboration to produce cost estimates at 30 percent, 60 percent, and 90 percent design completion. At the conclusion of this process, owners receive a guaranteed maximum price (GMP), a set project schedule, and contract drawings to build the Production Facility.

iv. Code Compliance Review

Upon completion of the contract drawings, submittal will be made for Code Compliance Review. During the Code Compliance review, plans and specifications to meet necessary codes will be submitted to the appropriate regulatory agencies for approval. Upon approval by regulatory agencies, construction can begin.

b. Retrofit and Renovation - Construction

A phased build-out is expected to produce enough medicinal product to serve patient needs for a few years. As patient count and demand increases, the remaining space of the Production Facility could be built-out and expanded in additional phases to meet increased need. The cost of additional phase build-outs is not included in the Capital Expenditures Preliminary Program and Budget Estimate for Phase 1, as reflected at the exhibit in **Section IV.a.**

i. Site Work and Utilities

The anticipated site work will commence with installing/repairing the site perimeter security fencing and gates. The utility feeds will be upgraded as necessary.

ii. Structural and Foundation

It is anticipated that saw cutting concrete and implementing design changes to the site's foundation for efficient irrigation and drainage will be required. Structural modifications to the roof system may also be required to support the roof top HVAC systems.

iii. Interior Build-out

The interior build-out will consist of constructing walls and creating functional and secure spaces as designed and represented on final-approved construction documents.

iv. Mechanical, Electrical, Plumbing, Specialty

The mechanical, electrical, and plumbing work (MEP) is anticipated to be substantial. Installation of the MEP infrastructure will be required to create rough-in connections for equipment installation and final connection. HVAC equipment must be installed coordinating with the structural modifications made to roof systems. Specialty research and production equipment must be installed as more fully outlined below. Finally, a security system meeting the requirements of the Act and regulatory agency rules must be installed.

v. Commissioning and Construction Acceptance

The Commissioning and Construction Acceptance phase involves the final inspection of the project and the creation of a deficiency punch list. Then, the building systems and equipment will be commissioned, and any outstanding issues will be added to a deficiencies punch list. Performance testing of the research and production systems and equipment will be conducted prior to implementation of the production and research processes.

c. Production Equipment

Lighting

Because the plants will be grown indoors, lighting is a key component of the Production Facility. Intelligent grow lights can replicate the parts of a sunlight spectrum that marijuana plants require at each stage of growth. The Private Entity/LLC will accomplish the same through a variety of lighting system options.

Air Filtration

Air filtration and circulation systems are essential for controlling heat buildup and eliminating exhaust odors. Air circulation will be designed in conjunction with grow lights coordination since lighting emits large amounts of heat. HVAC replacement and operational costs will be significant and have been accounted for within the Project Concept presumptions herein.

Irrigation

An irrigation system appropriate for growing marijuana indoors will be developed, and may include drip irrigation, hydroponic flood benches, or trough benches. The irrigation system will be designed with a nutrient management system for maximizing the production yield of marijuana plants. The irrigation systems are common for growing a variety of plants in different industries, and are not expected to be specialized products.

Other Fixtures and Systems

Other fixtures and supplies such as rolling grow tables will maximize the efficiency of the grow space. Due to Louisiana’s climate, dehumidification equipment will also be used, along with computer controlled CO2 injection and monitoring systems.

i. Grow

The estimated cost to set up a grow facility for production are set forth as follows:

Medicial Marijuana Plant Production Facility - Initial and Recurring Annual Estimated Expenditures					
1000 sf Mother rm, 2000 sf Veg rm, 4500 sf Grow space and 3000 sf for Research					8/10/2016
Equipment and Supplies (Plant Production Rooms _seed-bud harvest)	Quantity (unit) ea/sq ft/gal	Unit Cost	Totals	Start-Up Initial Costs	Recurring Annual Costs
Pots (20-25 gal) - ea	125	\$12.00	\$1,500.00	X	
Pots (2 gal) - ea	6000	\$1.25	\$7,500.00	X	
Pots (5 gal) - ea	8000	\$2.25	\$18,000.00	X	
Wire / Plastic Frames (upright plants) sq ft	9000	\$2.50	\$22,500.00	X	
Sterlite Plastic Boxes (10-20 gal) -ea	100	\$6.00	\$600.00	X	
Potting Media (rock, soil, sand, perlite, vermiculite, coco. fiber) -sq ft	20,000	\$2.00	\$40,000.00		X
Potting Media Amendments - sq ft	6562	\$3.00	\$19,686.00		X
Hydroponic / Aeroponic Nutrient Solutions - gal	7000	\$40.00	\$280,000.00		X
Cleaning / Disinfecting Strategies - gal	300	\$4.00	\$1,200.00		X
IPM (Pest) Strategies - sq ft	15,500	\$7.50	\$116,250.00		X
Sterlizers - ea	2	\$20,000.00	\$40,000.00	X	
Plastic Sheeting - sq ft	14,500	\$0.25	\$3,625.00	X	
Uniforms (Tyvek) - ea	1460	\$11.00	\$16,060.00		X
Miscellaneous Equip / Hort. Supplies (tapes, potting, bags, bands, gloves), -ea			\$25,000.00		X
Miscellaneous Equip / Hort. Supplies (tools,measuring,etc) -ea			\$12,000.00	X	
Supply/ Equipment			\$603,921.00		
Personnel Salary and Benefits			Annual		
Sr. Horticulturist (Experienced) / Supervisor			\$171,600.00		X
Horticulturist (Intro Level)			\$78,650.00		X
Technician (I)			\$57,200.00		X
Technician (I)			\$57,200.00		X
Personnel			\$364,650.00		
Subtotal			\$968,571.00		

ii. Extraction – Research

The estimated cost to set up an extraction facility for research are set forth as follows:

Cost To Set Up Extraction Lab-Research			
Equipment	Description	Price	Annual Service Contracts
Chemglass Reactor	Jacketed Ethanol Extractor	\$ 40,164.60	\$ 4,000.00
Genevac RKT Synergy	Ethanol Evaporator	\$ 83,958.61	\$ 7,225.11
Thomas Wiley Mini Mill	Plant Mill	\$ 5,584.61	\$ 1,000.00
Twister T4	Trimmer	\$ 10,000.00	\$ 1,000.00
Miscellaneous	Supplies	\$ 25,000.00	
Contingency (10%)		\$ 16,470.78	
Total		<u>\$181,178.60</u>	<u>\$ 13,225.11</u>
Annual Operating Budget			
Service Contracts		\$ 13,225.11	
Supplies		\$ 50,000.00	
Total		<u>\$ 63,225.11</u>	

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iii.Extraction – Production

The estimated costs to set up an extraction lab for the Production Entity's is as follows:

Cost To Set Up Extraction Facility - Production			
Equipment	Description	Price	Annual Service Contracts
Chemglass Reactor	Jacketed Ethanol Extractor	\$ 41,764.20	\$ 4,000.00
Genevac RKT 4D Synergy	Ethanol Evaporator	\$ 89,786.51	\$ 8,423.90
Thomas Model 4 Wiley Mill	Plant Mill	\$ 19,409.55	\$ 2,000.00
Twister T2	Trimmer	\$ 25,000.00	\$ 2,500.00
Miscellaneous	Supplies	\$ 25,000.00	
Contingency (10%)		\$ 20,096.03	
Total		<u>\$ 221,056.29</u>	<u>\$ 16,923.90</u>
Grand Total		<u>\$ 221,056.29</u>	
Annual Operating Budget			
Personnel (Salary + 42% Fringe)			
Master's Level Chemist (1)		\$ 171,600.00	
Bachelor's Level Chemist (1)		\$ 66,740.00	
Technician (1)		\$ 57,200.00	
QA/QC Personnel (1)		\$ 66,740.00	
Total		\$ 362,280.00	
Service Contracts		\$ 16,923.90	
Supplies		\$ 25,000.00	
Total		<u>\$ 404,203.90</u>	

iv. Formulation

The estimated cost to set up a formulation facility is as follows:

Cost to set up formulation facility (Capsules, tinctures and sprays only)			
Equipment	Description	Price	Annual Service Contracts
Vanguard VSL-2	Capsule Counter	\$ 36,150.00	\$ 5,000.00
Vanguard Capping &	Capping & Labeling	\$ 88,450.00	\$ 10,000.00
Schaefer Bander	Capsule Bander	\$ 26,175.00	\$ 3,000.00
Schaefer RoboCap	Filler	\$ 96,973.91	\$ 10,000.00
Miscellaneous	Supplies	\$ 25,000.00	
Contingency (20%)		\$ 54,549.78	
Total		#####	\$ 28,000.00
Annual Operating Budget			
Personnel (Salary + 42% Fringe)			
	Technician (1)	\$ 57,200.00	
Total			\$ 57,200.00
Service Contracts			\$ 28,000.00
Supplies			\$ 25,000.00
Total			\$ 110,200.00

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d. Testing Lab

The estimated cost to set up an internal testing laboratory are set forth as follows:

Costs to set up cannabis testing lab			
(Will be ISO 17025)			
Equipment	Description	Price	Annual Service Contracts
Q Exactive	LC/MS for cannabinoid, pesticide and mycotoxin analysis	\$ 592,312.55	\$ 33,149.04
Labconco Hood	Chemical fume hoods	\$ 32,537.00	\$ 250.00
Miscellaneous	Lab supplies	\$ 25,000.00	
Contingency (10%)		\$ 64,984.96	
Total		\$ 714,834.51	\$ 33,399.04
Annual Operating Budget			
Personnel (Salary + 42% Fringe)			
Bachelor's Level Chemist (1)		\$ 66,740.00	
Service Contracts		\$ 33,399.04	
Supplies		\$ 25,000.00	
Total		\$ 125,139.04	

Internal Testing and Equipment

Pursuant to the Department's rules and regulations, Section 2303, and the Pharmacy Board rules and regulations, Section 2443, all products must be third-party tested to pass a series of stringent testing limits. However, internal testing will be necessary. The Thermo Scientific QExactive MS System with Ultimate 3000 HPLC will meet both the production and research internal testing requirements for quantification and identification of active ingredients. This instrument is designed to test for active ingredient identification and potency, mycotoxin analysis, and the presence of some residual pesticides. It will also assist the research operations in identifying novel compounds from marijuana that may be of biological interest that could lead to profitable intellectual property.

e. Security

Physical Security of Production Facility

There is a tentative agreement with the East Baton Rouge Parish Sheriff's Office to handle the physical security at the Production Facility during hours of operation. Off-duty officers will be contracted at an hourly rate. These costs are estimated to be \$30-\$40 per hour.

i. Internal.

The following is a summary of security overview topics, both internal and external. A detailed Security Plan is included in **Appendix F**.

Strict security and operational protocols are critical due to the amount of product and materials that will be stored at the Production Facility. Procedures for protecting the facility and inventory will include Electronic Security Systems, Alarm Systems, Transportation Safety Systems and Operating Procedures. Security issues will encompass physical site security, product storage security, transportation/delivery plans, computer network security, white-collar crime prevention, workplace safety, and security of assets. Security will also be enforced by employee training, proper conduct and behavior, and restricting access to authorized personnel, as required by the Act.

Electronic Security

The Security Plan for the proposed facility incorporates physical security elements, electronic security systems, security staffing, and policies and procedures to provide a comprehensive integrated secure environment for the production and distribution of medical marijuana.

Efficient Workflow and Access Control

Policies and procedures will be established to address work-flow and ensure access to restricted areas is granted only to essential authorized staff. Access levels will be programmed into the electronic security systems to dictate what users will be granted access to specific locations, and at what times. Production Facility supervisors will have the immediate ability to control and adjust employee's access via remote devices such as cell phones. All access will be recorded and stored through a video surveillance system. Areas of higher levels of security may require multiple access systems to enter (PIN code and card reader). Advanced access control features such as threat escalation, mantrap door control, and a "two-man rule" will be implemented at select restricted areas. Employees will wear colored pocket less uniforms based on access level, and all employees must display licensed issued ID cards at all times.

The Production Facility will implement and enforce policies, procedures and training for its employees to ensure a safe and secure environment for the production of marijuana products, as described herein and in the following sections.

Eligibility for Access

Access throughout the Production Facility will be controlled based on the position and responsibility of the employee through an accessed and controlled monitoring system ("ACMS"). All employees will have access to common areas such as restrooms, break rooms, and main hallways, during their scheduled shift times. Restricted areas will only

be accessible by those employees with authorized access. Security personnel will have un-hindered access throughout the facility, for purposes of fulfilling their assigned job functions.

Issue of Access Badges and Passwords

All employees will be issued access badges with access rights in accordance with their job function(s). Computer access will be granted through the IT department upon the request of management. All employees will be required to wear their licensed issued ID cards and employee badges on a lanyard, with the badge above the waist, in a conspicuous location on the outside of any clothing, apron, or other protective clothing. Further, the licensed issued ID and employee badge and employee face must be clearly viewable by the video surveillance system. Employees will not be permitted to wear sunglasses or front-brimmed hats in the workplace.

Security Presence

The Production Entity will employ a Manager or Director equivalent position that in addition to other duties will oversee the security procedures of the operation and to establish and maintain regular liaison with local, parish and state law enforcement and first responders. The ultimate goal of this liaison is to establish and maintain a close working relationship with first responders and oversight departments, which will ensure operational transparency and compliance with state regulations.

During hours of operation, multiple East Baton Rouge Parish Sheriff's Office Deputies will be on site. Security officers will control access to the Production Facility via pedestrian entrances and will monitor surveillance cameras and security systems. The Sheriff's Office will be responsible for patrolling the Production Facility, providing visitor escorts, overseeing deliveries, and supporting the guardhouse operations.

Vaults and Safes

All final marijuana products will be stored in a DEA-approved safe or vault that meets or exceeds requirements for storage and handling of Schedule I- and II-controlled substances.

See further Security Plan details in **Appendix F**.

ii. External

Perimeter Security

The Production Facility will be protected by a complete perimeter security fence. A guardhouse may be constructed along the fence line of the perimeter. The entire

perimeter and interior of the facility will be monitored by a closed-circuit television system.

Design Details

The Production Facility itself will be constructed with high-security materials and design. The exterior walls and roof will be fortified. All perimeter walls and interior wall partitions around restricted areas will extend to the bottom side of the deck. Interior walls around restricted areas will be fortified with either layers of one-half inch fire resistant wood panels or concrete masonry unit block (“CMU”).

Secured Points of Entry

All exterior doors for the Production Facility will be within the perimeter security fence. All employees, visitors, contractors, and deliveries must first gain access to the proposed facility through the guardhouse or main entrance. The security personnel at the guardhouse or main entrance will verify individual information and instruct each employee, visitor, contractor and delivery to the appropriate pedestrian, or overhead shipping/receiving doors to gain access to the Production Facility. Employees will also utilize smart card readers to gain access to the Production Facility. Areas of higher security will be controlled via smart card readers supplemented by PIN pad access or other secondary verification method.

Private Vehicle Control

Parking for employees, contractors, and visitors will be in a parking lot that is situated outside of the fenced perimeter. Employees, visitors, and contractors will be required to enter the perimeter security fence of the Production Facility through the guardhouse and will be directed by security personnel stationed at the guardhouse or escorted by security personnel to a secured point of entry. The parking lot and perimeter of the facility will be monitored by CCTV. The CCTV system will capture and document the license plates of all vehicles entering and exiting the parking lot.

Procedures for Documentation and Destruction of Marijuana Waste and By-Products

Marijuana products may require destruction due to expired expiration dates, contamination, recalls etc. Marijuana products will be tracked and destroyed in a manner to render them completely unusable and unidentifiable and in accordance with state law and local regulations. As provided in the Department’s rules and regulations, the testing laboratory will destroy any quantity of marijuana product that is not consumed in samples used for testing.

All plants or materials designated for destruction will be done so in a manner to render them completely unusable and unidentifiable. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance. The

Production Facility will notify the Department at a minimum of seven days prior to rendering the product unusable and disposing of the product.

Marijuana waste will be destroyed by incineration or grinding and incorporating the marijuana waste with other ground materials so the resulting compost mixture is at least fifty-percent non-cannabis waste soil by volume.

Video Surveillance System

The Production Facility will utilize state-of-the-art security systems with battery and cogenerated power back-up. The video surveillance system, access control system, and alarm systems will all be integrated, redundant and support one another. The features of the designed electronic security systems for the Production Facility will meet and exceed all state requirements. System backup, testing and maintenance will be performed regularly. In the event of a power outage the system will have battery backup and be connected to emergency circuit panels that are part of a local cogeneration power source.

Seed to Sale Inventory Tracking

The Production Facility will use the Louisiana Medical Marijuana Tracking System (LMMTS), a seed to sale tracking system for all record keeping processes related to medical marijuana production and processing. It is anticipated that this system will be selected by the Department at a later date. Any additional internal systems will integrate with LMMTS. Audit processes will be established and take place at scheduled and unscheduled intervals.

Video Management Systems

A comprehensive Video Management System (VMS) comprised of server based Network Video Recorders (NVRs) will be the backbone of the CCTV system.

The NVRs will record video signals from Network IP cameras that are connected to a dedicated LAN for the CCTV system, and allow for video surveillance at the PC-based workstations throughout the Production Facility. A local color high-resolution printer will be maintained and can be used to print a hard copy of any stored video camera image if necessary. The VMS system will record at the full resolution of the Network IP cameras of 3.0 megapixels and will be designed to provide minimum of 30 days of recording onsite on the NVRs with an additional 30 days of recording maintained offsite.

If requested by the Department or investigative body, an unaltered copy of such recording will be provided. Upon becoming aware of pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the unaltered copy of the recording shall be retained until the

investigation or proceeding is closed or the entity conducting the investigation or proceeding makes the notification that it is no longer necessary to retain the recording.

See further Security Plan details at **Appendix F**.

f. Insurance

Pricing Considerations

While the commercial insurance marketplace generally allows for competitive pricing, the marijuana industry is considered a significantly higher risk, making it difficult to find willing underwriters. The standard market major insurance carriers currently decline to write most marijuana-related insurance coverages due to marijuana's Schedule I status under the Controlled Substances Act. Therefore, capacity in this market segment is very limited for all lines of coverage. While non-admitted carriers are writing both property and liability insurance, the coverage is very restrictive and not nearly as broad as coverage for more traditional manufacturing, agricultural, pharmaceutical, and retail industries. With the very recent announcement from the DEA that marijuana will not be taken off of Schedule I, these market conditions will persist well into next year, or until the political and social climates change at both the state and federal level.

Insurance carriers are beginning to offer a broader array of coverages to those in the marijuana business, albeit at higher than average pricing. Heightened risk factors associated with the legal marijuana industry include theft, potential pollution by grower/processors, and neighbor complaints.

Fortunately, marijuana businesses operated for medical purposes find more coverage options from more carriers, due to the exacting controls in place for patient safety. However, the list of insurance carriers is constantly changing. An insurance broker working with marijuana accounts must constantly monitor who the participating carriers are and how policy forms are changing. If federal laws regulating the status of marijuana change, the entire marketplace will change.

Coverages to Consider

Insurance coverages available for the Production Entity to secure will evolve along with its readiness for production under the Act. Builder's Risk, Commercial General Liability, Executive Risk, Workers' Compensation, and other coverages should be placed while the Production Facility is undergoing retrofitting and renovation. Once the Private Entity/LLC readies for production, permanent commercial property coverages should be placed, along with product liability, equipment breakdown, and crop insurance. Some of the initial coverages would continue.

Key coverages for the Production Entity consideration:

Executive Risk (needed when entity first formed)	Casualty	Property	Health & Welfare Plans
Directors & Officers	Builders Risk (during period of construction)	Building – Real Property	Employee Health Insurance
Crime (Employee Dishonesty, Burglary, Theft)	General Liability (start of operations)	Business Personal Property (furniture, fixtures, equipment, supplies)	Disability (Long term, short term)
Employment Practices Liability	Products Liability	Business Income/Extra Expense	Dental
Medical Professional – potential exposure associated with R&D that may involve clinical trials or any dispensary exposure	Auto Liability	Raw Stock - Finished Stock	Group Life
Cyber Risk	Workers’ Compensation	Crop Insurance (if available)	AD&D
Intellectual Property	Pollution Liability	Equipment Breakdown	
Employee Benefits Liability		Cargo	

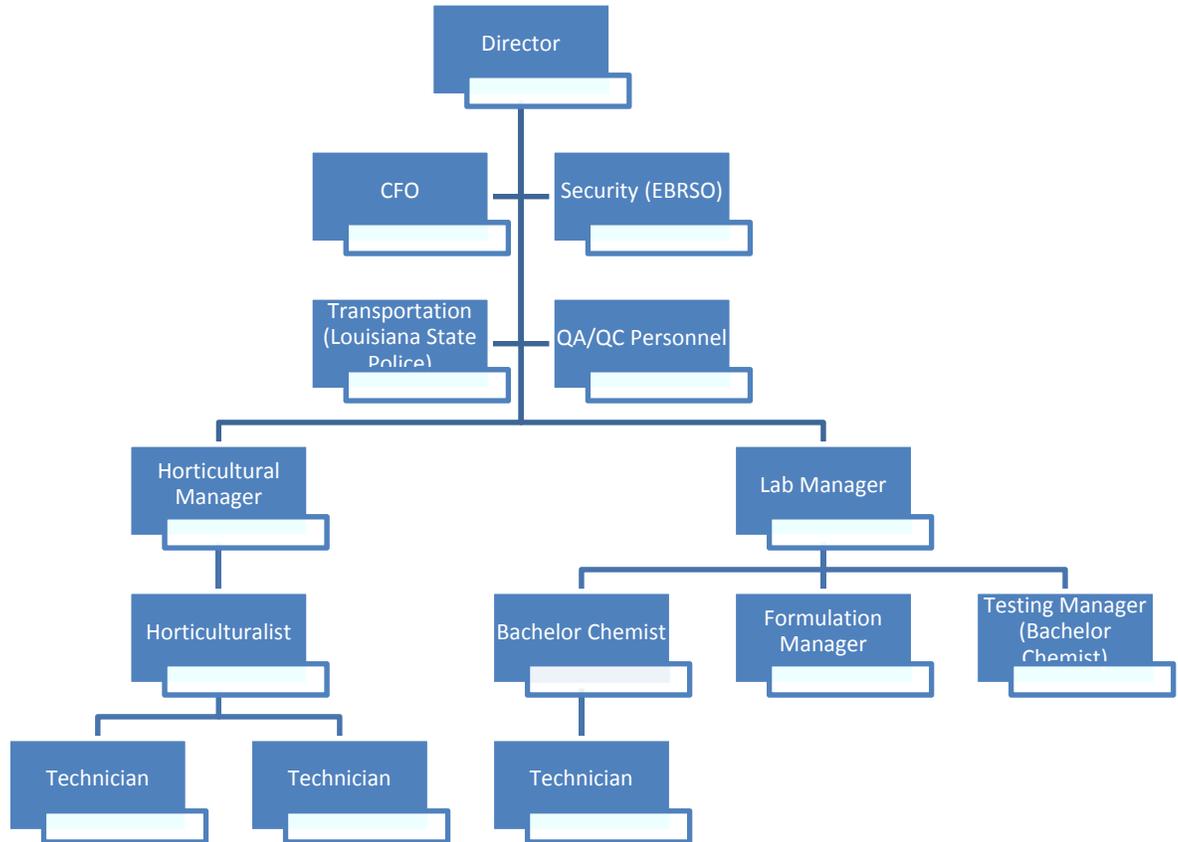
Claims Made Policies

Note that insurance coverage is only written on a “Claims Made” basis in the marijuana industry. Claims-Made policies will respond when a demand or lawsuit is presented to the insured. The policy year that will respond is the year the claim or demand is made, not when the incident occurred as is common for a property or auto policy. The Claims Made form is the common policy form used for Products Liability and Executive Risk policies (D&O, Employment Practices, Fiduciary, Professional Liability). If an insured discontinues operations, an extended reporting period will need to be purchased (often referred to as “tail” coverage) for a period to match or comfortably exceed the relevant statute of limitations period or the product shelf life plus the statute period.

For a preliminary estimate of premiums for the Production Entity’s consideration, see **Appendix G**. The premium projections presented are based upon a traditional guaranteed cost insurance program. Alternative Risk financing may be another option to explore. The above list of coverages will likely be placed through various carriers and through certain business package plans.

V. Operations.

a. General Operations



This chart represents the potential organizational structure based on initial needs and duties set forth in this project concept.

b. Cultivation

An estimated budget has been prepared for the commercial cultivation of the marijuana plant as follows:

Medical Marijuana Plant Production Facility			
Initial & Recurring Annual Estimated Expenditures			
1000 sf Mother room, 2000 sf Veg room, 4500 sf Bud space and 3000 sf for Research			
Equipment and Supplies (Plant Production Rooms _seed-bud harvest)	Quantity (unit)	Unit Cost	Totals
Pots (20-25 gal) - ea	125	\$ 12.00	\$ 1,500.00
Pots (2 gal) - ea	6000	\$ 1.25	\$ 7,500.00
Pots (5 gal) - ea	8000	\$ 2.25	\$ 18,000.00
Wire / Plastic Frames (upright plants) sq ft	9000	\$ 2.50	\$ 22,500.00
Sterlite Plastic Boxes (10-20 gal) -ea	100	\$ 6.00	\$ 600.00
Potting Media (rock, soil, sand, perlite, vermiculite, coco. fiber) -sq ft	20,000	\$ 2.00	\$ 40,000.00
Potting Media Amendments - sq ft	6562	\$ 3.00	\$ 19,686.00
Hydroponic /Aeroponic Nutrient Solutions - gal	7000	\$ 40.00	\$ 280,000.00
Cleaning / Disinfecting Strategies - gal	300	\$ 4.00	\$ 1,200.00
IPM (Pest) Strategies - sq ft	15,500	\$ 7.50	\$ 116,250.00
Sterlizers - ea	2	\$ 20,000.00	\$ 40,000.00
Plastic Sheeting - sq ft	14,500	\$ 0.25	\$ 3,625.00
Uniforms (Tyvek) - ea	1460	\$ 11.00	\$ 16,060.00
Miscellaneous Equip / Hort. Supplies (tapes, potting, bags, bands, gloves), -ea			\$ 25,000.00
Miscellaneous Equip / Hort. Supplies (tools,measuring,etc) -ea			\$ 12,000.00
Supply/ Equipment			\$ 603,921.00
Personnel Salary and Benefits			Annual
Sr. Horticulturist (Experienced) / Supervisor			\$ 171,600.00
Horticulturist (Intro Level)			\$ 78,650.00
Technician (I)			\$ 57,200.00
Technician (I)			\$ 57,200.00
Personnel			\$ 364,650.00
Subtotal			\$ 968,571.00
Contingency (20%)			\$ 193,714.20
Total Budget Estimate			\$ 1,162,285.20

c. Extraction and Formulation.

An estimated budget has been prepared for the extraction and formulation of the marijuana plant as follows:

Annual Operating Budget	
Personnel (Salary + 42% Fringe)	
Master's Level Chemist (1)	\$ 171,600.00
Technician (2)	\$ 114,400.00
Bachelor's Chemist (1)	\$ 66,740.00
QA/QC Personnel (1)	\$ 66,740.00
Total	<u>\$ 419,480.00</u>
Service Contracts	\$ 44,925.00
Supplies	\$ 75,000.00
Total	<u>\$ 539,405.00</u>

d. Testing Lab Operations

An estimated budget for the testing lab operations has been estimated as follows:

Annual Operating Budget	
Personnel (Salary + 42% Fringe)	
Bachelor's Level Chemist (1)	\$ 66,740.00
Total	<u>\$ 66,740.00</u>
Service Contracts	\$ 33,399.00
Supplies	\$ 25,000.00
Total	<u>\$ 125,139.00</u>

e. Transportation

Transportation

The Production Facility will contract for the shipment and delivery of marijuana products and funds when necessary. This secure transportation service will own and maintain its own transport vehicles. At current time, the optimal plan includes all cash pickups and deliveries to be performed by the Production Entity. The following practices are designed to lower the risk of loss, theft, or mishandling, and improve the overall security environment.

Transportation Vehicle

All medical marijuana products and cash will be transported between the Production Facility and dispensing facilities utilizing an up-armored delivery van, such as a Ford E-350 that has been modified to possess a ballistic protection rating of Level 3A, as defined by the National Institute of Justice (NIJ) standards. The vehicle should be manned by a minimum of two armed security guards, with the ability to transport a third security guard if necessary. The vehicle will possess no external markings or advertising, allowing it to blend into other traffic and not draw attention to its purpose.

Shipping Container Consideration

To ensure safe efficient delivery of product to the dispensing pharmacies, the following represents a potential best-practice policy:

The medical marijuana will be sealed within packages that possess tamper resistant closures and are labeled and sized accordingly for the respective weight/amount of product. Those packages will be transported within larger tamper resistant containers. The labels on the sealed package within the larger tamper resistant containers will reflect the weight, strain, and identity of the dispensary for each package. Radio Frequency Identification (RFID) tags will be assigned to each package inside the larger tamper-resistant container to accurately track this information. The tamper-resistant containers will be sealed and include a description, where it is coming from, where it is going to, the weight of the product contained inside the tamper-resistant container, the “lot unique identifier,” and the container serial number so that all match a corresponding number recorded on the delivery manifest.

Global Positioning System (GPS) Tracking

To prevent theft or diversion of packaged medical marijuana, the Production Facility will utilize GPS tracking in delivery vehicles to provide real-time locations of all medical marijuana shipments that have left the Production Facility. The GPS location of each tracker will be monitored from the central security station. Additional security measures may utilize additional GPS tracking technology.

Manifest

Each tamper-resistant container containing medical marijuana will be accompanied by a shipping manifest using the form prescribed by the Department. A copy of the manifest will remain with the packaged medical marijuana from the time it leaves the Production Facility until the time it is received and accepted at the dispensing facility. The transporting security guard will maintain a copy of all manifests of the product transported from receipt to delivery. The Production Facility will electronically transmit a copy of the manifest in a secure manner to the dispensing facility that will receive the products and to the Department prior to the close of business the day before the product will be transported. The Production Facility will maintain all shipping manifests for a period of five (5) years and will be made available to the Department for inspection upon request.

Preparation for Shipping

Only individuals who have been fully vetted and properly authorized will have access to the product shipment room where finished product will be weighed, loaded into packages, and labeled in preparation for transportation to authorized dispensary locations. Digital scales will be used to verify product weight and identify any loss, theft or diversion of product. The manifest will reflect the weight, strain, and identity of the dispensary for each package. The product shipment room will be monitored by video surveillance and controlled by the electronic security access systems.

Shipping Security Measures

For a complete discussion of pick-up procedures, please see **Appendix F**.

Key features include:

- Prior to transporting any approved medical marijuana product, a shipping manifest will be completed using a form determined by the Department.
- A copy of the shipping manifest must be transmitted to the dispensing facility that will receive the products and to the Department prior to the close of business the day before the product will be transported.
- The transportation team will pick up, depart the production facility and deliver product at randomized times.
- The transport team will possess a copy of the shipping manifest at all times when transporting or delivering approved medical marijuana products and will provide it to the Department, the Department's authorized representative, or law enforcement officials upon request.
- Only approved medical marijuana products will be transported from the Production Facility to dispensing facilities.

In-Transit Considerations

- The secure transport vehicle will be GPS-tracked, and its location will be monitored at ten (10)-second intervals with a Global Positioning System.
- The sealed tamper-proof containers will be transported from the Production Facility to the state authorized dispensary locations in a locked, safe and secure storage compartment of the transport vehicle and will not be visible from outside the secure transport vehicle.
- All secure transport vehicles transporting medical marijuana will travel directly from the Production Facility to the dispensary facility and shall not make any stops in between except to other dispensary facilities, for refueling or in case of an emergency. In case of emergency, it will be reported immediately to law enforcement through the “911” emergency system and the central security station, which will immediately notify the Department.
- The Production Facility will ensure that all delivery times and routes are randomized.

Delivery and Receipt Procedures

- Deliveries at dispensary locations will take place within the dispensaries hours of operation.
- Dispensary employees will confirm the container identification number matches the identification number on the shipping manifest.
- The employee will visually inspect each airtight package and confirm that the packages identification number matches the identification number on the shipping manifest.
- If there are any issues or discrepancies with the transfer, the shipment in question is to be rejected and returned to the point of origin immediately. Upon its return to the manufacturing facility, the staff will immediately segregate and secure the rejected delivery. The employee in charge will determine any error, discrepancy or loss of the disputed shipment. Any error, discrepancy, or loss that cannot be rectified will immediately be reported to the Department and law enforcement, as per Department regulations.

Delivery of Medical Marijuana for Testing

The Production Facility must make available samples of the final medical marijuana product to designated independent laboratories for testing and quality control. The Department will be responsible for acquiring and delivering samples to the third party testing laboratory.

These costs are yet to be determined and agreed upon.

Please see **Appendix F** for security-related transportation guidelines under the Act.

f. Software Tracking

Chapter 13 of the Department’s rules and regulations require the Production Facility to keep extensive reporting and record keeping that clearly reflect all financial transactions, including all evidence of purchases, taxes, financial transactions, production, disposal, transportation, inventory, samples, and distribution. Chapter 19 of the Department regulations specifically calls for an Inventory Tracking System to reconcile all on-premises and in-transit medical marijuana and product inventories each day through use of the LMMTS. The Production Facility must maintain records of its inventory of all plant material, medical marijuana, medical marijuana waste, product waste, and plant material waste for disposal. Such meticulous record keeping is common in the marijuana industry. Chapter 19 authorizes the use of a third-party software application to accomplish these requirements.

g. Banking

Financial institutions are caught between state law that has legalized marijuana and federal law that bans it. Federal banking regulators do not fully recognize marijuana businesses and impose onerous reporting requirements on banks that deal with them. Many bankers are challenged by losing accreditation, or money-laundering charges if a marijuana business client turns out to be a front for the illegal drug trade no matter how diligent the bank was at vetting them. It is a notion that has permeated the banking industry.

By providing a loan and placing the proceeds in a checking account, the institution could be considered to conspire to distribute marijuana or to be acting as an accessory after the fact. Banking institutions obviously avoid aiding and abetting the distribution of marijuana. Because the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. Section 801, Et. Seq (1970), prohibits the “manufacture, distribution, and dispensation” of marijuana, and any transfer or deposit of monies yielded from marijuana sales may be deemed “money laundering” in violation of the Currency and Foreign Transactions Reporting Act, 31 U.S.C. Section 5311-5330, most banks, and credit unions refuse to provide marijuana growers, processors or dispensers with financial services. In addition to the criminal liability for such acts, federal regulators have the power to impose millions of dollars in fines or revoke a bank’s deposit insurance. Thus, in state-regulated industries, marijuana-related businesses have been forced to use cash to pay their employees, purchase equipment or pay taxes. Business owners often use armored trucks to transport money and must hire armed security guards.

Although efforts have been made in the United States Senate and House of Representatives to propose budget amendments to prevent federal regulators from penalizing financial institutions that worked with legitimate marijuana businesses,

inevitably such measures are stricken by partisan obstruction. For example, in April 2016, Representative Ed Perlmutter (D., Colo.) introduced legislation that would have provided a “safe harbor” to banks working with marijuana businesses by prohibiting federal regulators from terminating or limiting their deposit insurance coverage, among other steps. The bill and others like it have languished.

The Obama administration has issued some guidelines for banks that choose to deal with marijuana businesses in states where it is legal. In a 2013 memo, the Justice Department indicated it may not challenge states’ marijuana laws as long as they don’t conflict with its enforcement priorities. The Treasury Department’s Financial Crimes Enforcement Network, or FinCen, may be read to imply that it didn’t consider banks’ dealings with marijuana businesses illegal in states like Colorado by laying out rules saying financial institutions can conduct such transactions as long as they file “suspicious activity reports.” These are forms banks are generally required to file when they face a suspected incident of money laundering or fraud, a process that can be complex and costly. The Justice Department and Treasury rules have had only a limited impact, because they don’t absolve banks from rules set by other federal agencies. But, it is a signal that the future of banking will become less risky and thus less difficult to obtain.

h. Insurance

The overall insurance needs from renovation of the Production Facility until operations commences has been discussed herein. Once the Production Facility readies for production, permanent commercial property coverage should be placed, along with product liability, equipment breakdown, and crop insurance. Note that only one carrier is writing crop insurance coverage for marijuana, and most cultivators are foregoing this coverage and absorbing crop losses. For a preliminary estimate of premiums see **Appendix G**.

i. Reporting

i. Internal

Chapter 11 of the Department’s rules mandate written systems for Internal Controls. The written systems must satisfy the requirements of the Act and the administrative rules and regulations and are to be submitted to the Department prior to implementation for its approval and signed by the Manager/ Director and chief financial officer (CFO) of the Production Entity. Changes or amendments to the written systems are to be promptly submitted to the Department for approval as a written report signed by the CFO. The Department will determine if the written systems do not meet the standards and will notify the Production Entity. The Private Entity/LLC will have thirty (30) days to take remedial measures and resubmit the written system to the Department for approval.

- (1) Operational and Management of Production Facility. This system is to include a comprehensive control of the internal fiscal affairs of the producer, per administrative and accounting records. The written system is to be submitted to the Department for approval. An ongoing requirement to immediately report any changes or amendments made to the written systems by way of a report signed by the CFO exists with a thirty (30)-day response to notifications made by the Department of insufficiencies or changes required.
- (2) Application Control – Information Systems. This system is to include a comprehensive plan for the IT environment, including: the LMMTS, computer records, equipment, safeguarding of the IT system, procedures for accuracy and reliability of electronic records, transaction recording a business continuity plan with back-up/recovery and an organizational chart with positions and duties/responsibilities of same. The written system with process and procedures is to be submitted to the Department for approval at licensing application with Manager/Director and CFO signatures. Reports are to be generated and reviewed on a daily basis with copies of system-generated reports to be kept for a minimum of five (5) years in either printed or electronic format. The same immediate reporting requirement for changes or amendments made to the written systems exists with a thirty (30)-day response to notifications made by the Department of insufficiencies or changes required.

Chapter 13 of the Department’s rules and regulations mandates “Business Records” to be maintained by the Private Entity/LLC to include:

- (1) Current books, kept on site and available for immediate inspection for 5 years.
- (2) System data backup to be conducted on a monthly basis.
- (3) Written contingency plan.
- (4) Production Facility records that show all financial transactions and comprehensive fiscal condition of business. To be kept on premises for five (5) years and available for immediate inspection and audit as noticed by the Department.
- (5) Production records that show amount of marijuana cultivated on a daily basis, products produced and distribution of same to be reported to the Department within twenty-four (24) hours. Reporting to be done through the LMMTS.

Chapter 15 of the Department’s rules and regulations mandates Production Facility requirements to be included in its written Internal Controls system under Chapter 11 to include: restricted access areas, best practices for the secure and proper production

of medical marijuana and products, the storage and usage of toxic products and water usage.

Chapter 17 of the Department's rules and regulations mandates Surveillance and Security systems.

- (1) Specifications for required surveillance equipment, surveillance system plans, security alarm system, and personnel.
- (2) Storage and retrieval of video recordings to be maintained for a minimum of thirty (30) days, with indefinite preservation of illegal or suspected activity.
- (3) A written security plan is to be submitted to the Department for their approval prior to commencement of operations.
- (4) Security logs of all visitors to the production facility and unusual incidents shall be retained by month and year with immediate notification to the Department of any theft, violation of the Act, or rules or suspicious incidents.

Chapter 19 of the Department's rules and regulations mandate the utilization by the Production Entity of inventory the LMMTS, to include training, usage, access, ID tags, conduct, and system notifications for compliance to be resolved in a timely fashion.

Chapter 21 of the Department's rules and regulations mandates a written Quality Assurance Program.

- (1) Storage and Shelf Life. The Production Entity is to develop and implement a written quality assurance program to determine storage and shelf life for both medical marijuana concentrates and products, such records to be retained for at least five (5) years and available for inspection by regulatory agencies.
- (2) Response to Contamination. The Production Entity is to develop written procedures for responding to mandated testing results indicating contamination of any kind. Samples submitted for testing are to be maintained for at least one (1) year, thereafter to be destroyed. All destruction of medical marijuana, products, and waste are to be logged into the LMMTS as conducted.

Chapter 23 of the Department's rules and regulations regulates laboratory approval and testing, all results to be reported through the LMMTS for availability by the Department, the producer and the pharmacies as conducted.

Chapter 25 of the Department's rules and regulations mandates "Transportation" rules and regulations. All transportation records are to be reported as conducted through the LMMTS with a system of Manifests.

ii. External

The Production Facility is required to submit an annual report before January 15th of each calendar year. The Annual Report includes:

- Amount of gross medical marijuana and product produced for each calendar year.
- All production costs.
- Items or services subcontracted with costs.
- Amount of products produced.
- Amounts paid to the Licensee on an annual basis for its production of medical marijuana and products.
- Amount of medical marijuana and products distributed to pharmacies annually.
- Amount of material destroyed.

The Internal Control Operational and Management written system must be signed by the Production Entity's Manager/Director and CFO as accurate. A general requirement of immediate reporting of changes or amendments made to written systems is ongoing, with response from the Department due within thirty (30) days. A general requirement of immediate reporting for security incidents, theft, violations of Act or rules and any suspicious incidents is also ongoing.

iii. Maintenance of Records

1. File storage

The file maintenance requirements under the Act and through the agency regulations can be handled by the software tracking and management system selected by the Private Entity and the Department. Files to be maintained are all financial records, operational records, management records, and information system records that are part of the Production Entity's Internal Control written systems. Additionally, business records must be submitted to the Department for approval prior to implementation with the above immediate reporting requirement for changes or amendments. The overarching storage mandate is five (5) years for records maintained on-site. Back-up of electronic and system records is mandated monthly with records of illegal and unusual activities to be maintained in perpetuity.

2. Digital Video Storage

The requirements of video storage under the Act are addressed by the Production Entity's security plan which includes digital surveillance. Ch. 11 of the Department's rules include the specifications for the written Internal Control Application/Information Systems plan, which includes the policies and procedures for housing and safeguarding all digital equipment. Ch. 17 of the Department's rules

establishes the surveillance and security requirements to be contained in a written Surveillance System Plan to be submitted to the Department for approval prior to implementation with the above immediate reporting requirement for changes or amendments and a thirty (30)-day response to notifications of insufficiency by the Department for remediation. A mandate of video storage for thirty 30 days is the overarching requirement with records maintained on-site. Backup of records must be performed monthly and suspicious activity to be maintained in perpetuity.

VI. Research & Development

In addition to having a major research institution operating the Medical Marijuana Program in Louisiana, the research component adds an additional level of validity to Louisiana's program. The ability to research marijuana for medical uses is an important program component that will inform medical professionals and patients and will assist legislators in the continuing efforts to provide a safe research-based system of medical marijuana for Louisiana. By implementing research and data collection to the program, the ability to develop strains of plants tailored to specific disease states and patient needs exists. There is not currently available detailed information on the impact of specific compounds within the cannabis plant on specified disease states. By identifying the specific compounds and tracking the impact of various delivery methods and doses to patients, the hope is to be able more clearly identify those compounds that are beneficial.

VII. Dispensing/Pharmacies Coordination/Board of Pharmacy

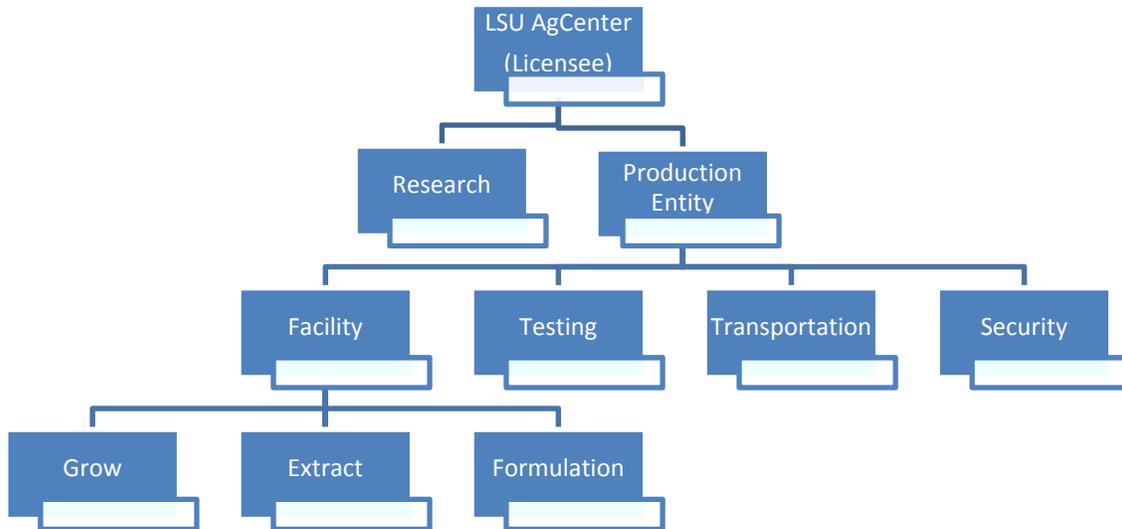
The cultivation of marijuana and production of medical marijuana and products are under the purview of the Production Entity. As part of this process, the Production Entity will test both its medical marijuana and products through in-house laboratories as well as through mandated independent, licensed laboratories. An interplay between the Department rules and Pharmacy Board rules and regulations exists at this phase through centralized reporting of testing and results in the LMMTS and again in compliance with packaging and labeling. Both the Production Entity and the pharmacies must meet the requirements by agreement. Transportation for testing is solely under the Department, which must transport the medical marijuana and products to the independent licensed laboratories for testing. Once the medical marijuana and products are produced and pass testing, there is an overlap between the Department rules and regulations and the Pharmacy Board rules and regulations regarding transportation. Under the Department rules and regulations, the Production Facility handles the secured, private loading of the medical marijuana and products for delivery to one (1) of the (up to) nine (9) pharmacies granted permission to dispense medical marijuana under the Act. Once the medical marijuana and product are delivered to the pharmacies, the Pharmacy Board regulations take affect. The Department requires the Private Entity/LLC to transport the medical marijuana and

products to the pharmacies while the Pharmacy Board leaves transportation to either the pharmacies or the Production Entity. Transportation security requirements and manifests of same through the LMMTS have areas of overlap between the two sets of administrative rules and regulations, but generally are not in conflict.

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VIII. Corporate Structure & Financing

The AgCenter will operate a separate research division for independent research. The research division will operate alongside and in the same facility as the Production Entity's commercial operation, which will produce therapeutic medical marijuana products for qualified patients of Louisiana. The proposed corporate structure is set forth as follows:



a. Production Entity

The AgCenter's therapeutic medical marijuana program will be administered by subcontract with a Production Entity.

Function of Production Entity

As depicted in the organizational chart above, the Production Entity may own the Production Facility, directly or via a third-party real property holding entity, and in accordance with the requirements of the Act will develop procedures to handle:

- Personnel.
- Testing.
- Transportation and Distribution.
- Security.

The Production Facility will house the facilities responsible for growing, extracting, and formulating the final product(s).

b. Sub-Contract

The AgCenter will create its own internal contracting requirements for the use of its state-awarded license to produce medical marijuana. The AgCenter will create an extensive subcontract agreement with the Production Entity that outlines all aspects and elements of the Project Concept. The subcontract agreement will outline all reporting requirements, inspection obligations, regulatory conditions, liability constraints, revocation procedures, and appeal processes as required by, and supplemented to, the Act.

c. Financial Forecast

The following forecast has been prepared using data from comparable states under similar medical marijuana programs, taking into consideration the specific population of Louisiana.

Cash flow forecasts, from 2017 through 2024 for low-level, mid-level and high-level (based on patient count) have been prepared for the Production Entity based on similarly regulated medical marijuana states, projections of Louisiana's patient count under current qualifying conditions, and data acquired from across the marijuana industry nationally, as follows:

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Cash Flow Projections

		Low Level (in \$000's rounded)							
				Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6
		2017	2018	2019	2020	2021	2022	2023	2024
Revenues									
	Gross Sales	\$ 0	\$ 727	\$ 3,634	\$ 5,851	\$ 7,905	\$ 9,793	\$ 11,518	\$ 13,078
	COGS	0	545	2,726	4,389	5,928	7,345	8,639	9,809
Gross Profit (Loss)		\$ 0	\$ 182	\$ 909	\$ 1,463	\$ 1,976	\$ 2,448	\$ 2,880	\$ 3,270
Expenses									
	Administrative Payroll	421	843	1,277	1,309	1,342	1,375	1,410	1,445
	Banking/Payment Processing	24	24	24	25	25	26	26	27
	Insurance	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	License Fees	0	54	257	413	556	689	809	918
	Maintenance & Repair	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	Professional Fees	240	240	240	246	252	258	265	272
	Public Relations	90	90	90	92	95	97	99	102
	Security	52	104	158	161	165	170	174	178
	Utilities	89	178	COGS	COGS	COGS	COGS	COGS	COGS
	Rent	315	315	315	315	315	315	315	315
	Other	74	149	225	231	236	242	248	255
Total Expenses		\$ 1,306	\$ 1,996	\$ 2,586	\$ 2,791	\$ 2,987	\$ 3,172	\$ 3,347	\$ 3,512
Cash Flow		\$ (1,306)	\$ (1,814)	\$ (1,677)	\$ (1,329)	\$ (1,011)	\$ (724)	\$ (467)	\$ (242)

Cash Flow Projections

		Mid Level (in \$000's rounded)							
				Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6
		2017	2018	2019	2020	2021	2022	2023	2024
Revenues									
	Gross Sales	\$ 0	\$ 1,396	\$ 6,982	\$ 9,362	\$ 11,292	\$ 13,058	\$ 14,659	\$ 16,097
	COGS	0	1,047	5,237	7,022	8,469	9,793	10,994	12,072
Gross Profit (Loss)		\$ 0	\$ 349	\$ 1,746	\$ 2,341	\$ 2,823	\$ 3,264	\$ 3,665	\$ 4,024
Expenses									
	Administrative Payroll	421	843	1,277	1,309	1,342	1,375	1,410	1,445
	Banking/Payment Processing	24	24	24	25	25	26	26	27
	Insurance	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	License Fees	0	101	492	658	793	917	1,029	1,130
	Maintenance & Repair	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	Professional Fees	240	240	240	246	252	258	265	272
	Public Relations	90	90	90	92	95	97	99	102
	Security	52	104	158	161	165	170	174	178
	Utilities	89	178	COGS	COGS	COGS	COGS	COGS	COGS
	Rent	315	315	315	315	315	315	315	315
	Other	74	149	225	231	236	242	248	255
Total Expenses		\$ 1,306	\$ 2,043	\$ 2,820	\$ 3,037	\$ 3,224	\$ 3,400	\$ 3,567	\$ 3,723
Cash Flow		\$ (1,306)	\$ (1,694)	\$ (1,075)	\$ (697)	\$ (401)	\$ (136)	\$ 98	\$ 301

Cash Flow Projections									
High Level									
(in \$000's rounded)									
		2017	2018	Yr 1 2019	Yr 2 2020	Yr 3 2021	Yr 4 2022	Yr 5 2023	Yr 6 2024
Revenues									
	Gross Sales	\$ 0	\$ 2,423	\$ 12,113	\$ 14,043	\$ 15,809	\$ 17,411	\$ 18,848	\$ 20,121
	COGS	0	1,817	9,085	10,533	11,857	13,058	14,136	15,090
Gross Profit (Loss)		\$ 0	\$ 606	\$ 3,028	\$ 3,511	\$ 3,952	\$ 4,353	\$ 4,712	\$ 5,030
Expenses									
	Administrative Payroll	421	843	1,277	1,309	1,342	1,375	1,410	1,445
	Banking/Payment Processing	24	24	24	25	25	26	26	27
	Insurance	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	License Fees	0	173	851	986	1,110	1,222	1,322	1,411
	Maintenance & Repair	COGS	COGS	COGS	COGS	COGS	COGS	COGS	COGS
	Professional Fees	240	240	240	246	252	258	265	272
	Public Relations	90	90	90	92	95	97	99	102
	Security	52	104	158	161	165	170	174	178
	Utilities	89	178	COGS	COGS	COGS	COGS	COGS	COGS
	Rent	315	315	315	315	315	315	315	315
	Other	74	149	225	231	236	242	248	255
Total Expenses		\$ 1,306	\$ 2,115	\$ 3,179	\$ 3,365	\$ 3,540	\$ 3,705	\$ 3,860	\$ 4,005
Cash Flow		\$ (1,306)	\$ (1,509)	\$ (151)	\$ 146	\$ 412	\$ 648	\$ 852	\$ 1,026

The above charts for low, mid and high level cash flow projections use the assumption of 750, 1,441, and 2500 respectively for 2019. Subsequent years from 2019 in each chart increased patient estimates by 500 per year.

*The calculations and assumptions below were obtained using the mid-level projections which are detailed below:

Gross Revenues: Given an estimated eighteen (18) month build-out, there will be no Gross Revenue for 2017 and a trickle of Gross Revenue for 2018 (20% of 2019) as the build-out is completed and production and sales ramp up. Gross Revenue (mid-level) for 2019 is taken from an initial number of 1,441 estimated patients, with a presumption that a physician for infused marijuana will recommend at the rate of four and one-half (4.5) 10mg doses per day for each patient⁸, and at an approximate startup expense of \$2.95 per dose⁹. Gross Revenues for 2020, 2021, 2022, 2023, and 2024 assume to increase by roughly five-hundred (500) patients per year (based on increased public and medical acceptance and interest in medical marijuana use by potential patients in the state of Louisiana) and a continuous decline year over year of per doses costs.

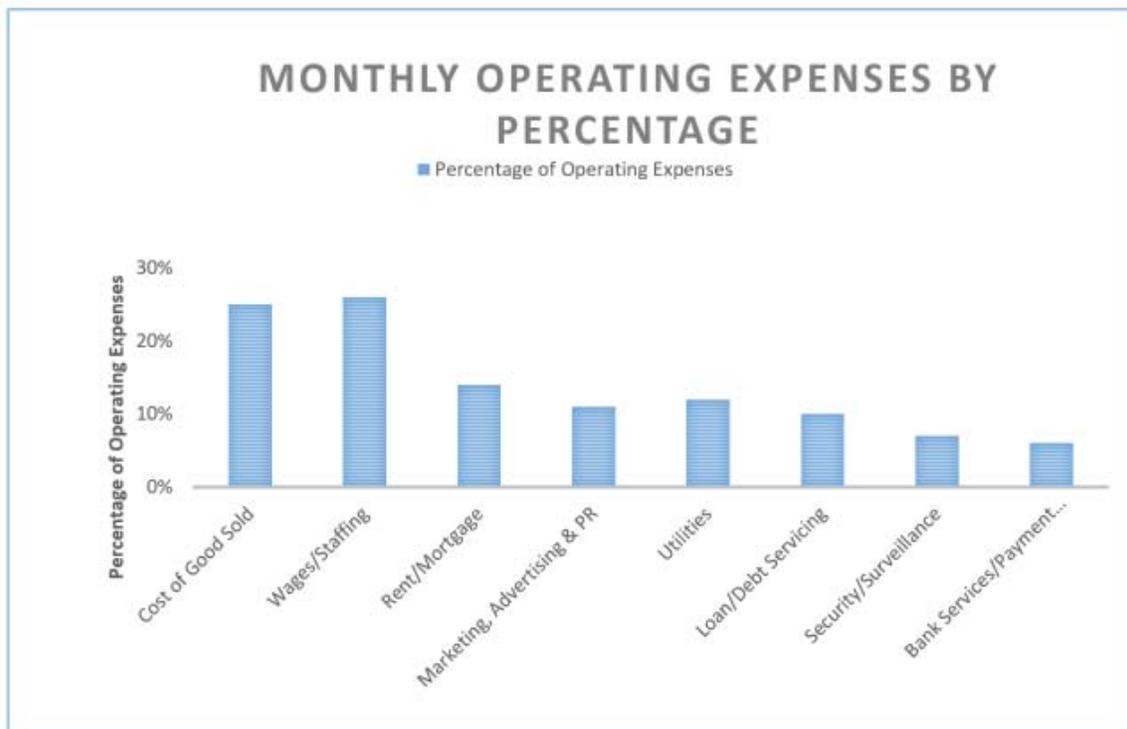
Cost of Goods Sold: Given the estimated eighteen (18) month build-out, it is assumed there will be no COGS for 2017. COGS for 2018 is estimated at a rate of 40% of 2019,

⁸ Health Canada, *Access to Cannabis for Medical Purposes Regulations – Daily Amount Fact Sheet (Dosage)* (July 2016), at n. 19, <http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/daily-quotidienne-eng.php#fnb20> (last updated August 19, 2016) (citing Abbott Products Inc. Marinol® Product Monograph 2010, concluding an average daily dose of medical marijuana is 20mg THC per day).

⁹ Based on price of \$165 per ounce, and generally accepted industry standards that include fifty-six 10mg edible doses are equivalent to one ounce of flower.

to reflect the build-out being fully completed sometime after the second quarter of the year with modest production. COGS for 2019 is based upon an estimated calculation, as follows: 75% of annual Gross Sales, or \$5,237,000.00. COGS for 2020, 2021, 2022, and 2023 are based on a consistent 75% rate for COGS as compared to Gross Sales, by year, respectively.

Expenses: Expenses (except for “Professional Fees” and “Public Relations”) for 2017 and 2018 are based 33% and 66% of 2019, respectively, to account for the phase in of the build-out by the end of 2018. Professional Fees are estimated at \$20k/month through 2019 and are assumed to decrease by 40% each year thereafter. Public Relations are estimated at \$7,500/month. Expenses are based on existing and historical contracts and operating costs for similar items. License fees are included at the rate of 7% paid to the Department per legislative mandate, plus individual employee permitting costs. Insurance, utilities, and maintenance are included in COGS (See Internal Revenue Code 280E in **Appendix I**). “Other” is simply a contingency of 10%. Expenses for 2020, 2021, 2022, 2023, and 2024 are based on a 2.5% contingency increase over the previous year. Also for illustrative and comparative purposes, see the following charts.¹⁰



¹⁰ Adapted from Marijuana Business Daily TM, *Marijuana Business Factbook*, Chare 4.14 (4th ed. 2016).

d. Start-Up Budget

The Production Entity's production area, warehouse, laboratory, and administration facility will encompass approximately 15,000-30,000 as to program evolves, and could include a "phase-in" expansion plan as the program is implemented. Initial build-out for operations are estimated to encompass fifteen-thousand (15,000) square feet, which may be further sub-phased-in.

The estimated budget for renovating and retrofitting an existing facility is **\$5,971,400.00** based on assumptions and calculations made by the AgCenter as more fully set forth below:

The total estimated budget for annual operating costs for year one (as incrementally modified based upon volume of productions) for the Production Entity's facility, (warehouse laboratory, and administration) is \$1,306,000.00, and until which time the Private Entity/LLC projects positive cash flow, the operational carry cost is estimated at **\$5,309,000.00** (the sum of negative cash flow, years 2017-2022, per the forecast contained at **Article VIII.d.**).

Thus, total estimated capital raise for a seed-to-sale Production Facility (partial buildout) based on the above is **\$11,280,400**, without further contingency. The total estimated operating cost does not include the purchase price for leased production facility. (See Mid-Level Cash Flow Chart.)

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Capital Expenditures - Budget Estimate			
Activity	Quantity (sq. ft.)	Unit Cost (sq. ft.)	Totals
Construction (Renovation, Retrofit and Equipment Install)			
Utilities Infrastructure (Electrical w/ Emergency Power, Water, Gas)	1	\$ 250,000.00	\$ 250,000.00
Security System	1	\$ 400,000.00	\$ 400,000.00
Environmental Controls (lights, irrigation, A/C, exhaust, circulating fans)	1	\$ 125,000.00	\$ 125,000.00
Grow/Veg Lights (Production and Research)	5000	\$ 35.00	\$ 175,000.00
Hydroponic Irrigation Sys (tanks, racks, tables, fertigator)	5000	\$ 40.00	\$ 200,000.00
Miscellaneous Equip (fork lift, pallet jack, storage racks, etc.)	1	\$ 100,000.00	\$ 100,000.00
Space Build-out (utilities, CO2, HVAC, dehumidifier, epoxy floors, FRP wall):			
Grow/Veg/Mother Rooms, Research grow space (2000 sf)	3000	\$ 225.00	\$ 675,000.00
Research Grow Space	2000	\$ 225.00	\$ 450,000.00
Labs, Vault, Research Lab space (1000 st)	3100	\$ 300.00	\$ 930,000.00
Drying/Storage, Enclose Loading Dock	2420	\$ 100.00	\$ 242,000.00
Burden Area	4500	\$ 50.00	\$ 225,000.00
Construction Sub-Total:			\$ 3,772,000.00
Design and Contingency (20%):			\$ 754,400.00
Total Construction Budget/Estimate			\$ 4,526,400.00

The estimated budget for equipment and supplies for the plant production rooms and the seed to bud harvest \$724,705.00 based on assumptions and calculations made by the AgCenter as more full set forth below:

Capital Expenditures Budget Estimate			
Activity	Quantity (ea/sq ft/gal)	Unit Cost	Totals
Equipment and Supplies (Plant Production Rooms/Seed-Bud Harvest)			
Pots (20-25 gal) - ea*	125	\$ 12.00	\$ 1,500.00
Pots (2 gal) - ea*	6000	\$ 1.25	\$ 7,500.00
Pots (5 gal) - ea*	8000	\$ 2.25	\$ 18,000.00
Wire / Plastic Frames (upright plants) sq ft*	9000	\$ 2.50	\$ 22,500.00
Sterlite Plastic Boxes (10-20 gal) -ea*	100	\$ 6.00	\$ 600.00
Potting Media (rock, soil, sand, perlite, vermiculite, coco. fiber) - sq ft**	20,000	\$ 2.00	\$ 40,000.00
Potting Media Amendments - sq ft**	6562	\$ 3.00	\$ 19,686.00
Hydroponic / Aeroponic Nutrient Solutions - gal**	7000	\$ 40.00	\$ 280,000.00
Cleaning / Disinfecting Strategies - gal**	300	\$ 4.00	\$ 1,200.00
IPM (Pest) Strategies - sq ft**	15,500	\$ 7.50	\$ 116,250.00
Sterlizers - ea*	2	\$ 20,000.00	\$ 40,000.00
Plastic Sheeting - sq ft*	14,500	\$ 0.25	\$ 3,625.00
Uniforms (Tyvek) - ea**	1460	\$ 11.00	\$ 16,060.00
Misc Equip / Hort. Supplies (tapes, potting, bags, bands, gloves), -ea**			\$ 25,000.00
Misc. Equipment/Hort. Supplies (tools, measuring, etc) -ea*			\$ 12,000.00
	Supply/ Equipment		\$ 603,921.00
	Contingency (20%):		<u>\$ 120,784.00</u>
	Total Plant Equip. Budget Est.:		\$ 724,705.00

*Start Up Cost

**Recurring Cost

The estimated budget for the testing lab (\$714,834.51), research extraction lab (\$181,178.60), production extraction (\$221,056.29), and formulation equipment (\$327,298.69) for a total of **\$1,444,368.09** based on assumptions and calculations made by the AgCenter as more full set forth below:

Capital Expenditures - Budget Estimate		
Activity		Cost
Testing Lab Equipment		
Q Exactive	LC/MS for cannabinoid, pesticide and mycotoxin analysis	\$ 592,312.55
Labconco Hood	Chemical fume hoods	\$ 32,537.00
Miscellaneous	Lab supplies	\$ 25,000.00
Contingency (10%)		\$ 64,984.96
Total Testing Lab Equipment:		\$ 714,834.51

Capital Expenditures - Budget Estimate		
Activity		Cost
Research Extraction Lab Equipment		
Chemglass Reactor	Jacketed Ethanol Extractor	\$ 40,164.60
Genevac RKT Synergy	Ethanol Evaporator	\$ 83,958.61
Thomas Wiley Mini Mill	Plant Mill	\$ 5,584.61
Twister T4	Trimmer	\$ 10,000.00
Miscellaneous	Supplies	\$ 25,000.00
Contingency (10%)		\$ 16,470.78
Total Extraction Lab-Research:		\$ 181,178.60

Capital Expenditures - Budget Estimate		
Activity		Cost
Research Extraction Lab Equipment		
Chemglass Reactor	Jacketed Ethanol Extractor	\$ 41,764.20
Genevac RKT Synergy	Ethanol Evaporator	\$ 89,786.51
Thomas Model 4 Wiley Mill	Plant Mill	\$ 19,409.55
Twister T4	Trimmer	\$ 25,000.00
Miscellaneous	Supplies	\$ 25,000.00
Contingency (10%)		\$ 20,096.03
Total Extraction Lab-Research:		\$ 221,056.29

Capital Expenditures - Budget Estimate			
Activity		Cost	
Formulation Equipment			
Vanguard VSL-2	Capsule Counter	\$	36,150.00
Vanguard Capping & Labeling Line	Capping & Labeling	\$	88,450.00
Schaefer Bander	Capsule Bander	\$	26,175.00
Schaefer RoboCap	Filler	\$	96,973.91
Miscellaneous	Supplies	\$	25,000.00
Contingency (20%)		\$	54,549.78
Total Formulation Equipment:		\$	327,298.69

e. Market Appreciation Opportunities

Increasing Opportunities

The Louisiana Legislature is expected to consider adding debilitating medical conditions to the Act in the future based on feedback from the implementation of the medical marijuana program. Present and ongoing research demonstrates medical marijuana effectively treat many debilitating conditions not listed under the current Act. Once legislators expand the list of debilitating medical conditions, more patients will have access to the program; thus, the market could increase to create an emerging industry.

Nationwide statistics reflect that the addition of chronic pain expands the potential patient base. Many forms of chronic pain are treatable with topical delivery methods currently allowed under the Act. Post-Traumatic Stress Disorder and anxiety are also conditions that might increase the number of patients who prefer medical marijuana to avoid the many side effects and risks that accompany pharmaceutical medications, particularly when taken long term.

Lifting the limitation of ethanol based extractions may further increase profitability, as will allowing more commonly used delivery methods. In short, as the industry across the nation matures, Louisiana's program is also expected to evolve, resulting in the potential of greater success for this program.

New Research Opportunities

On August 11, 2016, DEA Acting Administrator Chuck Rosenberg announced that while marijuana will remain classified as a Schedule I substance under the federal Controlled Substances Act, the DEA is working with the National Institute of Drug Abuse (NIDA), the FDA, and the United States Department of Health and Human Services (HHS) to promote legitimate research of marijuana and its constituent parts.

In ushering in a new era of a research oriented approach to marijuana, the DEA appears to be paving the way for such research to eventually support removal from Schedule I status.

The DEA is opening up research to allow both private and public institutions to obtain approval to become registered to cultivate and research marijuana for scientific purposes. This new development could lead to the ability to cultivate and research marijuana with federal permission, thus removing some of the federal risk associated with Louisiana's program and providing enhanced opportunities to develop patentable strains on particular plants. Additionally, the AgCenter could become a supplier of other institutions' research efforts. Consideration for further regulatory approvals is under way.

Rosenberg touted the DEA's efforts to foster marijuana research as follows:

- Citing a doubling of the number of research registrations since 2014, Rosenberg declared the DEA would propose rules to be published in the Federal Register to approve additional marijuana growers to increase the supply for research.
- Rosenberg noted that no application from a researcher to study lawfully produced marijuana has been denied, if the HHS deemed the study to be meritorious.
- In December 2015, the DEA decided to waive certain regulatory requirements for cannabidiol (CBD) clinical-trials on human subjects. Rosenberg noted that no request for a waiver under this program has been denied.
- An online application process is being created to expedite research registration, and the DEA is developing guidance materials to assist researchers in the online application process.

Rosenberg concluded, “[i]f the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands.” Rosenberg also promised the DEA “will continue to seek ways to make the process for those researchers more effective.”

For a copy of the DEA's August 11, 2016 scheduling decision, and the DEA's Policy Statement regarding rules to be proposed in the Federal Register, see **Appendix B**.

IX. Intellectual Property Development

One of the most powerful tools a business can have is exclusivity in the market. One way to gain exclusivity is for a business to strategically acquire and maintain intellectual property (IP) rights to various aspects of the business. Patents, trademarks, copyrights, trade secrets, contracts, and Plant Variety Protection Certificates are among the options available to growers and marijuana business owners of all types. Appropriately identifying which types of IP a company has is the first step.

Patents

Two types of patents are relevant to marijuana: utility and plant.

Plant patents are used to protect asexually reproducible varieties of plants, *i.e.*, clones. While a plant patent is useful for protecting a clone, it is quite narrow in that it is essentially only a design patent protecting the novel and visually perceived attributes of the plant.

Utility patents are regularly used to protect plants, extraction and formulation methods, growing techniques, and hardware, to name a few. At this time, no express law or governing body will limit patentability of a specific marijuana strain. In fact, many marijuana strain patents have been issued by the U.S. Patent and Trademark Office (USPTO).

Trademarks

Trademarks, on the other hand, are more challenging. While a trademark registration gives the owner exclusivity of a name, design, or phrase, at this time, the USPTO will not grant trademark registration for marks used in conjunction with marijuana or marijuana-related products. Thus, to acquire trademark registration, a marijuana business owner must be willing to be flexible.

One way to acquire trademark protection is to register a name, design, or phrase with the secretary of state's office in a state where marijuana is legal, thus avoiding violation of any federal laws. At this time, the only option a marijuana-business owner has for acquiring trademark protection *at the federal level* is to register with the USPTO for legal and non-marijuana-related products being sold in interstate commerce. For example, some marijuana-business owners choose to distribute legal hemp products in interstate commerce.

Trade Secrets

Trade secrets and other contracts can also be effective tools for obtaining exclusivity. Trade secret protection can be created by virtue of contractually protecting the development and maintenance of marijuana-business methods, for example, methods

of producing proprietary marijuana strains. This means only letting pre-screened individuals who have signed confidentiality and non-disclosure contracts *and* who have a “need to know” to have access to such methods.

Other contracts are useful as well; for example, a material-use contract or technology-use contract could be used to restrict the use of seeds and/or clones, while a clone supply agreement may be used to protect a specific strain from improper use by end users or purchasers. Ultimately, the use of strategic contracting can be a less expensive option for the cost-conscious business owner.

Plant Variety Protection Act

The Plant Variety Protection Act (PVPA) can be used to protect the development of new seed varieties. Similar to patent protection, a grower can enjoy exclusivity for selling and growing of proprietary varieties of seed and tuber propagated plants that are new, distinct, uniform, and stable. Specifically, having a PVPA certificate makes it unlawful for an unauthorized third party to sell or grow a PVPA protected seed variety without permission from the PVPA certificate holder.

Maximization of IP Potential

Once a marijuana business owner has determined the types of IP his or her business has, the next step is to properly plan and budget for the acquisition/registration and maintenance of that IP. Because IP is extremely valuable, significant costs are associated with acquiring it and thus, depending on what is needed, a business owner may be faced with the decision of what to protect and when.

In a market where every detail down to the marijuana strain type is protectable, proper understanding of how and when to protect your IP is vital. The AgCenter will register and own all of the IP developed in the Production Facility. The public benefit corporation that will be set up to operate the Production Facility will have the right of first refusal on the commercialization of any IP generated by the AgCenter.

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X. Timeline/Chronology

The timeline for this project will be determined by implementation of the terms of the contract with the selected production entity. Based upon legislative expectation, the LSU AgCenter and any sub-contractor will expedite the implementation for production of medical marijuana product. The act sunsets on January 1, 2020 and will require reauthorization by the legislature.

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XI. APPENDICES

APPENDIX A – Dr. Alison Neustrom Obituary

APPENDIX B – Federal Announcements

- **Cole Memo**
- **DEA Policy on Research**
- **DEA Scheduling Announcement**
- **Department of Justice Guidance Regarding Marijuana Related Financial Crimes**
- **Department of the Treasury Financial Crimes Enforcement Network (BSA Expectations Regarding Marijuana Related Businesses)**

APPENDIX C – Legislation, Rules and Regulations

APPENDIX D – Patient Count Source Data

APPENDIX E – Comparison by State

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a. APPENDIX A – Dr. Alison Neustrom Obituary

Mother's dying wish to legalize medical marijuana granted

"THIS IS SOMETHING SHE FOUGHT FOR EVEN THOUGH SHE KNEW IT WOULDN'T HELP HER. WE FEEL LIKE HER DOOR CLOSED, BUT SHE OPENED A WINDOW TO HELP SO MANY OTHER PEOPLE IN THE STATE."



Alison Neustrom Carner

(Photo: Jeremiah Ariaz)



Emily Neustrom plays with her niece Ceci Carner, 3, at their family's home in Lafayette, La., Friday, June 5, 2015. (Photo: Paul Kieu, The Advertiser)

Sunflowers are a prominent feature in the Neustrom home.

The big, yellow blooms were the favorite of Alison Neustrom, the second eldest daughter of Sheriff Mike and Ceci Neustrom and sister to Kim, Emily, Vanessa, Ben and Tom.

Neustrom was also the main reason why a landmark bill made it through the Louisiana Legislature.

"It's bittersweet," Kim Neustrom, Alison's older sister, said. "This is something she fought for even though she knew it wouldn't help her. We feel like her door closed, but she opened a window to help so many other people in the state."

Alison Neustrom died in September 2014 of pancreatic cancer at age 42. She left behind a husband, Dave Carner, and a 2-year-old daughter, Ceci.

In the fall of 2013, Neustrom's sisters said, the family got the devastating news that Alison had the fatal disease. Her battle with the illness lasted 11 months.

"(Marijuana) was legalized but no there were no rules about how to grow it, prescribe it and dispense it," Sen. Fred Mills said. "Many of my customers were families that, having tried all else, had come across the plant's medical benefits through researchers and doctors."

Mills had been studying the issue for years. Last year, as he was crafting legislation to fix the existing law, he got a call from Neustrom who was in her final stages of life. She wanted to help. She told the senator she would be willing to testify before a committee if her health allowed.

On the day she testified, many were brought to tears.

"It was so inspiring," Vanessa Neustrom recalled. "She told them what she was going through and about her illness and how it was too late for her. But (at one point) she said, 'Don't worry, I'm not radioactive.' They laughed. She was a one-woman warrior, trying to make a difference. She felt like 'Why shouldn't I speak up?' "

Although the bill died in committee last year, Neustrom's testimony had a powerful effect.

Mills said his biggest mistake was not involving local and state law enforcement. As it turned out, Neustrom helped change that when she made a personal plea to Louisiana Sheriff's Association director Mike Ranatza who later told reporters he was "moved by her testimony."

Mills went back to the drawing board and brought the issue back up again this year. This time, he said, he contacted all the state's law enforcement groups and tried to convince them that the law would make sure the drug could only be used for medical purposes, with no chance for recreational use.

His efforts paid off.

On June 4, despite some dissension from the Louisiana District Attorneys Association, the House approved the proposal with a 70-29 vote.

[\(http://www.theadvertiser.com/story/news/local/louisiana/2015/05/27/legislators-giving-marijuana-bill-thumbs/28037361/\)](http://www.theadvertiser.com/story/news/local/louisiana/2015/05/27/legislators-giving-marijuana-bill-thumbs/28037361/)

The bill then returned for a final vote in the Senate on June 8 and was approved by a vote of 30-6. By Wednesday, the bill was headed to Bobby Jindal's desk to be signed into law.

READ MORE: How Louisiana's medical marijuana bill has evolved.

[\(http://www.theadvertiser.com/story/news/local/louisiana/2015/05/11/louisianas-medical-marijuana-bill-evolved/27047555/\)](http://www.theadvertiser.com/story/news/local/louisiana/2015/05/11/louisianas-medical-marijuana-bill-evolved/27047555/)

Mills said the new law will only allow patients to consume refined forms of marijuana, such as an oil. It will prohibit inhalation or smoking the plant. He said patients won't be able to get high from the drug, but should be able to benefit from its therapeutic effects.

"At this point the law will help those who have glaucoma, symptoms resulting from chemotherapy for cancer treatment and spastic quadriplegia," Mills said. "But this process will continue to look at additional diseases."

Not everyone is pleased with the outcome. Last month, David Brown, the director of Sensible Marijuana Policy for Louisiana, told The Advertiser that since the bill does not approve the use of marijuana for all illnesses, it falls short of the groups expectations.

"With respect to 143, we had hoped for more," Brown said. "While SMPL is "delighted" that cancer, glaucoma and some spinal cord patients may find relief under the legislation, there's a long list of other maladies — Post Traumatic Stress Disorders, AIDS "wasting" and chronic spasticity disorders, among them — that could be treated as well."

Still, for the Neustrom family, knowing the suffering their loved one went through, the success of the bill and the hope that some patients may benefit from it, is cause for celebration.

"I was watching it stream live from work," recalled Vanessa Neustrom. "And, I was like, 'Yes!' Because it was something that had come to represent what she did with her life, with families, all the (advocacy) work she did for others. It was a unique way for Alison to make a difference."

Though Lafayette Parish Sheriff Mike Neustrom is also part of the LSA, his daughters said he stayed out of the issue. Mills said the Sheriff did advise him on how to work with law enforcement but did not actively campaign for the bill. Sheriff Neustrom did not want to comment for this story.

"It was something she did on her own, without her dad," Emily Neustrom said. "Until she was recognized at a PAR (Public Affairs Council) luncheon, I never realized the scope of what she did."

The sisters estimated close to a thousand people filled the Cathedral of St. John the Evangelist, where Neustrom's funeral was held in September. Many were high school and college friends. Others were there to show support for her family, including Ceci, Neustrom's blonde-haired, blue-eyed toddler.

To make sure Ceci would remember her, Alison and her husband Dave compiled an oral history video and published it on YouTube (<https://www.youtube.com/watch?v=Pr3zJDnvnK0>). The eight-part video diary includes her reflections on her life and her hopes for her daughter, now 3, in the future. It also includes her father, Mike Neustrom, playing guitar and singing, 'We Shall All Be Reunited.'

The videos are a touching and heartbreaking look at who Alison Neustrom was. At home, there are constant reminders of her in photos, many showing her surrounded by her favorite sunflowers.

"She was very straight-laced," said Kim Neustrom. "This was not at all a part of her lifestyle. But she knew the kind of pain others were experiencing and without thought of her own, she wanted to help other people. That's the kind of person she was."

For husband Dave, the law is only a small part of Alison Neustrom's legacy that he'll be sharing with their daughter.

"I don't want to lessen the contribution Alison made to SB143 and the positive things that have resulted from it. It is important," he said. "But when I tell our daughter about her mother and the legacy she left, the Alison Neustrom Act will be a small part of it. More importantly, I will tell her about how her mother spent her life, both personally and professionally, striving to ensure that government and law worked for the benefit of all people, no matter what side of the sphere of influence they happen to find themselves on."



Alison Neustrom's Obituary on
The Advertiser
<http://www.legacy.com/obituaries/theadvertiser/obituary.aspx?n=alison-neustrom&pid=172432548&fhid=12380>

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b. APPENDIX B – Federal Announcements

i. Cole Memo

(See Next Page.)



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole 
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

These priorities will continue to guide the Department's enforcement of the CSA against marijuana-related conduct. Thus, this memorandum serves as guidance to Department attorneys and law enforcement to focus their enforcement resources and efforts, including prosecution, on persons or organizations whose conduct interferes with any one or more of these priorities, regardless of state law.¹

Outside of these enforcement priorities, the federal government has traditionally relied on states and local law enforcement agencies to address marijuana activity through enforcement of their own narcotics laws. For example, the Department of Justice has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property. Instead, the Department has left such lower-level or localized activity to state and local authorities and has stepped in to enforce the CSA only when the use, possession, cultivation, or distribution of marijuana has threatened to cause one of the harms identified above.

The enactment of state laws that endeavor to authorize marijuana production, distribution, and possession by establishing a regulatory scheme for these purposes affects this traditional joint federal-state approach to narcotics enforcement. The Department's guidance in this memorandum rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice. Jurisdictions that have implemented systems that provide for regulation of marijuana activity

¹ These enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA. By way of example only, the Department's interest in preventing the distribution of marijuana to minors would call for enforcement not just when an individual or entity sells or transfers marijuana to a minor, but also when marijuana trafficking takes place near an area associated with minors; when marijuana or marijuana-infused products are marketed in a manner to appeal to minors; or when marijuana is being diverted, directly or indirectly, and purposefully or otherwise, to minors.

must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above. Indeed, a robust system may affirmatively address those priorities by, for example, implementing effective measures to prevent diversion of marijuana outside of the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity. If state enforcement efforts are not sufficiently robust to protect against the harms set forth above, the federal government may seek to challenge the regulatory structure itself in addition to continuing to bring individual enforcement actions, including criminal prosecutions, focused on those harms.

The Department's previous memoranda specifically addressed the exercise of prosecutorial discretion in states with laws authorizing marijuana cultivation and distribution for medical use. In those contexts, the Department advised that it likely was not an efficient use of federal resources to focus enforcement efforts on seriously ill individuals, or on their individual caregivers. In doing so, the previous guidance drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for-profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution. In drawing this distinction, the Department relied on the common-sense judgment that the size of a marijuana operation was a reasonable proxy for assessing whether marijuana trafficking implicates the federal enforcement priorities set forth above.

As explained above, however, both the existence of a strong and effective state regulatory system, and an operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests. Accordingly, in exercising prosecutorial discretion, prosecutors should not consider the size or commercial nature of a marijuana operation alone as a proxy for assessing whether marijuana trafficking implicates the Department's enforcement priorities listed above. Rather, prosecutors should continue to review marijuana cases on a case-by-case basis and weigh all available information and evidence, including, but not limited to, whether the operation is demonstrably in compliance with a strong and effective state regulatory system. A marijuana operation's large scale or for-profit nature may be a relevant consideration for assessing the extent to which it undermines a particular federal enforcement priority. The primary question in all cases – and in all jurisdictions – should be whether the conduct at issue implicates one or more of the enforcement priorities listed above.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

cc: Mythili Raman
Acting Assistant Attorney General, Criminal Division

Loretta E. Lynch
United States Attorney
Eastern District of New York
Chair, Attorney General's Advisory Committee

Michele M. Leonhart
Administrator
Drug Enforcement Administration

H. Marshall Jarrett
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Executive Office for United States Attorneys

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Assistant Director
Criminal Investigative Division
Federal Bureau of Investigation

ii. DEA Policy on Research

(See Next Page.)



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Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-447]

Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Policy statement.

SUMMARY: To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States. This policy statement explains how DEA will evaluate applications for such registration consistent with the CSA and the obligations of the United States under the applicable international drug control treaty.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background

Reasons For This Policy Statement

There is growing public interest in exploring the possibility that marijuana or its chemical constituents may be used as potential treatments for certain medical conditions. The Federal Food, Drug and Cosmetic Act requires that before a new drug is allowed to enter the U.S. market, it must be demonstrated through adequate and well-controlled clinical trials to be both safe and effective for its intended uses. Congress long ago established this process, recognizing that it was essential to protect the health and welfare of the American people.

Although no drug product made from marijuana has yet been shown to be safe and effective in such clinical trials, DEA – along with the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) – fully supports expanding research into the potential medical utility of marijuana and its chemical constituents.¹

¹ There are two FDA-approved drugs that contain a synthetic form of dronabinol, which is one of the chemicals found in marijuana. These drugs are Marinol (which the FDA approved for the treatment of nausea and vomiting associated with cancer chemotherapy, and for the treatment of anorexia associated with weight loss in patients with AIDS) and Syndros (which was approved for the same indications as Marinol).

There are a variety of factors that influence whether and to what extent such research takes place. Some of the key factors—such as funding—are beyond DEA's control.² However, one of the ways DEA can help to facilitate research involving marijuana is to take steps, within the framework of the CSA and U.S. treaty obligations, to increase the lawful supply of marijuana available to researchers.

For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research. This grower operates under a contract with the National Institute on Drug Abuse (NIDA). This longstanding arrangement has historically been considered by the U.S. Government to be the best way to satisfy our nation's obligations under the applicable international drug control treaty, as discussed in more detail below. For most of the nearly 50 years that this single marijuana grower arrangement has been in existence, the demand for research-grade marijuana in the United States was relatively limited—and the single grower was able to meet such limited demand. However, in recent years, there has been greater public interest in expanding marijuana-related research, particularly with regard to certain chemical constituents in the plant known as cannabinoids.

² Funding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place. What appears to have been the greatest spike in marijuana research in the United States occurred shortly after the State of California enacted legislation in 1999 to fund such research. Specifically, in 1999, California enacted a law that established the "California Marijuana Research Program" to develop and conduct studies on the potential medical utility of marijuana. CAL. HEALTH & SAFETY CODE § 11362.9. The state legislature appropriated a total of \$9 million for the marijuana research studies. Over the next five years, DEA received applications for registration in connection with at least 17 State-sponsored pre-clinical or clinical studies of marijuana (all of which DEA granted). 74 FR 2101, 2105 (2009). However, it appears that once the State stopped funding the research, the studies ended.

The term "cannabinoids" generally refers to those chemicals unique to the cannabis plant (marijuana).³ To date, more than 100 different cannabinoids have been found in the plant. One such cannabinoid – known as cannabidiol or CBD – has received increased attention in recent years. Although the effects of CBD are not yet fully understood by scientists, and research is ongoing in this area, some studies suggest that CBD may have uses in the treatment of seizures and other neurological disorders. A growing number of researchers have expressed interest in conducting research with extracts of marijuana that have a particular percentage of CBD and other cannabinoids. DEA fully supports research in this area. Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA. This policy statement explains the new approach, provides details about the process by which potential growers may apply for a DEA registration, and describes the steps they must take to ensure their activity will be carried out in conformity with U.S. treaty obligations and the CSA.

The historical system, under which NIDA relied on one grower to supply marijuana on a contract basis, was designed primarily to supply marijuana for use in federally funded research—not for commercial product development. Thus, under the historical system, there was no clear legal pathway for commercial enterprises to produce

³ An acceptable and broader definition of "cannabinoids" includes not only those chemicals unique to the

marijuana for product development. In contrast, under the new approach explained in this policy statement, persons may become registered with DEA to grow marijuana not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development. Likewise, under the new approach, should the state of scientific knowledge advance in the future such that a marijuana-derived drug is shown to be safe and effective for medical use, pharmaceutical firms will have a legal means of producing such drugs in the United States—independent of the NIDA contract process.

Legal Considerations

Applicable CSA Provisions

Under the CSA, all persons who seek to manufacture or distribute a controlled substance must apply for a DEA registration. 21 U.S.C. 822(a)(1). Applications by persons seeking to grow marijuana to supply researchers are governed by 21 U.S.C. 823(a); *see generally* 76 FR 51403 (2011); 74 FR 2101 (2009). Under section 823(a), for DEA to grant a registration, two conditions must be satisfied: (1) the registration must be consistent with the public interest (based on the enumerated criteria listed in section 823(a)) and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). An applicant seeking registration under section 823(a) has "the burden of proving that the requirements for such registration pursuant to [this section] are satisfied." 21 CFR 1301.44(a). Although each application for registration that DEA receives will be evaluated individually based on its own merit, some general considerations warrant mention here.

cannabis plant but also their derivatives and transformation products.

First, while it is DEA's intention to increase the number of registered marijuana growers who will be supplying U.S. researchers, the CSA does not authorize DEA to register an unlimited number of manufacturers. As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." *See* 74 FR at 2127–2130 (discussing meaning of subsection 823(a)(1)). This provision is based on the long-established principle that having fewer registrants of a given controlled substances tends to decrease the likelihood of diversion.

Consistent with subsection 823(a)(1), DEA will evaluate each application it receives to determine whether adding such applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States.⁴

Second, as with any application submitted pursuant to section 823(a), in determining whether the proposed registration would be consistent with the public interest, among the factors to be considered are whether the applicant has previous experience handling controlled substances in a lawful manner and whether the applicant has engaged in illegal activity involving controlled substances. In this context, illegal activity includes any activity in violation of the CSA (regardless of whether such activity is permissible under State law) as well as activity in violation of State or local law. While past illegal conduct

⁴ In making this determination, DEA will consult with NIH and FDA, as warranted.

involving controlled substances does not automatically disqualify an applicant, it may weigh heavily against granting the registration.

Third, given the in-depth nature of the analysis that the CSA requires DEA to conduct in evaluating these applications, applicants should anticipate that, in addition to the information requested in the application itself, they will be asked to submit other information germane to the application in accordance with 21 CFR 1301.15. This will include, among other things, detailed information regarding an applicant's past experience in the manufacture of controlled substances. In addition, applicants will be asked to provide a written explanation of how they believe they would be able to augment the nation's supply of research-grade marijuana within the meaning of subsection 823(a)(1). Applicants may be asked to provide additional written support for their application and other information that DEA deems relevant in evaluating the application under section 823(a).

Treaty Considerations

As stated above, DEA may only issue a registration to grow marijuana to supply researchers if the registration is consistent with U.S. obligations under the Single Convention. Although this policy document will not list all of the applicable requirements of the Single Convention,⁵ the following is a summary of some of the key considerations.

Under articles 23 and 28 of the Single Convention, a party (i.e., a country that is a signatory to the treaty) that allows the cultivation of cannabis for lawful uses (e.g., FDA-authorized clinical trials) must:

(a) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis shall be permitted;

(b) License cultivators authorized to cultivate cannabis;

(c) Specify through such licensing the extent of the land on which the cultivation is permitted;

(d) Purchase and take physical possession of all cannabis crops from all cultivators as soon as possible, but not later than four months after the end of the harvest; and

(e) Have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis.

As DEA has stated in a prior publication, DEA carries out those functions of article 23, paragraph 2, that are encompassed by the DEA registration system (paragraphs (a) through (c) above), and NIDA carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution (paragraphs (d) and (e) above).⁶ 76 FR at 51409.

As indicated, DEA's historical approach to ensuring compliance with the foregoing treaty requirements was to limit the registration of marijuana growers who supply researchers to those entities that operate under a contract with NIDA. Under this historical approach, the grower could be considered an extension of NIDA and thus all marijuana produced by the grower was effectively owned by NIDA, with NIDA controlling all distribution to researchers.

⁵ A detailed explanation of the relevant Single Convention requirements can be found in 74 FR at 2114–2118.

⁶ In accordance with the CSA, DEA carries out functions that are indirectly related to those specified in article 23, paragraph 2(e). For example, DEA controls imports and exports of cannabis through the CSA registration and permitting system.

However, as further indicated, DEA has concluded, based on discussions with NIDA and FDA, that it would be beneficial for research to allow additional marijuana growers outside the NIDA-contract system, provided this could be accomplished in a manner consistent with the CSA and the treaty. Toward this end, DEA took into account the following statement contained in the official commentary to the Single Convention:

Countries . . . which produce . . . cannabis . . . , [i]n so far as they permit private farmers to cultivate the plants . . . , cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. . . . [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 . . . and article 28 . . . therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

Commentary at 278.

Given the foregoing considerations, DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the NIDA-contract system to supply researchers, *provided the growers agree that they may only distribute marijuana with prior, written approval from DEA*. In other words, in lieu of requiring the growers to operate under a contract with NIDA, a registered grower will be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA. DEA believes this new approach will

succeed in avoiding one of the scenarios the treaty is designed to prevent: private parties trading in marijuana outside the supervision or direction of the federal government.

Also, consistent with the purposes and structure of the CSA, persons who become registered to grow marijuana to supply researchers will only be authorized to supply DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services (HHS) to be scientifically meritorious. *See* 21 U.S.C. 823(f). In 2015, HHS announced the details of its current policy for evaluating the merits of research protocols involving marijuana. 80 FR 35960 (2015).

Finally, potential applicants should note that any entity granted a registration to manufacture marijuana to supply researchers will be subject to all applicable requirements of the CSA and DEA regulations, including those relating to quotas, record keeping, order forms, security, and diversion control.

How To Apply For A Registration

Persons interested in applying for a registration to become a bulk manufacturer of marijuana to supply legitimate researchers can find instructions and the application form by going to the DEA Office of Diversion Control website registration page at www.deadiversion.usdoj.gov/drugreg/index.html#regapps. Applicants will need to submit Form 225.

Note Regarding The Nature of This Document

This document is a general statement of DEA policy. While this document reflects how DEA intends to implement the relevant statutory and regulatory provisions, it does not establish a rule that is binding on any member of the public. Any person who applies for a registration to grow marijuana (as with any other applicant for registration under the

CSA) is entitled to due process in the consideration of the application by the Agency. To ensure such due process, the CSA provides that, before taking action to deny an application for registration, DEA must serve upon the applicant an order to show cause why the application should not be denied, which shall provide the applicant with an opportunity to request a hearing on the application in accordance with the Administrative Procedure Act. 21 U.S.C. 824(c).

Dated: July 25, 2016

Chuck Rosenberg,
Acting Administrator.

iii. DEA Scheduling Announcement

(See Next.)



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

August 11, 2016

The Honorable Gina M. Raimondo
Governor of Rhode Island
82 Smith Street
Providence, Rhode Island 02903

The Honorable Jay R. Inslee
Governor of Washington
P.O. Box 40002
Olympia, Washington 98504-0002

Mr. Bryan A. Krumm
[REDACTED]
[REDACTED]

Dear Governor Raimondo, Governor Inslee, and Mr. Krumm:

The enclosed materials provide the legal and factual bases for our decision, in response to your petitions, regarding the rescheduling of marijuana.¹ I will get to that decision, but I will first highlight broader considerations with respect to (1) the law regarding drug scheduling and (2) the current state of marijuana research.

The Law Regarding Drug Scheduling:

The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of the drug. Under the CSA, the Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), reviews, analyzes, and assesses that data and its medical and scientific conclusions legally bind the Drug Enforcement Administration (DEA).

The FDA and the DEA make a determination based on a full review of the relevant scientific and medical literature regarding marijuana. That process, too, is outlined in the enclosed materials.

A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. These criteria are set by statute.

¹ Governors Raimondo and Inslee succeeded petitioner Governors Chafee and Gregoire, respectively.

Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger.

In that sense, drug scheduling is unlike the Saffir-Simpson scale or the Richter scale. Movement up those two scales indicates increasing severity and damage (for hurricanes and earthquakes, respectively); not so with drug scheduling. It is best not to think of drug scheduling as an escalating “danger” scale – rather, specific statutory criteria (based on medical and scientific evidence) determine into which schedule a substance is placed.

Marijuana Research:

Research is the bedrock of science, and we will – as we have for many years – support and promote legitimate research regarding marijuana and its constituent parts. For instance, DEA has never denied an application from a researcher to use lawfully produced marijuana in a study determined by the Department of Health and Human Services (HHS) to be scientifically meritorious.

In fact, during the last two plus years, the total number of individuals and institutions registered with DEA to research marijuana, marijuana extracts, derivatives, and tetrahydrocannabinols (THC) has more than doubled, from 161 in April 2014 to 354 at present. Some of the ongoing research includes studies of the effects of smoked marijuana on human subjects. Folks might be surprised to learn that we support this type of research. But, we do.

DEA and NIDA have also increased the amount of marijuana available for research. Indeed, we consistently meet legitimate demand by researchers for marijuana. Currently, NIDA is filling requests for research marijuana in an average of 25 days.

We will continue to work with NIDA to ensure that there is a sufficient supply of marijuana and its derivatives (in terms of quantity and the variety of chemical constituents) to support legitimate research needs. This includes approving additional growers of marijuana to supply researchers. Details of this proposal to support legitimate research will be published in the Federal Register.

Further, in December 2015, we waived certain regulatory requirements for researchers conducting FDA-authorized clinical trials on cannabidiol (CBD), a constituent part of marijuana. These waivers, when granted, enable researchers to modify or expand the scope of their studies more easily. Currently, there are 90 researchers registered with the DEA to conduct CBD research on human subjects. We have approved every waiver application that has been submitted by these researchers – to date, a total of 47.

The Honorable Gina M. Raimondo
The Honorable Jay R. Inslee
Mr. Bryan A. Krumm

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If, for instance, CBD proves to be safe and effective for the treatment of a specific medical condition, such as childhood epilepsy (some trials have shown promise), that would be a wonderful and welcome development. But we insist that CBD research – or any research – be sound, scientific, and rigorous before a product can be authorized for medical use. That is specifically – and properly – the province of the FDA.

DEA continues to work on other measures to support marijuana research. For instance, DEA is building an online application system for researchers to apply for Schedule I research registrations, including for marijuana. DEA also is drafting clear guidance to assist Schedule I researchers in that application process.

The Decision:

The FDA drug approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science, and properly so, because the safety of our citizens relies on it.²

Using established scientific standards that are consistent with that same FDA drug approval process and based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, marijuana will remain a schedule I controlled substance. It does not have a currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

If the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands. It certainly would be odd to rely on science when it suits us and ignore it otherwise.

² The FDA's scientific assessment determines the safety and efficacy of drugs intended for human consumption. The FDA's team, charged with conducting that assessment, consists of clinical pharmacologists, epidemiologists, toxicologists, physicians, chemists, statisticians and other scientists, working together to ensure approved drugs are safe and effective. As our partners at HHS note, "[An] expert [in this discipline] is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug." Although medical doctors are highly trained and qualified to treat patients with FDA-approved drugs, as HHS notes, "[m]edical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe or effective or meets NDA (New Drug Application) requirements." 57 FR 10499. Simply put, evaluating the safety and effectiveness of drugs for their intended use is a highly specialized endeavor undertaken by the FDA's Center for Drug Evaluation and Research.

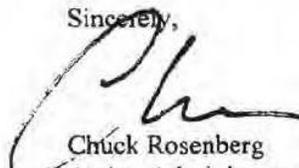
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The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.

We fully support legitimate medical and scientific research on marijuana and its constituent parts and we will continue to seek ways to make the process for those researchers more efficient and effective.

Sincerely,



Chuck Rosenberg
Acting Administrator

Enclosures

**iv. Department of Justice Guidance Regarding
Marijuana Related Financial Crimes**

See Next Page



U.S. Department of Justice
Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

February 14, 2014

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole 
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Related Financial Crimes

On August 29, 2013, the Department issued guidance (August 29 guidance) to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). The August 29 guidance reiterated the Department's commitment to enforcing the CSA consistent with Congress' determination that marijuana is a dangerous drug that serves as a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. In furtherance of that commitment, the August 29 guidance instructed Department attorneys and law enforcement to focus on the following eight priorities in enforcing the CSA against marijuana-related conduct:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

Under the August 29 guidance, whether marijuana-related conduct implicates one or more of these enforcement priorities should be the primary question in considering prosecution

under the CSA. Although the August 29 guidance was issued in response to recent marijuana legalization initiatives in certain states, it applies to all Department marijuana enforcement nationwide. The guidance, however, did not specifically address what, if any, impact it would have on certain financial crimes for which marijuana-related conduct is a predicate.

The provisions of the money laundering statutes, the unlicensed money remitter statute, and the Bank Secrecy Act (BSA) remain in effect with respect to marijuana-related conduct. Financial transactions involving proceeds generated by marijuana-related conduct can form the basis for prosecution under the money laundering statutes (18 U.S.C. §§ 1956 and 1957), the unlicensed money transmitter statute (18 U.S.C. § 1960), and the BSA. Sections 1956 and 1957 of Title 18 make it a criminal offense to engage in certain financial and monetary transactions with the proceeds of a “specified unlawful activity,” including proceeds from marijuana-related violations of the CSA. Transactions by or through a money transmitting business involving funds “derived from” marijuana-related conduct can also serve as a predicate for prosecution under 18 U.S.C. § 1960. Additionally, financial institutions that conduct transactions with money generated by marijuana-related conduct could face criminal liability under the BSA for, among other things, failing to identify or report financial transactions that involved the proceeds of marijuana-related violations of the CSA. *See, e.g.*, 31 U.S.C. § 5318(g). Notably for these purposes, prosecution under these offenses based on transactions involving marijuana proceeds does not require an underlying marijuana-related conviction under federal or state law.

As noted in the August 29 guidance, the Department is committed to using its limited investigative and prosecutorial resources to address the most significant marijuana-related cases in an effective and consistent way. Investigations and prosecutions of the offenses enumerated above based upon marijuana-related activity should be subject to the same consideration and prioritization. Therefore, in determining whether to charge individuals or institutions with any of these offenses based on marijuana-related violations of the CSA, prosecutors should apply the eight enforcement priorities described in the August 29 guidance and reiterated above.¹ For example, if a financial institution or individual provides banking services to a marijuana-related business knowing that the business is diverting marijuana from a state where marijuana sales are regulated to ones where such sales are illegal under state law, or is being used by a criminal organization to conduct financial transactions for its criminal goals, such as the concealment of funds derived from other illegal activity or the use of marijuana proceeds to support other illegal activity, prosecution for violations of 18 U.S.C. §§ 1956, 1957, 1960 or the BSA might be appropriate. Similarly, if the financial institution or individual is willfully blind to such activity by, for example, failing to conduct appropriate due diligence of the customers’ activities, such prosecution might be appropriate. Conversely, if a financial institution or individual offers

¹ The Department of the Treasury’s Financial Crimes Enforcement Network (FinCEN) is issuing concurrent guidance to clarify BSA expectations for financial institutions seeking to provide services to marijuana-related businesses. The FinCEN guidance addresses the filing of Suspicious Activity Reports (SAR) with respect to marijuana-related businesses, and in particular the importance of considering the eight federal enforcement priorities mentioned above, as well as state law. As discussed in FinCEN’s guidance, a financial institution providing financial services to a marijuana-related business that it reasonably believes, based on its customer due diligence, does not implicate one of the federal enforcement priorities or violate state law, would file a “Marijuana Limited” SAR, which would include streamlined information. Conversely, a financial institution filing a SAR on a marijuana-related business it reasonably believes, based on its customer due diligence, implicates one of the federal priorities or violates state law, would label the SAR “Marijuana Priority,” and the content of the SAR would include comprehensive details in accordance with existing regulations and guidance.

services to a marijuana-related business whose activities do not implicate any of the eight priority factors, prosecution for these offenses may not be appropriate.

The August 29 guidance rested on the expectation that states that have enacted laws authorizing marijuana-related conduct will implement clear, strong and effective regulatory and enforcement systems in order to minimize the threat posed to federal enforcement priorities. Consequently, financial institutions and individuals choosing to service marijuana-related businesses that are not compliant with such state regulatory and enforcement systems, or that operate in states lacking a clear and robust regulatory scheme, are more likely to risk entanglement with conduct that implicates the eight federal enforcement priorities.² In addition, because financial institutions are in a position to facilitate transactions by marijuana-related businesses that could implicate one or more of the priority factors, financial institutions must continue to apply appropriate risk-based anti-money laundering policies, procedures, and controls sufficient to address the risks posed by these customers, including by conducting customer due diligence designed to identify conduct that relates to any of the eight priority factors. Moreover, as the Department's and FinCEN's guidance are designed to complement each other, it is essential that financial institutions adhere to FinCEN's guidance.³ Prosecutors should continue to review marijuana-related prosecutions on a case-by-case basis and weigh all available information and evidence in determining whether particular conduct falls within the identified priorities.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA, the money laundering and unlicensed money transmitter statutes, or the BSA, including the obligation of financial institutions to conduct customer due diligence. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct of a person or entity threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

² For example, financial institutions should recognize that a marijuana-related business operating in a state that has not legalized marijuana would likely result in the proceeds going to a criminal organization.

³ Under FinCEN's guidance, for instance, a marijuana-related business that is not appropriately licensed or is operating in violation of state law presents red flags that would justify the filing of a Marijuana Priority SAR.

**v. Department of the Treasury Financial Crimes
Enforcement Network (BSA Expectations
Regarding Marijuana Related Businesses)**

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Department of the Treasury Financial Crimes Enforcement Network

Guidance

FIN-2014-G001

Issued: February 14, 2014

Subject: BSA Expectations Regarding Marijuana-Related Businesses

The Financial Crimes Enforcement Network (“FinCEN”) is issuing guidance to clarify Bank Secrecy Act (“BSA”) expectations for financial institutions seeking to provide services to marijuana-related businesses. FinCEN is issuing this guidance in light of recent state initiatives to legalize certain marijuana-related activity and related guidance by the U.S. Department of Justice (“DOJ”) concerning marijuana-related enforcement priorities. This FinCEN guidance clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations, and aligns the information provided by financial institutions in BSA reports with federal and state law enforcement priorities. This FinCEN guidance should enhance the availability of financial services for, and the financial transparency of, marijuana-related businesses.

Marijuana Laws and Law Enforcement Priorities

The Controlled Substances Act (“CSA”) makes it illegal under federal law to manufacture, distribute, or dispense marijuana.¹ Many states impose and enforce similar prohibitions. Notwithstanding the federal ban, as of the date of this guidance, 20 states and the District of Columbia have legalized certain marijuana-related activity. In light of these developments, U.S. Department of Justice Deputy Attorney General James M. Cole issued a memorandum (the “Cole Memo”) to all United States Attorneys providing updated guidance to federal prosecutors concerning marijuana enforcement under the CSA.² The Cole Memo guidance applies to all of DOJ’s federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

The Cole Memo reiterates Congress’s determination that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Cole Memo notes that DOJ is committed to enforcement of the CSA consistent with those determinations. It also notes that DOJ is committed to using its investigative and prosecutorial resources to address the most

¹ Controlled Substances Act, 21 U.S.C. § 801, *et seq.*

² James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement* (August 29, 2013), available at <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, the Cole Memo provides guidance to DOJ attorneys and law enforcement to focus their enforcement resources on persons or organizations whose conduct interferes with any one or more of the following important priorities (the “Cole Memo priorities”):³

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

Concurrently with this FinCEN guidance, Deputy Attorney General Cole is issuing supplemental guidance directing that prosecutors also consider these enforcement priorities with respect to federal money laundering, unlicensed money transmitter, and BSA offenses predicated on marijuana-related violations of the CSA.⁴

Providing Financial Services to Marijuana-Related Businesses

This FinCEN guidance clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations. In general, the decision to open, close, or refuse any particular account or relationship should be made by each financial institution based on a number of factors specific to that institution. These factors may include its particular business objectives, an evaluation of the risks associated with offering a particular product or service, and its capacity to manage those risks effectively. Thorough customer due diligence is a critical aspect of making this assessment.

In assessing the risk of providing services to a marijuana-related business, a financial institution should conduct customer due diligence that includes: (i) verifying with the appropriate state authorities whether the business is duly licensed and registered; (ii) reviewing the license application (and related documentation) submitted by the business for obtaining a state license to operate its marijuana-related business; (iii) requesting from state licensing and enforcement authorities available information about the business and related parties; (iv) developing an understanding of the normal and expected activity for the business, including the types of

³ The Cole Memo notes that these enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA.

⁴ James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Memorandum for All United States Attorneys: Guidance Regarding Marijuana Related Financial Crimes* (February 14, 2014).

products to be sold and the type of customers to be served (e.g., medical versus recreational customers); (v) ongoing monitoring of publicly available sources for adverse information about the business and related parties; (vi) ongoing monitoring for suspicious activity, including for any of the red flags described in this guidance; and (vii) refreshing information obtained as part of customer due diligence on a periodic basis and commensurate with the risk. With respect to information regarding state licensure obtained in connection with such customer due diligence, a financial institution may reasonably rely on the accuracy of information provided by state licensing authorities, where states make such information available.

As part of its customer due diligence, a financial institution should consider whether a marijuana-related business implicates one of the Cole Memo priorities or violates state law. This is a particularly important factor for a financial institution to consider when assessing the risk of providing financial services to a marijuana-related business. Considering this factor also enables the financial institution to provide information in BSA reports pertinent to law enforcement's priorities. A financial institution that decides to provide financial services to a marijuana-related business would be required to file suspicious activity reports ("SARs") as described below.

Filing Suspicious Activity Reports on Marijuana-Related Businesses

The obligation to file a SAR is unaffected by any state law that legalizes marijuana-related activity. A financial institution is required to file a SAR if, consistent with FinCEN regulations, the financial institution knows, suspects, or has reason to suspect that a transaction conducted or attempted by, at, or through the financial institution: (i) involves funds derived from illegal activity or is an attempt to disguise funds derived from illegal activity; (ii) is designed to evade regulations promulgated under the BSA, or (iii) lacks a business or apparent lawful purpose.⁵ Because federal law prohibits the distribution and sale of marijuana, financial transactions involving a marijuana-related business would generally involve funds derived from illegal activity. Therefore, a financial institution is required to file a SAR on activity involving a marijuana-related business (including those duly licensed under state law), in accordance with this guidance and FinCEN's suspicious activity reporting requirements and related thresholds.

One of the BSA's purposes is to require financial institutions to file reports that are highly useful in criminal investigations and proceedings. The guidance below furthers this objective by assisting financial institutions in determining how to file a SAR that facilitates law enforcement's access to information pertinent to a priority.

"Marijuana Limited" SAR Filings

A financial institution providing financial services to a marijuana-related business that it reasonably believes, based on its customer due diligence, does not implicate one of the Cole Memo priorities or violate state law should file a "Marijuana Limited" SAR. The content of this

⁵ See, e.g., 31 CFR § 1020.320. Financial institutions shall file with FinCEN, to the extent and in the manner required, a report of any suspicious transaction relevant to a possible violation of law or regulation. A financial institution may also file with FinCEN a SAR with respect to any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by FinCEN regulations.

SAR should be limited to the following information: (i) identifying information of the subject and related parties; (ii) addresses of the subject and related parties; (iii) the fact that the filing institution is filing the SAR solely because the subject is engaged in a marijuana-related business; and (iv) the fact that no additional suspicious activity has been identified. Financial institutions should use the term “MARIJUANA LIMITED” in the narrative section.

A financial institution should follow FinCEN’s existing guidance on the timing of filing continuing activity reports for the same activity initially reported on a “Marijuana Limited” SAR.⁶ The continuing activity report may contain the same limited content as the initial SAR, plus details about the amount of deposits, withdrawals, and transfers in the account since the last SAR. However, if, in the course of conducting customer due diligence (including ongoing monitoring for red flags), the financial institution detects changes in activity that potentially implicate one of the Cole Memo priorities or violate state law, the financial institution should file a “Marijuana Priority” SAR.

“Marijuana Priority” SAR Filings

A financial institution filing a SAR on a marijuana-related business that it reasonably believes, based on its customer due diligence, implicates one of the Cole Memo priorities or violates state law should file a “Marijuana Priority” SAR. The content of this SAR should include comprehensive detail in accordance with existing regulations and guidance. Details particularly relevant to law enforcement in this context include: (i) identifying information of the subject and related parties; (ii) addresses of the subject and related parties; (iii) details regarding the enforcement priorities the financial institution believes have been implicated; and (iv) dates, amounts, and other relevant details of financial transactions involved in the suspicious activity. Financial institutions should use the term “MARIJUANA PRIORITY” in the narrative section to help law enforcement distinguish these SARs.⁷

“Marijuana Termination” SAR Filings

If a financial institution deems it necessary to terminate a relationship with a marijuana-related business in order to maintain an effective anti-money laundering compliance program, it should

⁶ Frequently Asked Questions Regarding the FinCEN Suspicious Activity Report (Question #16), available at: http://fincen.gov/whatsnew/html/sar_faqs.html (providing guidance on the filing timeframe for submitting a continuing activity report).

⁷ FinCEN recognizes that a financial institution filing a SAR on a marijuana-related business may not always be well-positioned to determine whether the business implicates one of the Cole Memo priorities or violates state law, and thus which terms would be most appropriate to include (i.e., “Marijuana Limited” or “Marijuana Priority”). For example, a financial institution could be providing services to another domestic financial institution that, in turn, provides financial services to a marijuana-related business. Similarly, a financial institution could be providing services to a non-financial customer that provides goods or services to a marijuana-related business (e.g., a commercial landlord that leases property to a marijuana-related business). In such circumstances where services are being provided indirectly, the financial institution may file SARs based on existing regulations and guidance without distinguishing between “Marijuana Limited” and “Marijuana Priority.” Whether the financial institution decides to provide indirect services to a marijuana-related business is a risk-based decision that depends on a number of factors specific to that institution and the relevant circumstances. In making this decision, the institution should consider the Cole Memo priorities, to the extent applicable.

file a SAR and note in the narrative the basis for the termination. Financial institutions should use the term “MARIJUANA TERMINATION” in the narrative section. To the extent the financial institution becomes aware that the marijuana-related business seeks to move to a second financial institution, FinCEN urges the first institution to use Section 314(b) voluntary information sharing (if it qualifies) to alert the second financial institution of potential illegal activity. See *Section 314(b) Fact Sheet* for more information.⁸

Red Flags to Distinguish Priority SARs

The following red flags indicate that a marijuana-related business may be engaged in activity that implicates one of the Cole Memo priorities or violates state law. These red flags indicate only possible signs of such activity, and also do not constitute an exhaustive list. It is thus important to view any red flag(s) in the context of other indicators and facts, such as the financial institution’s knowledge about the underlying parties obtained through its customer due diligence. Further, the presence of any of these red flags in a given transaction or business arrangement may indicate a need for additional due diligence, which could include seeking information from other involved financial institutions under Section 314(b). These red flags are based primarily upon schemes and typologies described in SARs or identified by our law enforcement and regulatory partners, and may be updated in future guidance.

- A customer appears to be using a state-licensed marijuana-related business as a front or pretext to launder money derived from other criminal activity (i.e., not related to marijuana) or derived from marijuana-related activity not permitted under state law. Relevant indicia could include:
 - The business receives substantially more revenue than may reasonably be expected given the relevant limitations imposed by the state in which it operates.
 - The business receives substantially more revenue than its local competitors or than might be expected given the population demographics.
 - The business is depositing more cash than is commensurate with the amount of marijuana-related revenue it is reporting for federal and state tax purposes.
 - The business is unable to demonstrate that its revenue is derived exclusively from the sale of marijuana in compliance with state law, as opposed to revenue derived from (i) the sale of other illicit drugs, (ii) the sale of marijuana not in compliance with state law, or (iii) other illegal activity.
 - The business makes cash deposits or withdrawals over a short period of time that are excessive relative to local competitors or the expected activity of the business.

⁸ Information Sharing Between Financial Institutions: Section 314(b) Fact Sheet, available at: http://fincen.gov/statutes_regs/patriot/pdf/314bfactsheet.pdf.

- Deposits apparently structured to avoid Currency Transaction Report (“CTR”) requirements.
 - Rapid movement of funds, such as cash deposits followed by immediate cash withdrawals.
 - Deposits by third parties with no apparent connection to the accountholder.
 - Excessive commingling of funds with the personal account of the business’s owner(s) or manager(s), or with accounts of seemingly unrelated businesses.
 - Individuals conducting transactions for the business appear to be acting on behalf of other, undisclosed parties of interest.
 - Financial statements provided by the business to the financial institution are inconsistent with actual account activity.
 - A surge in activity by third parties offering goods or services to marijuana-related businesses, such as equipment suppliers or shipping servicers.
- The business is unable to produce satisfactory documentation or evidence to demonstrate that it is duly licensed and operating consistently with state law.
 - The business is unable to demonstrate the legitimate source of significant outside investments.
 - A customer seeks to conceal or disguise involvement in marijuana-related business activity. For example, the customer may be using a business with a non-descript name (e.g., a “consulting,” “holding,” or “management” company) that purports to engage in commercial activity unrelated to marijuana, but is depositing cash that smells like marijuana.
 - Review of publicly available sources and databases about the business, its owner(s), manager(s), or other related parties, reveal negative information, such as a criminal record, involvement in the illegal purchase or sale of drugs, violence, or other potential connections to illicit activity.
 - The business, its owner(s), manager(s), or other related parties are, or have been, subject to an enforcement action by the state or local authorities responsible for administering or enforcing marijuana-related laws or regulations.
 - A marijuana-related business engages in international or interstate activity, including by receiving cash deposits from locations outside the state in which the business operates, making or receiving frequent or large interstate transfers, or otherwise transacting with persons or entities located in different states or countries.

- The owner(s) or manager(s) of a marijuana-related business reside outside the state in which the business is located.
- A marijuana-related business is located on federal property or the marijuana sold by the business was grown on federal property.
- A marijuana-related business's proximity to a school is not compliant with state law.
- A marijuana-related business purporting to be a "non-profit" is engaged in commercial activity inconsistent with that classification, or is making excessive payments to its manager(s) or employee(s).

Currency Transaction Reports and Form 8300's

Financial institutions and other persons subject to FinCEN's regulations must report currency transactions in connection with marijuana-related businesses the same as they would in any other context, consistent with existing regulations and with the same thresholds that apply. For example, banks and money services businesses would need to file CTRs on the receipt or withdrawal by any person of more than \$10,000 in cash per day. Similarly, any person or entity engaged in a non-financial trade or business would need to report transactions in which they receive more than \$10,000 in cash and other monetary instruments for the purchase of goods or services on FinCEN Form 8300 (Report of Cash Payments Over \$10,000 Received in a Trade or Business). A business engaged in marijuana-related activity may not be treated as a non-listed business under 31 C.F.R. § 1020.315(e)(8), and therefore, is not eligible for consideration for an exemption with respect to a bank's CTR obligations under 31 C.F.R. § 1020.315(b)(6).

* * * * *

FinCEN's enforcement priorities in connection with this guidance will focus on matters of systemic or significant failures, and not isolated lapses in technical compliance. Financial institutions with questions about this guidance are encouraged to contact FinCEN's Resource Center at (800) 767-2825, where industry questions can be addressed and monitored for the purpose of providing any necessary additional guidance.

c. APPENDIX C – Legislation, Rules and Regulations

The current Louisiana laws, rules and regulations for the marijuana program can be found through the following links to the Louisiana Legislature, Louisiana Department of Agriculture and Forestry, the Louisiana Board of Pharmacy and the Louisiana Board of Medical Examiners.

Louisiana Department of Agriculture and Forestry:

www.ldaf.state.la.us

Louisiana Board of Pharmacy

www.labp.com

Louisiana Board of Medical Examiners

www.lsbme.gov

d. APPENDIX D – Patient Count Source Data

The estimated patient counts for the state of Louisiana compiled herein were derived by several sources as cited herein. Please note only use of limited statistics were performed for benchmarking, and many statistics were not commonly available via public records, either due to a lack of verifiable tracking or reporting by corresponding agencies.

An estimated patient count for the notable conditions contained in the Act is approximately 580,000, as seen at the tabulation contained within this Project Concept. Further factors need be applied to total patient count estimates to arrive at forecasted production activities and needs.

The number of people living with diseases and disorders (prevalence) in the restricted list¹¹ of possible conditions for which medical marijuana could be used in Louisiana was, in many cases, difficult or impossible to find in any U.S. or state data base due to the following: (1) the disease or disorder was not a reportable condition; (2) the disease or syndrome had multiple causes; and (3) only incidences (new cases) were reported, or Louisiana did not report statistics on the disease or condition. Overall U.S. prevalence may be cited and then adjusted for the population of Louisiana when no state information is available. However, this would only be a rough estimate, since some conditions are more prevalent in Louisiana than in other areas, and some less so. State Medicare beneficiary data was available for some diseases, but only refers to Medicare patients and not to the general population.

HIV/AIDS

HIV/AIDS is a reportable disease and Louisiana had a prevalence of 19,000 cases in 2013.¹² Medical marijuana has been used as an appetite stimulant in this disease as well as for other symptoms such as pain, anxiety, and for neuropathy caused by HIV medications.¹³ Louisiana ranked 11th among the 50 states for new HIV/AIDS cases in 2013.¹⁴

¹¹ HIV/AIDS, Cancer, Wasting Syndrome, Seizure Disorders/Epilepsy, Spasticity, Crohn's Disease, Muscular Dystrophy and Multiple Sclerosis.

¹² Louisiana State Health Profile-2015, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, available at: https://www.cdc.gov/nchstp/stateprofiles/pdf/louisiana_profile.pdf (last visited August 31, 2016).

¹³ Joy, JE, Watson, SJ, and Benson, JA Jr., *Marijuana and Medicine, Assessing the Science Base*, INSTITUTE OF MEDICINE, (ND), available at: http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf.

¹⁴ Louisiana State Health Profile-2015, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, available at: https://www.cdc.gov/nchstp/stateprofiles/pdf/louisiana_profile.pdf (last visited August 31, 2016).

CANCER

Medical marijuana has been used for pain, nausea/vomiting, wasting syndrome, anorexia and other symptoms of cancer as well as early and late symptoms caused by cancer treatments.¹⁵ There were 206,490 cancer survivors in Louisiana as of January 1, 2014. This includes patients diagnosed, undergoing treatment, in remission, during intermittent periods of active cancer requiring treatment, living cancer free, etc.¹⁶ Slightly more than 23,000 people are diagnosed with cancer each year in Louisiana.¹⁷

WASTING SYNDROME

Wasting syndrome has multiple causes. HIV/AIDS is usually thought of as the most common cause, but cancer (cancer cachexia), heart failure (cardiac cachexia), certain types of infections such as tuberculosis, autoimmune diseases such as rheumatoid arthritis, chronic inflammatory diseases, such as Crohn's Disease, COPD, and cystic fibrosis, can all cause wasting syndrome. The elderly can develop wasting syndrome due to chronic disease, lack of appetite, and medications, among other causes.

Cancer and HIV/AIDS: see above.

Heart failure: No overall statistics are available. However, of 793,159 Louisiana Medicare beneficiaries, the Centers for Medicare and Medicaid Services reported that 16% had been treated for heart failure at some point in 2014¹⁸ for a total of 126,000 patients. It is not known how many of these patients suffer from wasting syndrome, anorexia or nausea/vomiting – either from the disease and/or medications – nor how many patients not eligible for Medicare had heart failure.

COPD (emphysema): Although the number of cases in Louisiana is unknown, 12.2% of Medicare patients were treated for the disease in 2014 for a total of 96,750 patients. Again, it is not known the overall number of COPD patients or how many overall patients suffer from wasting syndrome.

¹⁵Cannabis and Cannabinoids (PDQ®) Patient Version, NATIONAL CANCER INSTITUTE AT THE NATIONAL INSTITUTES OF HEALTH, available at: <http://www.cancer.gov/about/cancer/treatment/cam/patient/cannabis-pdq> (last visited August 31, 2016).

¹⁶ Cancer Treatment & Survivorship Facts and Figures, 2014-2015, AMERICAN CANCER SOCIETY, available at: <http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-042801.pdf> (last visited August 31, 2016).

¹⁷ Cancer in LA, LOUISIANA CANCER RESEARCH CONSORTIUM, available at: <http://www.louisianacancercenter.org/cancer-in-louisiana> (last visited August 31, 2016).

¹⁸ Chronic Conditions Prevalence, State/County 2014, Heart Failure, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at: <https://ccw.maps.arcgis.com/apps/MapSeries/index.html?appid=c125954f1a1e4582916d8a666f2bf581> (last visited August 31, 2016).

Elderly: Malnutrition is a recognized problem in the elderly and causes are multifactorial.¹⁹ Anorexia (lack of appetite) in the elderly can place this population at risk for nutritional deficiencies,²⁰ and excellent reviews of causes can be found in the literature.²¹ The number of Americans over 65 totaled about 45 million in 2013. More than 850,000 people in Louisiana are over 60 years of age; more than 400,000 are over 70 and more than 100,000 are over 80 years of age.²² The prevalence of nutritional (calorie and protein) deficiencies in the elderly has been estimated to be as high as 16%.²³ No breakdown of numbers of people in this age range who had nutritional problems are available for Louisiana, but it could be a significant number – as high as 60,000 in the over 70 population, although some problems which cause nutritional deficits in the elderly are unrelated to lack of appetite.

SPASTICITY

Spasticity also has many causes, including multiple sclerosis, strokes, brain injury from trauma, infections or lack of oxygen, spinal cord injury, ALS, and cerebral palsy, among others. 80% of MS patients, 60-80% of cerebral palsy patients, and 20-30% of stroke patients have spasticity to some degree.

Stroke: Louisiana State Health Department 2005 data shows 15,500 stroke survivors²⁴, potentially resulting in 4,000-4,600 post-stroke patients with spasticity each year – but actual current prevalence of stroke survivors is not known.

Cerebral Palsy (CP): Due to the lack of state and national registries for CP, it is difficult to find numbers for total cerebral palsy cases in Louisiana. Nationally, almost a million people suffer from cerebral palsy – 1 in 323 children.²⁵ Between 2.4 and 3.8 children per 1,000 live births suffer from the disorder and at least in one geographic study, of four states studied, the southern state had the highest incidence.²⁶ The national statistics focus on children – no ages

¹⁹ Wells and Dumbrell, *Nutrition and Aging: Assessment and Treatment of Compromised Nutritional Status in Frail Elderly Patients*, Clin Interv Aging. (March 2006); 1(1): 67–79.

²⁰ Morley JE, *Anorexia of Aging: Physiologic and Pathologic*, Am J Clin Nutr. 1997 Oct; 66(4):760-73.

²¹ M Hickson, *Malnutrition and Aging*, Postgrad Med J., (January 2006) 82(963).

²² Louisiana Policy Academy State Profile, US ADMINISTRATION ON AGING, (April 2-3, 2012), http://www.aoa.gov/AoA_Programs/HPW/Behavioral/docs2/Louisiana.pdf (last visited August 31, 2016).

²³ Wells and Dumbrell, *Nutrition and Aging: Assessment and Treatment of Compromised Nutritional Status in Frail Elderly Patients*, Clin. Interv. Aging. (March 2006); 1(1): 67–79.

²⁴ Bhoi, *A. Defining the Burden of Heart Disease and Stroke in Louisiana*, HEART DISEASE AND STROKE PREVENTION PROGRAM, LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS, available at: <http://dhh.louisiana.gov/assets/oph/pcrh/heartdisease/2008LABurdenReport.pdf> (last visited August 31, 2016).

²⁵ Data & Statistics for Cerebral Palsy, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.cdc.gov/ncbddd/cp/data.html> (last visited August 31, 2016).

²⁶ Kirby RS1, Wingate MS, Van Naarden Braun K, Doernberg NS, Arneson CL, Benedict RE, Mulvihill B, Durkin MS, Fitzgerald RT, Maenner MJ, Patz JA, Yeargin-Allsopp M, *Prevalence and functioning of children with*

mentioned – and live births. This makes calculating the number of people actually living with CP in Louisiana difficult.

Spinal Cord Injury: National prevalence is approximately 275,000 people living with SCI.²⁷ The Brain Injury Association of Louisiana and the Louisiana Chapter of the United Spinal Association do not track the prevalence of SCI in the state.²⁸ This could potentially be a significant number.

MULTIPLE SCLEROSIS

No good prevalence study of MS has been made since 1975, and the MS Society is seeking to correct this need.²⁹ No national or global registry for MS exists.³⁰ Estimates of U.S. prevalence show about 400,000 people with MS—or about 110-120/100,000 people. The incidence of MS appears to be lower in southern states, and the prevalence in Louisiana could be estimated at somewhere between 57 and 78 cases/100,000 people – or 2,660 to 3,640.³¹

MUSCULAR DYSTROPHY

Data on muscular dystrophy by state is difficult to find. The CDC states there are between 5,600 and 7,700 males between the ages of 5 and 24 in the United States, and that approximately 1.3 to 1.8 males per 10,000 in this age group have the condition.³² Limited by one study and age range, it would appear that the numbers extrapolated to Louisiana using the same criteria would be approximately 120 patients.³³

cerebral palsy in four areas of the United States in 2006: a report from the Autism and Developmental Disabilities Monitoring Network, Res Dev Disabil_ (March/April 2011) 32(2):462-9. doi: 10.1016/j.ridd.2010.12.042. Epub 2011 Jan 26.

²⁷ Spinal Cord Injury (SCI) Facts and Figures at a Glance, NATIONAL SCI STATISTICAL CENTER, available at: https://www.nscisc.uab.edu/PublicDocuments/fact_figures_docs/Facts%202015.pdf (last visited August 31, 2016).

²⁸ Spinal Cord Injury, BRAIN INJURY ASSOCIATION OF LOUISIANA, available at: <http://www.biala.org/spinal-cord-injury> (last visited August 31, 2016).

²⁹ MS Prevalence, NATIONAL MULTIPLE SCLEROSIS SOCIETY, <http://www.nationalmssociety.org/About-the-Society/MS-Prevalence> (last visited August 31, 2016).

³⁰ Pietrangelo, A, Higuera, V, *Multiple Sclerosis by the Numbers: Facts, Statistics, and You*, HEALTH LINE, available at: <http://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic> (last visited August 31, 2016).

³¹ *Ibid.*

³² Muscular Dystrophy Data and Statistics, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, available at: <http://www.cdc.gov/ncbddd/muscular dystrophy/data.html>, (last visited August 31, 2016).

³³ Quick Facts Louisiana, US CENSUS BUREAU, available at: <http://www.census.gov/quickfacts/table/PST045215/22> (last visited August 31, 2016).

CROHN'S DISEASE

Approximately 780,000 people are estimated to be living with Crohn's Disease in the United States (and another 907,000 with inflammatory bowel disease) based on a 2011 study.³⁴ The number of patients currently living with Crohn's Disease in Louisiana is unknown.³⁵ Using prevalence data from the Centers for Disease Control and Prevention (CDC), of 200 cases of Crohn's Disease per 100,000 people in the US, Louisiana could potentially have 9,200 cases.³⁶

EPILEPSY/SEIZURE DISORDERS

Seizure disorders (epilepsy) have a multitude of causes, including stroke, gene mutations, brain injury, and central nervous systems infections – although in many cases the cause is unknown. The prevalence of epilepsy in the United States is thought to be approximately 7.1 for every 1,000 people.³⁷ This would mean that an estimated 32,650 people living in Louisiana suffer from epilepsy.

The CDC, however, reports that 1% of the adult population 18 or older currently (2013) have active epilepsy, which would be 1% of 3,249,177³⁸ of this demographic in Louisiana, or 32,500 people. The number of those under 18 years of age in Louisiana is 1,219,799. The CDC reports that approximately 0.6% of children in this demographic have epilepsy, or 7,320 people.³⁹ This would result in a slightly higher number – an estimated 39,820 people with a seizure disorder in the state.

³⁴ The Facts About Inflammatory Bowel Diseases, CROHN'S AND COLITIS FOUNDATION OF AMERICA, <http://www.ccfa.org/assets/pdfs/ibdfactbook.pdf> (last visited August 31, 2016).

³⁵ What are Crohn's and Colitis, CROHN'S AND COLITIS FOUNDATION OF AMERICA, available at: <http://www.ccfa.org/chapters/louisiana/> (last visited August 31, 2016).

³⁶ Epidemiology of the IBD, CENTERS FOR DISEASE CONTROL AND PREVENTION, available at: <http://www.cdc.gov/ibd/ibd-epidemiology.htm> (last visited August 31, 2016).

³⁷ Shafer, P.O. and Sirven, J.I., *Epilepsy Statistics*, EPILEPSY FOUNDATION, available at: <http://www.epilepsy.com/learn/epilepsy-statistics> (August 31, 2016).

³⁸ Quick Facts Louisiana, US CENSUS BUREAU, available at: <http://www.census.gov/quickfacts/table/PST045215/22> (last visited August 31, 2016).

³⁹ Epilepsy Fast Facts, CENTERS FOR DISEASE CONTROL, US DEPARTMENT OF HEALTH, available at: <http://www.cdc.gov/epilepsy/basics/fast-facts.htm> (last visited August 31, 2016).

e. APPENDIX E – Comparison by State

New York

New York's Compassionate Care Act was signed by Gov. Andrew Cuomo on July 5, 2014. The new law protects patients who use marijuana pursuant to their doctors' advice from civil and criminal penalties. Patients are not allowed to smoke medical marijuana, and there will be no more than five manufacturers, with a total of up to 20 locations, in the entire state.

To qualify, a patient must have a written certification from their physician that they suffer from Cancer, HIV/AIDS, ALS, Parkinson's, MS, Spasticity, Epilepsy, Crohn's, Neuropathies, or Huntington's disease. A certification must specify that the patient is in the physician's continuing care for the condition, that the patient is likely to receive therapeutic or palliative benefits from marijuana, and that he or she has a qualifying condition. The doctor must consider what form of medical marijuana the patient should use and state any recommendations or limitations on the certification. The health commissioner also may allow nurse practitioners to certify patients.

Patients may possess a 30-day supply of medical marijuana, and they may refill their 30-day supply seven days before it runs out. Registry identification cards will generally expire after a year, unless the patient has a terminal illness or the physician specified an earlier date. If police are presented with an ID card, the department will verify the card's validity.

Medical marijuana is available in processed forms through "registered organizations," which are responsible for the growth, production, and sale of medical marijuana. The state approved only five registered organizations, each of which may operate up to four dispensaries. New York began accepting applications for registered organizations on April 27, 2015, and it issued registrations on July 31, 2015. The first dispensaries opened in January 2016. Application fees are set at \$10,000. Registration costs \$200,000 and must be renewed every two years. Patients and caregivers pay \$50 to register with the program, but this fee may be waived for patients who face financial hardship.

The law established a medical marijuana fund into which 100% of fee revenues will be deposited. In addition to fees, the state will levy a 7% excise tax at the production level, the revenue from which will split between the county in which the registered organization operates and the county in which the marijuana was dispensed, as well as state-level addiction and law enforcement programs. The health commissioner is charged with setting the price of all medical marijuana sales.

Illinois

Gov. Patrick Quinn signed Illinois' medical marijuana legislation into law on August 1, 2013. The new law went into effect on January 1, 2014. In 2014 and 2016, the law was expanded. Medical marijuana rules were approved in July 2014. The law was created with a

“sunset” provision. Originally, the program would have ended in January 2018. In 2016, a bill extended the program until at least July 1, 2020. Following a series of unworkable laws in 2003, 2011, and 2013, a four-year medical marijuana pilot program was slow to start. While the program officially began in January 2014, no cultivator or dispensary applications were granted until early 2015. The program allows 60 dispensaries and 22 growers. Dispensaries began opening in November 2015. As of December 2, 2015, more than 29,000 patients had started the registration process with 3,600 approved.

To qualify for an ID card, a patient must have a qualifying medical condition and a statement from an Illinois-licensed MD or DO who is caring for the patient's condition. The qualifying medical conditions are: HIV/AIDS; Hepatitis C; ALS; Crohn's; Alzheimer's; Cachexia; Wasting Syndrome; MS; Fibromyalgia; Spinal Cord disease and injury; Tarlov cysts; Hydromyelia; Syringomyelia; Traumatic Brain Injury and Post-Concussion Syndrome; MS; Rheumatoid Arthritis; Arnold Chiari malformation; Spinocerebellar Ataxia (SCA); Parkinson's; post-traumatic stress disorder (PTSD); Tourette's Syndrome; Myoclonus; Dystonia; Reflex Sympathetic Dystrophy (RSD); Causalgia; CRPS; Neurofibromatosis; Chronic Inflammatory Demyelinating Polyneuropathy; Sjogren's Syndrome; Lupus; Interstitial Cystitis; Myasthenia Gravis; Hydrocephalus; nail patella syndrome; residual limb pain; seizures; or the treatment of these conditions; or any terminal illness in which the life expectancy is six months or less. The physician must certify that the physician has a bona fide physician-patient relationship with the patient and that they have a qualifying condition. The 2014 law allows minors to qualify if they suffer from seizures, and it allows the Department of Public Health to adopt rules allowing for minors with other conditions to qualify.

Patients may have a single caregiver who may pick up medical marijuana for them. Caregivers must be 21 or older and cannot have a disqualifying drug conviction. They may only assist a single patient. Registered patients may not be arrested or prosecuted or face criminal or other penalties for engaging in the medical use of marijuana in compliance with the law. There are also protections against patients being discriminated against in medical care, such as organ transplants, and in reference to child custody. Landlords may prohibit smoking medical marijuana on their premises. Employers may continue to enforce drug-free workplace policies, and they do not have to allow employees to possess marijuana at work or work while they are impaired.

Illinois' law allows a patient or caregiver with a registry ID card to possess 2.5 ounces of processed marijuana. Patients and caregivers are allowed to obtain medical marijuana from one of up to 60 state-regulated medical marijuana dispensaries, which may be for-profit. Dispensaries are also subject to rules created by the Department of Financial and Professional Regulation.

The cultivation fees are the highest in the nation: Applicants must pay a nonrefundable application fee of \$25,000 and a first-year registration fee of \$200,000. Medical marijuana is subject to a 7% privilege tax and a 1% sales tax. Patients pay \$100 a year to register, with a \$50 reduced fee for those who are eligible. Caregivers pay \$25. Dispensaries pay \$5,000 to apply

for a license and \$25,000 annually for the license itself. Growers pay \$25,000 to apply and \$200,000 to register once approved. This fee will be reduced to \$100,000 for every year thereafter. Between the 60 dispensaries and 22 growers, the state stands to make at least \$6.7 million dollars on application and initial registration fees alone. Illinois also levies a 7% excise tax and a 1% sales tax for medical marijuana.

Minnesota

On May 29, 2014 the governor of Minnesota signed the medical marijuana therapeutic use law, and it was among the most swiftly implemented programs. The Minnesota Department of Health's Office of Medical Marijuana developed the program, which began providing medical marijuana to registered patients in July 2015. The office has chosen two manufacturers for the state, and each will operate four dispensaries. Each manufacturer applicant was required to submit a nonrefundable \$20,000 application fee, and the chosen manufacturers will be required to pay a yearly "oversight" fee of \$75,000-\$100,000. Medical marijuana is not subject to sales tax. Fees are set at \$200 for patients and caregivers, with a \$50 reduced fee for those receiving certain forms of medical assistance.

To enroll in the program, a patient must have a qualifying condition and submit a certification to the health department from their treating practitioner. Qualifying conditions are: Cancer Nausea or severe vomiting; Cachexia or severe wasting; Glaucoma, HIV/AIDS; Tourette's syndrome; Amyotrophic lateral sclerosis (ALS); Seizures, including those characteristic of epilepsy; Severe and persistent muscle spasms, including those characteristic of multiple sclerosis; Crohn's disease; and Terminal Illness, with a probable life expectancy of under one year.

Registered patients are protected from criminal and civil penalties for possessing and using liquids, oils or pills made out of marijuana in compliance with the medical marijuana law. Patients may not use marijuana in any other form, including raw marijuana or smoking it. Vaporization of extracts is allowed.

The law required the state to register two medical marijuana manufacturers, and it did so by July 1, 2015. Each of the manufacturers established a total of four distribution points on July 1, 2016 for a total of 20. The law requires that only pharmacists working with the manufacturers may distribute marijuana products to qualified patients. They may only dispense up to a 30-day supply as determined by the on-site pharmacist after consulting with the individual patient.

On December 2, 2015, the commissioner announced his decision to add intractable pain to the list of the program's qualifying medical conditions, effective August 1, 2016. Department of Health statistics show that the input provided by patients to add intractable pain will substantially increase Minnesota's patient population.

Connecticut

Gov. Dannel Malloy signed Connecticut's medical marijuana law in 2012. Patients must obtain registry ID cards. To qualify for an ID card, a patient is required to have a qualifying condition Cancer, Glaucoma, HIV/AIDS, Parkinson's, MS, Spasticity, Epilepsy, Cachexia, Wasting Syndrome, Crohn's disease, PTSD, and any condition that is added by the Department of Consumer Protection. Since 2012 the state has added six conditions: sickle cell disease, post laminectomy syndrome ("failed back syndrome"), severe psoriasis, and psoriatic arthritis. Connecticut is the only state to exclude minor patients.

Patients may possess no more than 2.5 ounces of marijuana per month, unless a patient's physician allows a greater amount. Patients cannot ingest marijuana anywhere in public, in a workplace, in any moving vehicle, in the line of sight of a person under 18, or on any school or university grounds, including in dorm rooms.

Connecticut has approved nine dispensaries, six of which are open as of spring 2016. Dispensaries are allowed to obtain marijuana only from licensed producers. The department approved four growers. The department requires a nonrefundable \$25,000 application fee from producers, plus an additional \$75,000 annual fee if they are accepted. For dispensaries, the department requires an initial nonrefundable application fee of \$1,000. If accepted, there is a \$5,000 fee for registration and a yearly renewal fee of \$5,000.

As of December 15, 2015, 7,665 patients have registered into Connecticut's medical marijuana program. They are charged \$100 each for the registration, generating \$766,500 in revenue. The program generated \$1,166,000 in revenue in 2015.

f. APPENDIX F – Security Plan

A comprehensive security plan must be developed to consider the public welfare and safety; to protect the AgCenter, LSU and its employees from liability; and to comply with the stringent security requirements of the regulations implementing the Act. Primary considerations are addressed at **Article IV.f.** and are further detailed as follows:

I. Security Plan Overview

A Security Plan for a Medical Marijuana Production Facility will be implemented in compliance with all criteria and measures set forth in LAC 7:XLIX Chapters 1-31, to address all facets of security issues related to the medical marijuana industry, including:

- Compliance with state regulations.
- Vulnerability assessments.
- Physical site security planning and implementation.
- Access control measures.
- Electronic monitoring and alarm systems.
- Computer/cyber security.
- Inventory control and accountability.
- Product and cash storage and transportation.
- White collar crime and employee theft prevention.
- Creating and maintaining a safe work environment.
- Pre-employment background investigations.
- Employee and business policies and practices.
- Vetting security integrators.
- On-going compliance checks.

II. Key Features of Production Facility

The Production Facility Security Plan is core to successful operations. The comprehensive Security Plan is designed to ensure the safety and security of the Production Facility, its employees and patrons, its products, and the public. This Security Plan is based upon a security assessment of a potential Production Facility, and lessons learned from existing successful commercial marijuana operations in other states.

The Security Plan includes physical security elements from the perimeter to the interior of the facility, including state-of-the art security systems; seed to sale inventory and product tracking; and policies and procedures addressing the security operation to ensure accountability and responsibility throughout the process.

1. Perimeter Security – The exterior of the Production Facility will be protected by a perimeter security fence with anti-climbing features. There will be a single point of ingress and egress to the Production Facility through a guardhouse that will be constructed at this location with a pedestrian entrance and exit to serve as a check-point for all employees, visitors, and deliveries. There will be a gate entrance to allow for ingress and egress of motor vehicle traffic. The guardhouse will be manned by licensed contracted security officers (see, below regarding initial discussions with state officials studying the viability of sworn state law enforcement officers providing this service). These officers will be equipped with a visitor management system while maintaining constant video surveillance of the Production Facility.

2. High-Security Materials and Design – Exterior and interior walls will be fortified with insulated steel, ½ inch insulated wood paneling or concrete masonry unit (CMU) block. All perimeter walls and interior wall partitions around restricted areas will extend to the bottom side of the deck.

3. Vaults and Safes – All final marijuana products will be stored in an approved safe or vault that meets or exceeds the requirements for storage and handling of Schedule I and II controlled substances.

4. Controlled Points of Access to the Facility – Pedestrian access to the interior of the facility will be controlled by a mantrap door configuration. There will be two interior shipping/receiving loading docks with overhead doors that will be operated by security personnel and protected by bollards.

5. State-of-the-Art Security Systems With Battery and Cogenerated Power Backup – The video surveillance system, access control system, and alarm systems will all be integrated, redundant and support one another. The features of the designed electronic security systems for the facility will meet and exceed all state requirements. System backup, testing and maintenance will be performed regularly. In the event of a power outage, the system will have battery backup and be connected to emergency circuit panels that are part of a local cogeneration power source.

6. Efficient Workflow and Access Control – Policies and procedures will be established to address work flow and ensure access to restricted areas is granted only to essential authorized staff. Access levels will be programmed into the electronic security systems to dictate what users will be granted access to and the specific locations and at what times. Facility supervisors will have the ability to immediately eliminate a specific employee's access via remote devices such as cell phones. All access will be recorded and stored through the video surveillance system. Areas of higher levels of security will require multiple access systems to enter (PIN code and card reader). Advanced access control features such as threat escalation, mantrap door control, and “two-man rule” will be implemented at select restricted areas. Employees will wear colored pocketless uniforms based on their access level and display issued ID cards at all times.

7. Seed to Sale Inventory Tracking – The Production Facility will use the Louisiana Medical Marijuana Tracking System (LMMTS) a seed –to-sale tracking system for all record-keeping processes related to medical marijuana production and processing. Any additional internal systems will integrate with LMMTS. Audit processes will be established and take place at scheduled and unscheduled intervals.

8. Security Presence – During hours of operation, licensed contracted security officers will be on-site. Security officers will control access to the facility via a manned guardhouse and pedestrian entrances and will monitor surveillance cameras and security systems. They will be responsible for patrolling the facility, provide visitor escorts, oversee deliveries, and support the guardhouse operations. In the alternative, initial discussions have begun with state law enforcement officials studying the viability of sworn Louisiana law enforcement officers providing all on site security and all transportation security needs.

9. Transportation Security – Preliminary discussions with the Louisiana State Police have been made for transportation services. Pending further discussion, the Production Facility will contract the Louisiana State Police for the shipment and delivery of marijuana products

10. Employee Policies, Procedures, Training – The Production Facility will implement and enforce policies, procedures, and training for its employees to ensure a safe and secure environment for the production of marijuana products.

11. Security Director - The Production Entity will employ a Manager or Director equivalent position that in addition to other duties will oversee the security procedures of the operation and to establish and maintain regular liaison with local, parish and state law enforcement and first responders. The ultimate goal of this liaison is to establish and maintain a close working relationship with first responders and oversight departments, which will ensure operational transparency and compliance with state regulations.

12. Security Plan Requirements – The AgCenter, in collaboration with the sub-contractor, will submit to the Department a security plan prior to commencement of operation that addresses all security and transportation requirements as set forth by the Department.

III. Production Facility Security

The Security Plan for the proposed Production Facility incorporates physical security elements, electronic security systems, security staffing, and policies and procedures to provide a comprehensive integrated secure environment for the production and distribution of medical marijuana. The proposed Production Facility will be equipped with the following electronic security systems:

- Closed circuit television system (CCTV).
- Access control & monitoring system (ACMS).

- Visitor management system (VMS).
- Security alarm system (SAS).
- Intercom system (IC).
- Key management system (KMS).

These electronic security systems will be integrated, redundant, and support one another other. They will utilize the latest technology commercially available and the highest security features available for an operation of this nature. The systems will be flexible and scalable for future growth. The system will be integrated such that an alarm input from a security device (e.g., door contact, motion detector, panic alarm, etc.) will cause an automatic response by the CCTV so that the nature of the alarm will be captured, viewed, and analyzed, and the appropriate response initiated. Alarm systems will be redundant, both monitored internally as well as relayed to a third party contracted alarm company for appropriate emergency response. All security system equipment and recordings will be housed in secure locations in order to prevent theft, loss, destruction, or alterations.

1. Perimeter Security – The production facility will be protected by a complete perimeter security fence. The fence will be at least eight (8) feet high and include anti-climb features and will be monitored by CCTV.

A guardhouse may be constructed along the fence line of the perimeter. If constructed, the guardhouse will be manned by security personnel and be equipped with PC-based workstations to monitor the electronic security systems, and process employees, visitors, and contractors. All employees, visitors, contractors, and deliveries will be required to pass through the guardhouse to gain access to the Production Facility. The guardhouse and the pedestrian and vehicular traffic at this checkpoint will be monitored by CCTV. Images of the license plates of each delivery vehicle will be documented by CCTV. Movement of the employees, visitors, contractors and deliveries beyond the perimeter security fence and within the production facility will be controlled and monitored by the electronic access control systems. All visitors, contractors and deliveries will be escorted by security personnel. The entire perimeter and interior of the facility will be monitored by CCTV.

2. Pedestrian Doors – All exterior doors will be monitored and controlled by the electronic security systems. Two pedestrian doors will be identified as main entry/exit points for employees, contractors, and visitors and separate designated indoor shipping and receiving areas for deliveries and transportation of marijuana product. The two main pedestrian entry/exit points for employees, contractors, and visitors will be manned by security personnel 24 hours a day, 7 days a week and controlled by the electronic security access systems. A mantrap or small room with an entry door on one wall and an exit door on the opposite wall will be established for each main pedestrian entrance/exit. One door of the mantrap cannot be unlocked and opened until the opposite door has been closed and locked. Pass-through authorization is validated by smartcard through the access control system. A one-person-in / one-person-out policy will be enforced to prevent unauthorized entry.

Security personnel at these locations will be responsible for processing visitors and contractors and monitoring security systems. Additionally, security personnel will be available to escort visitors or contractors when necessary. An intercom substation also will be at both pedestrian entry points to allow for communication between visitors and security personnel without opening the pedestrian door.

All exterior pedestrian doors and select interior doors will be protected by Level 4 steel doors, Grade 1 panic bar hardware, and electronically monitored by two triple-biased magnetic contacts. When installed with concrete-filled frames, these doors will provide a high degree of physical security and will require substantial force and/or time to compromise.

Two types of electrified door hardware are recommended for used in the production facility:

- Electrified lever sets – Higher security lever sets with fewer moving parts secured in the device. The gap between door/frame is minimized. Interior doors that require access control will include this door hardware.
- Panic bar hardware with electric latch retraction – Rim-mounted panic bar hardware with electrified latch retraction will be implemented on all exterior doors since there is nothing on the outside of the door/frame to compromise, and it is a very robust design.

3. Overhead Doors – The facility will have designated enclosed, secure areas for the loading/unloading of medical marijuana products that will be protected by 20-gauge sectional steel overhead doors that will be electronically monitored by triple-biased magnetic contacts inside the perimeter security fence. Overhead door activity will be monitored and controlled by the electronic security access systems. Overhead doors will be activated only by authorized personnel who alone possess the proper electronic security credentials. Additionally, an intercom substation will be at each overhead door to allow for communication between individuals and security personnel without opening the door. All overhead doors will be protected by bollards to prevent external breaching.

4. Lighting – Safety lighting will be properly installed throughout the interior and exterior of the building. Proper lighting technology will be utilized to ensure optimal security surveillance and eliminate any interference with the CCTV system (e.g., no sodium vapor lights).

5. Signage – Signage for the Production Facility will include:

- “PERSONS UNDER 21 YEARS OF AGE NOT PERMITTED ON THESE PREMISES.”
- “THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.”

There will be no exterior signage depicting the name or description of the facility. The address of the facility will be posted to assist delivery drivers.

6. Closed Circuit Television System – The Production Facility will maintain a CCTV system consisting of a Video Management System, a dedicated Local Area Network (LAN), LAN switches, PC-based work-stations, Network Video Records (NVRs), uninterruptible power supply (UPS) units, and unobstructed Network IP cameras that are all installed in a tamper-resistant manner. Audio recording capability will be in specific areas. Safety and security purposes for the CCTV system include but are not limited to:

- Protection of individuals, including employees, visitors, contractors, and deliveries.
- Protection of property, marijuana product, building perimeter, entrances and exits, lobbies and corridors, receiving docks, and storage areas.
- Verification of alarms and electronic security systems.
- Video patrol of restricted areas.
- Deterrence of criminal activity.
- Investigation of criminal activity and disciplinary activity.

The CCTV system cameras will be equipped with lenses of sufficient magnification and clarity to clearly distinguish product identifiers, ID tags and facial recognition. Cameras will be located to provide coverage of the exterior of the building, parking areas, entrances and exits, marijuana growing areas, storage areas, production areas, and all safes and vaults. The Production Facility shall make recordings available for immediate viewing by any authorized request.

7. Video Management System – A comprehensive Video Management System (VMS) comprising server-based Network Video Recorders (NVRs) will be the backbone of the CCTV system. The VMS will include the following features:

- Display date and time stamp on all recorded video that is based on a synchronized, central master clock that is recorded and visible on any monitor.
- Produce a digital video disk using an installed media recording drive that provides video viewable on any windows PC.
- The ability to remain operational during power outage and provide uninterrupted power so that time and date generators remain active.
- Allow for the exporting of still color images in standard image format (including .jpeg, .bmp, and .gif) with a minimum of 9600 dpi from any camera image (live or recorded).
- Ability to archive exported video in proprietary format to ensure authentication of the video and guarantees that no alteration of the recorded image has taken place.
- Export video that will have the ability to be saved in an industry standard format.

- Allow recordings to be erased or destroyed prior to disposal or sale of facility.
- Maintain adequate replacement materials to immediately address equipment failure.

The NVRs will record video signals from Network IP cameras that are connected to a dedicated LAN for the CCTV system and allow for video surveillance at the PC-based workstations throughout the proposed facility. A local color high-resolution printer will be maintained and can be used to print a hard copy of any stored video camera image if necessary.

The VMS system will record at the full resolution of the Network IP cameras of 3.0 megapixels and will be designed to provide minimum of 30 days of recording onsite on the NVRs with an additional 30 days of recording maintained offsite. If requested by the Department or investigative body, an unaltered copy of such recordings will be provided. Upon becoming aware of pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the unaltered copy of the recording shall be retained until the investigation or proceeding is closed or the entity conducting the investigation or proceeding makes the notification that it is no longer necessary to retain the recording. The VMS system will be integrated with the Access Control & Monitoring System (ACMS) to allow camera signals to be displayed upon alarm conditions.

8. Network IP Cameras and Camera Placement – The CCTV system will use fixed 3.0 megapixel, or higher, network IP dome cameras with day/night (D/N and wide dynamic range (WDR) technology.

- Fixed cameras will be installed to provide a consistent recorded image of all areas and avoid any physical obstructions.
- 3.0 megapixel resolution provides useable video footage with true identification capabilities, including high quality facial and body images.
- D/N and WDR technology will be included in camera locations that have low light levels.
- Cameras will be angled to allow for facial recognition and the capture of clear and certain identification of any person entering or exiting the area.

The entire premises is to include all areas within and outside the Production Facility excluding restrooms and private offices where product is not located. The entire inside of the Production Facility and the immediate area of the exterior of the proposed facility will be under CCTV surveillance including:

- All building entrances and exits.
- Inside the vault area.
- All parking lot areas adjacent to the facility to document activity and the license plate and description of vehicles in the parking lot.

- All areas immediately adjacent to the Production Facility.
- The entire inside of the Production Facility, including all limited access areas and restricted areas where marijuana stored, handled, dispensed or destroyed, including safes, vaults and point-of-sale locations, including the individuals and computer monitors used for the sale.

All on-site security rooms shall remain locked at all times and will not be used for any other function. Security rooms will be in restricted areas, which are secured by access control readers, magnetic door contacts, motion detectors and network IP dome cameras. Access to any security areas will be limited solely to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the Department or the Department's authorized representative, and others when approved by the Licensee. A current list of authorized employees and service employees who have access to any surveillance room will be made available to the Department or the Department's authorized representative upon request.

Any malfunction of any component or alarm input of the SAS and video monitoring system will be monitored using a notifications system that can provide an audible, text or visual notification of any failure in the system. The failure notification system will provide an alert to the Production Facility within five (5) minutes of the failure, either by telephone, email, or text message.

Standard operating procedures will be implemented that require security personnel to perform routine checks of the SAS to ensure it is in good working order at all times. The SAS and its components will be under a 24 hours a day, 7 days a week maintenance agreement that will include no less than monthly testing of all security devices.

9. Access Control and Monitoring System – A network-based, electronic access control and monitoring system (ACMS) will be installed at the Production Facility to serve as the engine of the integrated electronic security systems. ACMS safety and security purposes include:

- Support crime prevention and control objectives.
- Ensure a secure locked Production Facility for the production and storage of medical marijuana at all times.
- Prevent the theft or diversion of medical marijuana; prevent unauthorized access; grant access based only on presented authorized credentials.
- Monitor and document all requests for access; monitor alerts of alarm conditions based on alarm inputs including magnetic contacts; reduce the use of easily duplicated mechanical locks and keys.
- Integrate the various security systems including CCTV, SAS, etc. to allow for higher level functionality of all electronic security systems.
- Aid in the investigation of criminal activity and disciplinary activity.

- Create an atmosphere of deterrence.

The ACMS will include controllers, PIN pads, smart card readers, and smart cards that are connected to a communications server and then connected to PC-based workstations on the dedicated security LAN. The ACMS will be cross-connected with the Security Alarm System (SAS) so that redundant communications with an alarm monitoring UL-listed central station will take place automatically. This system integrates with the CCTV system and NVRs and allows NVR stored or live video to be accessed within the access control software. All video is transmitted across security LAN connections.

Any ACMS component or alarm input malfunction will be monitored and can provide an audible, text or visual notification of any failure in the system. Photo ID Badging is integrated with this system and allows an employee ID template to be designed and a digital photo to be imported. User groups will be configured within the ACMS to dictate what users at what times will be granted access to specific locations. Access can immediately be denied by remote means.

Advanced access control feature such as threat escalation and Man Trap door control will be implemented as follows:

- Threat escalation – The ACMS will be programmed to update access control user groups and definitions real-time in the event of an alarm condition to further restrict or allow movement in the proposed facility.
- Man trap door control – At the main entrance the interior door to the limited access areas cannot be unlocked and opened until the opposite door has been closed and locked. Pass-through authorization is validated by smart card through the ACMS.

The ACMS will have battery backup to remain operational during a power outage. Doors and locks to restricted areas and limited access areas will be configured to remain locked and not release during a power outage unless required under fire codes/life safety standards. Standard operating procedures will be implemented that require security staff to perform routine ACMS checks to ensure it is in good working order at all times. The ACMS and its components will be under a 24 hours a day, 7 days a week maintenance agreement that will include monthly testing of all security devices.

10. Visitor Management System – A software application that streamlines the check-in process, captures detailed visitor information accurately, and prints professional looking full color customized badges will be implemented at the facility. The VMS allows for confidential record keeping of visitor information that easily generates a full range of reports based on filtering/sorting the VMS database to assist law enforcement, the Department, and Production Facility staff. This VMS will identify and help keep out unwanted people from gaining entry via a Watch List feature. When a visitor or limited duration contractor arrives, security and/or Production Facility staff will verify that the

visitor was expected and an ID badge will be generated by the VMS. This ID badge will include a photo, name field, and expiration date.

The ID badge will be attached to a neck lanyard holder. This will be worn by visitors and limited duration contractors at all times while on site and returned when leaving every day. Visitors and limited duration contractors will be required to be escorted throughout the facility by security staff. When scanned by a security officer, a STOP sign will appear after the badge has expired.

11. Security Alarm System – The previous described ACMS includes an intrusion alarm system and has a robust alarm monitor capability, including point monitoring (break access), motion detection, laser detection, alarm graphics, alarm email/text message notification and threat level escalation. The system includes the capability to detect when someone is attempting to obscure or deactivate all or a portion of the alarm system. The system uses TCP/IP network communications to provide user interaction and real time monitoring. The Security Alarm System will be connected to outputs of the ACMS system and include an automatic voice dialer. Up to two prerecorded voice messages when activated will be sent to a law enforcement, public safety or emergency services agency requesting dispatch. The SAS will have redundant communication paths to a remote central station via a dedicated landline (Plain Old Telephone Service – POTS) and Digital Cellular communications. GSM (wireless cellular signal) can be used as back up if there is ever an issue with the landline.

The SAS system comprises magnetic door contacts, request-to-exit (REX) sensors, motion detectors, glass break detectors, an alarm system control panel, zone expanders, alarm keypads, duress alarm, wireless panic/holdup alarms, and wireless panic/holdup transmitters. The SAS will provide coverage of all facility entrances and exits, exterior windows, rooms with exterior walls, storage rooms that contain safes and IT/security equipment, at the proposed facility. Every exterior door and select interior doors will have magnetic door contacts installed to monitor the security of these doors. These contacts will be surface mounted and are of a triple-biased design for increased security.

The motion detectors will have sensor data fusion technology, which uses a sophisticated software algorithm to gather signals from five sensors: two pyro electric sensors, a range adaptive radar sensor, a room temperature sensor and a white light level sensor.

Management areas and security command areas will have alarm keypads installed to allow authorized arming/disarming and reporting the alarms of the SAS. These 5-inch, full-color touchscreen display alarm keypads include easy-to-use icons, menus, distinct tones, and turn red in alarm conditions. A silent duress alarm will be sent if a distress code is entered in to the alarm keypad or if they are forced to disarm this system. Wired panic/holdup alarms will be installed in a fixed location and strategically placed.

In addition, a wireless transmitter is a portable handheld device that can be carried or placed near the individual so that it is convenient in an emergency condition to allow for security personnel or management to trigger a panic alarm, which means an audible security alarm signal generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response, or a holdup alarm, which means a silent alarm signal generated by the manual activation of the device intended to signal a robbery in progress. Wireless panic/holdup transmitters and necessary receivers are located at the security command areas, executive areas and loading dock areas.

12. Fire Alarm – The Production Facility will maintain an alarm system to provide fire detection.

13. Intercom System – An intercom system will be established at the Production Facility with substations and master stations in select locations to facilitate communication and provide a safe and secure environment.

14. Key Management System - A modular, scalable integrated key management and control system will be part of the Production Facility's security. The KMS will securely store all keys for the property and document all activity/use of each key. Security staff may gain access to the KMS by electronic passwords or biometrics. The key management system will be located in an area under control of the ACMS to document ingress and egress from that location and be monitored by CCTV. All keys will be stored in the key management system.

15. Cyber Security – Cyber security measures will be enacted to protect the electronic transmission and storage of information. These measures will prevent unauthorized access to data, prevent loss or theft of data, and allow for the recovery of lost or stolen data. Handling and protecting data is central to the security of the business, the privacy, and security of customers, employees and partners, and the integrity of the industry.

The Production Facility will develop a clear policy describing information that will be collected and how it will be stored and protected.

- Personal identification information.
- Personal health information that is Health Insurance Portability and Accountability Act (HIPAA) compliant.
- Payment information.
- Assign levels of security to the data.
- Highly confidential.
- Sensitive.
- Internal use only.

The Production Facility will identify means to control access to various levels of data, including:

- Passwords / password policies.
- PINS.
- Biometrics.
- Encryption (Federal Information Processing Standard – certified).
- Two-factor authentication.

The Production Facility will conduct comprehensive risk-management processes to ensure on-going cyber security. This includes not only preventing unauthorized access to data, but also protection of physical space and hardware.

The IT/network server will be stored in a secured location accessible only to persons who have been properly vetted and have a need to access the area. Access will be controlled by a two-factor entry control system that will create both an electronic audit and video image of those who enter and leave the secured area. Individuals who may access the area will include:

- Authorized employees.
- Law enforcement representatives.
- IT network service providers.
- Representatives of the Licensee.

Computer security entails the following:

- Computer monitors will not be oriented toward publically accessible areas.
- Login and passwords will not be written out at work stations.
- Laptops or other easy to grab equipment containing sensitive data will be secured.
- Aggressive login and passwords policy will be followed.

All software will be password protected and accessible only to authorized individuals to ensure the integrity of patient records, security measures, combination numbers, passwords, and electronic or biometric security systems.

The Production Facility will have backup servers both on and off-site to ensure redundancy of server storage, access and security. Backup servers will allow for the recovery of data, and continuation of operation in the event of primary server failure, or loss or theft of data.

All servers, computer hardware and telephone systems will have on-site power backup systems to ensure operational power during times of primary power loss.

Network security will be achieved by:

- Identifying all devices and connections on the network.
- Setting boundaries between the company's systems and others.
- Enforcing controls to ensure that unauthorized access, misuse, or denial-of-service events can be thwarted or rapidly contained and recovered if they do occur.

Secure Internal Networks and Cloud Services – The network will be separated from the public internet by strong user authentication mechanisms and enforcement systems such as firewalls and web-filtering proxies. Additional monitoring and security solutions, such as antivirus software and intrusion detection systems, will be employed to identify and stop malicious code or unauthorized access attempts.

The Production Facility will operate a multi-tiered wireless local area network (WLAN) to provide for incremental levels of security. The lowest level of WLAN access will be granted to customers, guests, and visitors. There will be a progression of levels of WLAN access for employees specific to the level of data authorization they possess. WLAN will be kept separate from the main company network so that traffic from the public network cannot traverse the company's internal systems at any point. The company will employ a wireless encryption system to ensure data security for wireless transmission. Due to security flaws known to exist in older forms of wireless encryption, the company's internal WLAN will employ Wi-Fi Protected Access 2 (WPA2) encryption.

The Production Facility will utilize antivirus software and firewall protection as the front line defender for electronic data. Any detected threat will be identified for remediation.

Electronic Equipment Disposal Policy – All devices will be wiped clean of all data or destroyed or rendered inoperable prior to disposal.

Email and internet use are a critical part of everyday business, from internal management to direct customer support. The Production Facility will be aware that both are vulnerable to viewing by unauthorized persons, and as such, the security risk will mitigate risk by:

- Prohibiting transmission of sensitive information via email.
- Using email and internet filters.
- Providing on-going employee training on Eemail and internet use.
- Developing email and browsing history retention policy.

The Production Facility will use mobile devices such as smartphones, tablets and wi-fi enabled laptops to conduct company business. Mobile devices create unique security issues. These issues must be recognized and addressed to protect sensitive data. But while mobility can increase workplace productivity, allowing employees to bring their own mobile devices

into the enterprise, it also creates significant security and management challenges. Therefore, the following measures are suggested:

- Prohibit transmission of sensitive data via mobile devices.
- Use security software on mobile devices.
- Encrypt data.
- Use password protection.
- Prohibit use of personal devices for business purposes.
- Prohibit use of personal electronic storage devices (flash drives etc.) in company computers.
- Ensure devices are wiped clean prior to disposal.

The most stringent security measures are useless without employee compliance with set policies and procedures. The Production Facility will establish formal recruitment and employment processes to hire and retain quality employees. The Production Facility will provide initial new employee training as well as on-going employee training concerning cyber security, electronic data, and computer use policies and procedures. The Production Facility will also:

- Perform background checks and credentialing.
- Properly vet employees who will have access to higher levels of data security.
- Set access controls for employees.
- Provide on-going security training.
- Implement employee departure procedures.

The Production Facility recognizes that potential breaches of data defenses exist and will have procedures in place to respond to security breaches if they occur. Types of breaches include:

- Physical breaches, such as burglaries, equipment theft, loss of equipment.
- Unauthorized installation of storage devices.
- Network and system security breaches.
- Data breaches.

If any type of breach occurs the Production Facility will:

- Notify law enforcement.
- Notify the Licensee.
- Limit damage.
- Initiate recovery plan.
- Conduct lessons learned.

16. Employee Kidnap or Abduction Plan – All executive level and upper management personnel will receive training on kidnap and abduction prevention and actions for both themselves and their families. Training will include:

- Home security measures.
- Situational awareness.
- Personal defense techniques.
- Randomizing travel routes.
- Identity protection.
- Abduction survival techniques.

Any abduction situation will immediately be reported to local law enforcement.

17. Emergency Evacuation and Response Plan – The critical ingredient to an emergency response plan is a simple uniform response to address any threat from outside forces. These may be weather events, fires, accidents, intruders, or violent criminals. The response must be planned and understood by all employees, and coordinated with local emergency responders.

The “Standard Response Safety Protocol” is based not on responding to a myriad of individual scenarios but on a simple and uniform response that provides the flexibility to react to any given scenario. The premise is simple: four actions can be performed to respond to any incident. Each action has a specific response to address the incident at hand.

The first step with any emergency response is to quickly and accurately communicate the situation with local law enforcement/including EMS services when necessary. Next, follow a simple, pre-planned and rehearsed command to initiate an action amongst all employees. The following are suggested protocols:

“Lockout” is the protocol used to safeguard everyone within the building. Lockout is designed to prevent entry into the Production Facility by unknown, suspicious or dangerous individuals, and to maintain accountability and security of all employees within the Production Facility. All exterior doors and windows are secured. No one is allowed into or out of the Production Facility until the situation that caused the lockout is resolved. Employees continue with normal duties during the duration of a lockout.

“Lockdown” is the protocol used to safeguard everyone within the building if a threat has entered into the Production Facility. Lockdown is used to secure individual rooms and to keep employees in place. Upon the initiation of a lockdown, all employees will rapidly move to predetermined lockable and secured sites within the Production Facility. All employees will remain secured within the locked sites until personally contacted by law enforcement or Production Facility management, indicating “all clear.” At the conclusion of a lockdown, 100% accountability of employees will be determined.

“Evacuate” is the protocol used to move employees from one location to another, whether in or out of the Production Facility. “Evacuate” may be necessary in the case of fire, industrial accidents or intruders. Each area of the Production Facility will have pre-determined evacuation routes clearly posted in all work areas, and employees will be briefed on these routes and periodically rehearse them. Upon the initiation of evacuate, all employees will immediately cease their work activity and quickly move to their pre-determined evacuation rally site. All employees will remain at the rally site until 100% accountability of employees is determined.

“Shelter” is always followed by a type and a method and is the protocol for group and self- protection. “Shelter” may be necessary to protect employees during severe weather events or other forces where seeking hardened protection is prudent. Upon the initiation of shelter all employees will cease all work activity and move to pre-determined hardened shelter and await further instructions.

This protocol enables rapid response determination when an unforeseen event occurs. By standardizing the vocabulary, all stakeholders can understand the response and status of the event. For employees, this provides continuity of expectations and actions throughout their career. For first responders, the common vocabulary and protocols establish a greater predictability that persists through the duration of an incident. Additionally, the protocol also allows for a more predictable series of actions as an event unfolds.

18. Disaster Recovery Plan – The Production Facility will maintain and continually update a Disaster Recovery Plan that includes:

- Details of all physical systems.
- Details of information systems.
- Details of network security processes and requirements.
- A list of all persons to be contacted when a disaster or other event necessitates it.

Disaster Recovery Plans must be printed out and stored in secure on-and off-site locations.

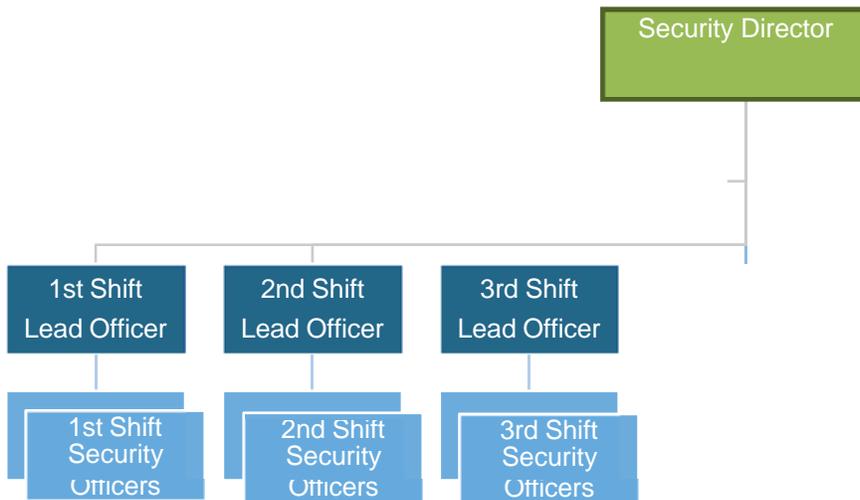
IV. Security Staffing

1. Security Officer Requirements – A licensed and armed security staff will be contracted to protect the facility, products, employees, and visitors 24 hours a day, 7 days a week. The security staff will apply technology and best industry practices regarding access control, detection of unauthorized intrusions, prevention of product theft and diversion, property and employee protection, emergency preparedness and incident. A minimum of two contract security staff will be working at the proposed facility to

monitor electronic security systems and ensure adherence to security procedures. The contracted security personnel will be designated as the responsible party for monitoring and administration of the security surveillance system and will not have any duties in the production process.

2. State Law Enforcement – As noted above, initial discussions have begun between the AgCenter and state law enforcement officials, studying the viability of sworn state law enforcement officers providing all security staff needs for the production facility.

3. Organizational Structure – Possible Security Organization:



4. Private/Civilian Officer Qualifications – Security officers selected to provide security related functions at the production facility will minimally meet the following qualifications:

- Former or current law enforcement officer.
- Good computer and technical skills. Familiarity with electronic security systems preferred.
- Ability to lawfully carry a firearm while on duty.
- Ability to pass a pre-employment background investigation, with no disqualifying or questionable conduct or incidents in the previous 10 years.
- Social Security number (SSN) check for validity and identity confirmation.
- National sex offender’s database.
- Terrorist watch list database.
- Previous employment verification and rehire status.
- Willing to submit to and not test positive to a seven-panel drug test.
- Capable of successfully completing pre-employment interview.
- Willingness and desire to work in a high security environment.

Four officers will be on duty during production hours. Officers will verify all employees entering the Production Facility and check all bags, briefcases, purses, etc. of employees leaving the facility. Visitors and contractors, with appointments, for the Production Facility will be registered, badged and escorted from this location.

Officers will provide roving perimeter patrols of the property, assisting with security of the shipping and receiving areas and providing relief during lunch and break periods for the other officers on duty.

Officers will maintain a security log of all visitors to the facility and unusual incidents. The log will contain:

- Assignment number.
- Date.
- Time.
- Description of incident.
- Persons involved.

V. Employee Training

1. Criminal History Check – All persons employed will successfully complete a criminal background investigation including fingerprint screening through the Louisiana State Police and FBI criminal records system.

2. Pre-Employment Background Investigation - Every applicant will undergo a pre-employment background investigation. The level detail and depth of the investigation will be determined by the duty position and responsibility of the position hired. The pre-employment background investigations will include:

- Name verification.
- DOB verification.
- SSN verification.
- Current and previous address verification.
- Criminal history check based on residence and employment locations for last 10 years.
- Credit report from recognized credit reporting agency (CRA).
- Department of Motor Vehicles driving record check, if employee will be tasked with driving responsibilities.

3. Employee Training – All employees will receive initial training on the following topics during their initial employee orientation:

- Data / information protection.
- Workplace violence prevention.
- Employee kidnap and abduction plan.
- Emergency response plan.
- Production facility security policies and procedures.
- Department regulations.
- Workplace safety.

Employees will receive periodic sustainment training on the above listed topics.

VI. Product Inventory Control

1. Operation and Management Practice for Control of Inventory – The product security plan will ensure that the medical marijuana is provided from the production facility and transported to the pharmacies with 100% accountability throughout the entire process.

Each stage in the production process of preparing marijuana for medical use will occur in a locked, controlled access, and secured area of the production facility, with growing and production operations conducted exclusively by personnel vetted, authorized, and having access to be within those locations. The number of employees will be limited to the minimum number of specifically authorized personnel essential for efficient operation. Employees will be required to wear specific color-coded work uniforms, to identify their job description and location that they are authorized to be within the Production Facility. All employees will continuously display their production facility issued employee identification badge while on the Production Facility's property.

All areas in the Production Facility shall be compartmentalized based on function, and access shall be restricted between compartments. Video surveillance cameras will monitor the secured locations at all times. Electronic smart cards and card readers will record and account for the identity and time that an individual entered secured and compartmentalized areas. All marijuana plants or products; from seed to final product or waste, will remain in a locked and secured area that is monitored by video surveillance at all times until removal from the facility. All individual growing plants will be accounted for utilizing radio frequency identification (RFID) technology in conjunction with the state approved computer inventory control system.

2. Inventory Control – The Production Facility will use the Louisiana Medical Marijuana Tracking System (LMMTS), a web based, real-time inventory control / point-of-sale system that is accessible by the Licensee 24 hours a day, 7 days a week. LMMTS will determine and account for the strain, exact location, and number of plants within the production facility at any given time as well as all product transactions. The production facility will maintain internal records and manifests within the automated data point- of-sale system.

3. Radio-Frequency Identification – The Production Facility will use radio-frequency identification technology (RFID) for inventory control. RFID technology will allow for every individual batch or plant to be tagged with a unique electronic RFID tag that will store specific information concerning the individual plant such as strain, batch of origin, physical location, production facility identification, etc. This information along with total number of plants, their location within the facility, date of planting, etc. is immediately obtainable utilizing hand-held RFID scanners. RFID technology will be integrated with LMMTS to provide real time accurate accountability of all marijuana plants and products within the facility at any given time. This technology has been successfully incorporated into the marijuana industry and has proven to be a highly effective and accurate means of providing inventory accountability from “seed to sale.”



RFID Scanner and Tag

4. Batch Identification – The production / growing of marijuana plants will be initiated either by using seeds, cuttings or grafting. Plants will be started within a batch of plants and a RFID tag will be attached to each separate batch. The RFID will contain the unique batch identification number of that group of plants, the number and strain of plants within the batch, and the Production Facility’s medical marijuana license number. Any removal of plants from the batch will be recorded within the inventory tracking system.

5. Plant Identification – When a plant reaches 18 inches high, it will be assigned its own plant identification number (PID) and tagged with its own tamper proof RFID tag, containing the unique plant identification number (PID), the strain and the production facility's medical marijuana license number. The RFID will remain permanently attached to the plant until harvest or destruction. All plants will be physically inventoried on a weekly basis and records of the inventory will be kept at the facility for at least five (5) years.



RFID tag during drying process

6. Grafted Material – A “daughter” RFID tag will be created and assigned to any plant material that is separated from an original plant, if the separated plant material will be used in the production of any type of marijuana product. The “daughter” RFID tag will contain the plant identification number of the original donor plant, the strain and the new plant identification number of the separated product. This information will be maintained, tracked and stored within the computer inventory system.

7. Harvest/Drying – At harvest, the plant will be cut at the base of the plant and the entire wet plant weight is recorded and logged into the inventory system. A RFID tag will remain throughout the drying process. The plant’s information will be updated within the inventory system to account for movement to the drying area and its status within the production process.



RFID Tags Utilized During the Growing Process

8. Production of Marijuana Concentrate – After the plant flower, stems and leaves are dried and weighed, they will be utilized in the production of marijuana extract. The pre-production dry weight will be documented on the RFID and in the inventory system. The post- production byproduct is then destroyed in accordance with Licensee standards, and their destruction is noted within the inventory system. The weight of the marijuana extract that is yielded from the production process is recorded in the inventory tracking system, and this

product is assigned its own RFID, documenting the weight and type of product. If the extract will be marketed in its current form, the extract will be packaged, and assigned a new RFID that will accompany the product for delivery to the pharmacy.

The Production Facility's inventory system will be updated showing delivery of all final products to the pharmacy.

The Production Facility will conduct a weekly inventory of all marijuana stock, which will include:

- Date of the inventory.
- Summary of the inventory findings.
- Name, signature and title of the individuals who conducted the inventory.
- Staff-in-charge who oversaw the inventory.
- Product name and quantity of marijuana plants or marijuana-infused products at the facility.
- The production facility will maintain records of marijuana sold or otherwise disposed of showing.
- The date of sale.
- The name of the pharmacy facility to which the medical marijuana was sold.
- The batch number, product name and quantity of marijuana sold.
- The date, quantity, manner in which, and reason why any marijuana was destroyed.

9. Product Inventories – Prior to commencing business, the Production Facility will conduct an initial comprehensive inventory of all marijuana at the facility. The Production Facility will perform a complete and accurate inventory of all plant stock or products of marijuana on hand on an annual basis in conjunction with the facilities start-up date.

All inventories, procedures, and other documents shall be maintained on the premises and made available to the Licensee at all times. All inventory records or receipts of those records will be maintained by the production facility for at least five years.

VII. Marijuana Product / Production Facility Storage

1. Production Facility Storage – The Production Facility will maintain policies and procedures regarding the handling, storage, and transfer of product and cash to deter theft and loss. All interior wall partitions around the vault room will extend to the bottom side of the deck and the will be fortified with either layers of ½-inch fire resistant wood panels or concrete masonry unit block. Only individuals who have been vetted and authorized will have access to the vault room where product and cash is stored.

Electronic door access key cards, PIN identification systems, and CCTV will record and account for the identity and time that an individual entered the vault room. The production facility will keep an electronic daily log of all employees with access to the vault and safes and knowledge of the access code or combination. The vault and safes will remain locked at all times, except during the storage or retrieval of product or cash. An access log will be maintained recording the identity, date and time when the safe or vault was opened. All locks and security equipment will be maintained in good working order at all times. Access codes will be periodically changed.

2. Vault and Safes – All cash and product will be stored within a Department approved vault or safe that meets the minimum security standard for non-practitioner handling of schedule I and II controlled substances.

- The vault walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.
- The walls or perimeter of the vault shall be equipped with a tamper-proof closed circuit alarm approved by Underwriter's Laboratories which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, a local police agency which has a legal duty to respond or a 24-hour control station operated by the registrant. If necessary, due to local conditions or other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.
- The vault door shall be equipped with a contact switch.
- The vault shall have one of the following security measures:
 - Complete electrical lacing of the walls, floor and ceiling for motion detection.
 - Sensitive ultrasonic detection within the vault.
 - Sensitive sound accumulator detection system. Or
 - Such other device designated to detect illegal entry as may be approved by the Licensee.
- Vault access shall be documented in a log that contains the name, reason, date, and time of entry and exit of the person who access the vault and description of any unusual events.

All final marijuana products will be stored in the secured vault room or vault. If additional storage measures are needed the production facility will comply with any additional security measures directed by the Department.

If the Production Facility is required to produce or store a larger than normal stock of marijuana for special or unforeseen circumstances, the Production Facility will augment the existing security measures, to include increased security guards for the duration.

Any area of a Production Facility containing marijuana, including a room with an approved safe or approved vault, shall have a sign posted at all entryways, which shall be a minimum of 12 high and 12 inches long and shall state: "Do Not Enter – Limited Access Area – Access Limited to Authorized Personnel Only" in lettering no smaller than 1 inch in height.

All marijuana and marijuana products shall be stored in a secure manner at the end of each workday.

Nothing shall prohibit members of the Department, local law enforcement or other federal, State or local government officials from entering any area of a Production Facility if necessary to perform their governmental duties.

3. Storage of Cash – All cash and currency will be locked within the tamper-proof safes located within the vault in the hardened vault room that has been secured to a main structure of the building. The staff in charge will inventory all cash on site on a daily basis. Cash will be logged by denomination and sealed in tamper proof bags.

4. Procedures for Destruction of Products – Marijuana waste will be stored in a locked and secured area of the production facility. All marijuana waste products will be managed in accordance with state regulations and treated as any other marijuana product until destroyed.

Marijuana products may require destruction due to expired expiration dates, contamination, recalls, etc. Marijuana products will be tracked and destroyed in a manner to render them completely unusable and unidentifiable and in accordance with state law and local regulations. As provided in the Department regulations, the testing laboratory will destroy any quantity of marijuana product that is not consumed in samples used for testing.

Marijuana waste will be stored in a locked and secured area of the Production Facility. All marijuana waste products will be managed in accordance with state regulations and treated as any other marijuana product until destroyed. Plants or plant material to be destroyed will be separated from their growing medium, weighed as-is, and recorded in the inventory system with the plant identification number (PID) and weight. Any plant matter, which is removed from a plant that will be destroyed, will be weighed and recorded in the inventory system with the PID indicating the amount of material removed before destruction.

All plants or materials designated for destruction will be done so in a manner to render them completely unusable and unidentifiable. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance. The Production Facility will notify the Department at a minimum of seven (7) days prior to rendering the product unusable and disposing of the product.

Marijuana waste will be destroyed by incineration or grinding and incorporating the

marijuana waste with other ground materials so the resulting compost mixture is at least 50% non-cannabis waste (soil) by volume.

Plants or plant material to be destroyed will be separated from their growing medium, weighed as-is, and recorded in the inventory system with the plant identification number (PID) and weight. Any plant matter, which is removed from a plant that will be destroyed, will be weighed and recorded in the inventory system with the plant identification number (PID) indicating the amount of material removed before destruction. Any individual plant that has not yet received an individual identification number (PID) that is slated for destruction will be identified by its “batch identification number” and the number of plants currently within that batch will be updated in the inventory system.

All plants or materials designated for destruction will be done so in a manner to render them completely unusable and unidentifiable. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance.

5. Procedures for Documentation of Production Loss – If a loss, theft or diversion of marijuana has occurred from a Production Facility, the Production Facility shall notify the Department and the Louisiana State Police. The production facility will comply with any additional security measures directed by the Licensee if additional storage measures are determined to be appropriate. If a reduction in the amount of medical marijuana in the production facility's inventory is due to suspected criminal activity, the production facility will immediately report the reduction to the Licensee and the Louisiana State Police.

VIII. Transportation

1. Transportation – The Production Facility will contract for the shipment and delivery of marijuana products and funds when necessary. This secure transportation service will own and maintain its own transport vehicles. The following practices are designed to lower the risk of loss, theft, or mishandling, and improve the overall security environment.

2. Transportation Vehicle – All medical marijuana products and cash will be transported between the production facility and dispensing facilities using an up-armored delivery van, such as a Ford E-350 that has been modified to possess a ballistic protection rating of Level 3A as defined by the National Institute of Justice (NIJ) standards. All doors to both the cab of the vehicle and to the storage area of the vehicle will be secured utilizing high security locks with deadbolts on all doors. The vehicle will possess a separate internal locked and secured storage area that is not visible from outside the vehicle for transportation of medical marijuana and cash. The storage area will be climate controlled to prevent spoilage of product during transportation and allow for the marijuana product to be stable for sixty (60) days. The vehicle should be manned by a minimum of two armed security guards, with the ability to transport a third security guard if necessary. The vehicle will possess no external

markings or advertising, allowing it to blend into other traffic and not draw attention to its purpose.

3. Shipping Container Consideration – The medical marijuana will be sealed within packages that possess tamper-resistant closures and are labeled and sized accordingly for the respective weight/amount of product. Those packages will be transported within larger tamper-resistant containers. The labels on the sealed package within the larger tamper-resistant containers will reflect the weight, strain, and identity of the dispensary for each package. RFID tags will be assigned to each package inside the larger tamper resistant container to accurately track this information. The tamper-resistant containers will be sealed and include a description, where it is coming from, where it is going to, and the weight of the product contained inside the tamper-resistant container, the “lot unique identifier,” and the container serial number so all match a corresponding number recorded on the delivery manifest.

4. Global Positioning System (GPS) Tracking – To prevent theft or diversion of packaged medical marijuana, the Production Facility will use GPS tracking to account for real-time locations of all medical marijuana that has left the Production Facility. Each tamper-resistant container will have a GPS tracking device sealed inside. The GPS location of each tracker will be monitored from the central security station.

5. Manifest – Each tamper-resistant container containing medical marijuana will be accompanied by a shipping manifest using the form prescribed by the Department. A copy of the manifest will remain with the packaged medical marijuana from the time it leaves the Production Facility until the time it is received and accepted at the dispensing facility. The transporting security guard will maintain a copy of all manifests of the product transported, from receipt to delivery. The Production Facility will electronically transmit a copy of the manifest in a secure manner to the dispensing facility that will receive the products and to the Department at least two business days prior to transport. The Production Facility will maintain all shipping manifests for a period of five (5) years and will be made available to the Department for inspection upon request.

6. Preparation for Shipping – Only individuals who have been fully vetted and properly authorized will have access to the product shipment room where finished product will be weighed, loaded into packages, and labeled in preparation for transportation to authorized dispensary locations. Digital scales will be used to verify product weight and identify any loss, theft or diversion of product. The manifest will reflect the weight, strain, and identity of the dispensary for each package. The product shipment room will be monitored by video surveillance and controlled by the electronic security access systems.

7. Shipping Security Measures – The following pickup procedures should be implemented at the Production Facility:

- Prior to transporting any approved medical marijuana product, a shipping manifest will be completed using a form determined by the department.

- A copy of the shipping manifest must be transmitted to the dispensing facility that will receive the products and to the Department at least two business days prior to transport.
- The armed transportation security guards will pick up and deliver product at random times.
- There will be a minimum of two armed security guards providing transportation of medical marijuana. The transport vehicle will be loaded and unloaded in a pre-designated area that is located inside the enclosed loading dock, out of view of the public and nonessential personnel.
- Transportation security guards will enter the Production Facility and display their employee credentials at all times.
- Pickup or deliveries of product will be completed under dual control with all transfers taking place inside the secured package room or vault room under the escort of Production Facility employees and security personnel.
- Product will be inventoried as it is loaded and matched to the shipping manifest by the armed transportation personnel.
- Once all manifested product is verified, a copy of the manifest will be placed inside the tamper proof container. Two signatures are required for verification of the contents.
- The transport team will possess a copy of the shipping manifest at all times when transporting or delivering approved medical marijuana products and will produce it to the Department, the Department's authorized representative, or law enforcement officials upon request.
- The tamper-proof container will be sealed with numbered bar code seal that contains that same identifying information from the RFID tag of origin, and a GPS unit will be placed in the container for GPS tracking.
- The bar code tag on the tamper proof container will be scanned by the armed transportation security guard and the container is now considered signed for and "accepted."
- All tamper-proof containers will be loaded into the transport vehicle and scanned in the secure transport vehicle as "received" by the armed transportation guards.
- Only approved medical marijuana products will be transported from the Production Facility to dispensing facilities.

8. In-Transit Considerations

- The secure transport vehicle will be GPS-tracked, and its location will be monitored at ten (10)-second intervals with a Global Positioning System.
- The sealed tamper-proof containers will be transported from the Production Facility to the state authorized dispensary locations in a locked, safe, and secure storage compartment of the transport vehicle and will not be visible from outside the secure transport vehicle.
- Each armed transportation guard will have access to a secure form of communication with personnel at the central security station and the ability to contact law enforcement

through the “911” emergency system. Each armored transportation vehicle is equipped with hazard alarms to notify the central security station if there is an issue. All team members shall possess his or her credentials all times when transporting or delivering medical marijuana and shall produce them for the Department, the Department's authorized representative, or law enforcement official upon request.

- All secure transport vehicles transporting medical marijuana will travel directly from the Production Facility to the dispensary facility, and shall not make any stops in between except to other dispensary facilities, for refueling, or in case of an emergency. In case of emergency, it will be reported immediately to law enforcement through the “911” emergency system and the central security station, which will immediately notify the Department.
- The Production Facility will ensure that all delivery times and routes are randomized.

9. Delivery and Receipt Procedures

- Deliveries at dispensary locations will take place within the dispensaries hours of operation.
- Prior to exiting the vehicle, the armed transportation personnel will assess the surrounding for potential threats to confirm the area is secure and safe prior to entering a dispensary delivery point.
- At least one armed officer will remain with the secure transport vehicle at all times that the vehicle contains approved medical marijuana products.
- The receiving employee will first inspect the exterior of the container for visual evidence of damage or tampering.
- Dispensary employees will confirm the container identification number matches the identification number on the shipping manifest.
- The employee will visually inspect each airtight package and confirm that the packages identification number matches the identification number on the shipping manifest.
- The entire contents delivered will be inventoried and verified against the manifest to ensure there was no tampering or loss during transfer.
- The received products will then be entered into the dispensary's point of sale inventory database and immediately stored in the locked and secured location designated for back stock of product.
- The cultivation center will confirm receipt of all products through a Department approved computer inventory control system.
- All incoming or outgoing shipments will be processed and documented in the restricted area only under dual control.
- At no time will patients or the general public witness incoming/outgoing inventory transactions.
- If there are any issues or discrepancies with the transfer, the shipment in question is to be rejected and returned to the point of origination immediately. Upon its return to the manufacturing facility, the staff will immediately segregate and secure the rejected delivery. The employee in charge will determine any error, discrepancy or loss of the

disputed shipment. Any error, discrepancy or loss that cannot be rectified will immediately be reported to the Department and law enforcement, as per Department regulations.

10. Delivery of Medical Marijuana for Testing – Samples of the final medical marijuana product must be submitted to designated, independent laboratories for testing and quality control. This will be the responsibility of the Department. The procedure for transporting these samples from the Production Facility to the testing facility will mirror the procedure for delivery of medical marijuana from the Production Facility to the dispensing facility.

These costs are yet to be determined and agreed upon. However, planning and budgeting is being performed for an in-house testing lab, which is permitted under the regulations.

About Kleiber Investigations and Training LLC

This Security Plan was prepared with input from Kleiber Investigations and Training LLC. (K.I.T.) K.I.T. considered the criteria and measures as set forth in the in LAC 7:XLIX Chapters 1-31, and visited the proposed Production Facility. The Security Plan is solely a recommendation based upon best security practices, and lessons learned while helping businesses obtain licensure for the production and distribution of marijuana, as well as conducting continual operational audits of marijuana businesses in Colorado, Illinois, New York, and Florida.

K.I.T. was founded on the knowledge and expertise Dave Kleiber has gained during a concurrent 28-year career in the U.S. Army and a 19-year career as a Police Detective. K.I.T. has become a nationally recognized source for all aspects of security relating to the marijuana industry.

As an Officer assigned to U.S. Army Special Forces units, Mr. Kleiber was entrusted with a Top Secret security clearance. He conducted site surveys, implemented and enforced tiers of security measures, and resourced and executed site security plans in some of the most remote and dangerous areas of the world.

As a police detective, Mr. Kleiber served with the FBI Safe Streets Task Force, the U.S. Marshall's Fugitive Task Force, and the Anchorage Police Department's Special Assignments Unit, investigating street level drug crimes and gang violence.

Upon the enactment of Colorado's medical and recreational marijuana amendments, Mr. Kleiber became the liaison for law enforcement to the local marijuana industry, ensuring operators possessed a full understanding of how to comply with rapidly changing marijuana regulations.

Understanding the interplay of complex state laws, regulations, and local ordinances that regulate the marijuana industry can be a daunting task. K.I.T. has composed a team of industry experts in vulnerability assessment, building construction, and security integration. Together, these experts successfully create and implement comprehensive security plans for marijuana license applications, production, and retail operations in the states of Colorado, Illinois, New York, and Florida. These plans have addressed the needs ranging from 800 square foot retail storefronts to 200,000 square foot production facilities. K.I.T. maintains on-going relationships with these entities by conducting periodic site surveys and regulatory compliance checks. Work performed by K.I.T. includes:

- Compliance with local and state regulations.
- Vulnerability assessments.
- Physical site security planning and implementation.
- Access control measures.
- Electronic monitoring and alarm systems.
- Computer / cyber security.

- Inventory control and accountability.
- Product and cash storage and transportation.
- White collar crime and employee theft prevention.
- Creating and maintaining a safe work environment.
- Pre-employment background investigations.
- Employee and business policies and practices.
- Vetting security integrators.
- On-going compliance checks.

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g. APPENDIX G – Insurance.

LSU AgCenter - PREMIUM PROJECTIONS - MEDICAL MARIJUANA INITIATIVE - FIRST YEAR INSURANCE BUDGET						
Disclaimer: All premiums noted below are market indications only and are not bindable . Information is based on national averages and current market conditions. We were conservative in our estimates and used data provided by Feldmann Nagel, LLC						
Information provided by: Moreton & Company, Denver, CO						
As of August 12, 2016	DRAFT					
Property & Casualty						
Policy type	Exposure/Limit	Annual Premium Indication	Policy fee	LA Surplus Lines Tax - 4.85%	Total	Timing/Coverage notes
Builders Risk - 6-8 months construction period	\$9,000,000	\$16,200 annual 8 months @ \$10,800	\$300	\$538	\$11,638	Timing: Start of construction/purchase date. May be provided by General Contract or purchased by owner. Recommend owner purchase to ensure existing building structure is covered as well as the renovation values. No coverage is provided for business property/equipment. Rate is higher due to renovation exposure vs. ground up new construction. Deductibles: \$1,000 all other perils/1-3% named storm, wind. Does not include Flood or Earthquake.
General Liability	\$1,000,000/ \$2,000,000 aggregate	\$5,000	\$250	\$255	\$5,505	Timing: Purchase on date of sale. Premises liability only.
Excess Liability	\$1,000,000	\$1,500	\$250	\$85	\$1,835	Timing: Purchase on date of purchase. Limit recommended will depend upon LA governmental immunity application and/or final entity structure. Price indicated is minimum price per million.

Permanent Property/Business Income and Extra Expense/ Inland Marine						Timing: At time Builders Risk policy expires or when business personal property/manufacturing equipment is delivered. For first year of operations, Extra Expense is critical when revenue has not begun or is minimal.
Building	\$9,000,000					
Property	\$100,000					Furniture, Fixtures, Equipment
Manuf. Equip	\$730,000					
Extraction lab research	\$470,000					
Testing facility	\$2,000,000					
Formulation/ packaging	\$305,000					
BI/Ex Expense	\$250,000					First year limit is primarily extra expense. Limit would adjust based on future income projections once fully operational.
Total Values	\$12,855,000	\$51,420	\$500	\$2,518	\$54,438	Deductible: \$5,000 all other perils, 1-3% wind, named storm
Finished Stock/Cargo	\$500,000	\$13,750	\$500	\$691	\$14,941	Timing: First date of harvest/product sales, delivery to dispensaries/patients/consumers.
Equipment Breakdown	\$12,855,000	\$6,428	N/A	N/A	\$6,428	Timing: Start of operations and/or when Builders Risk coverage expires.

Crop Insurance - 1,000 plants valued at \$1,000 per plant	\$1,000,000	\$30,000	\$500	\$1,479	\$31,979	Timing: start of first growing cycle. Valuation assumption - average yield 1/4 to 1/2 pound per plant for indoor grow. 2016 market value between \$625 and \$1,250 per plant. Used average of \$1,000 per plant mature plant value.
Products Liability - Could be combined with GL depending upon carrier with cost savings. Premium noted is stand-alone PL policy.	\$1,000,000 per claim/\$2,000,000 aggregate	\$5,000	\$250	\$255	\$5,505	Timing: First date of harvest/product sales, delivery to dispensaries/patients/consumers. Information required to quote includes list of products and copies of all product labels, application. Claims made coverage. Minimum premiums and deductibles will likely apply. Market pricing and terms change frequently due to Federal government's current position that marijuana remains on the Schedule 1 drug list. Standard admitted insurance carriers are declining to write coverage due to this Federal position. Information required to quote includes list of products, copies of all product labels, and carrier application. CV's may also be required for key personnel. Limit recommended will depend upon LA governmental immunity application and/or final entity structure.
Pollution Liability	\$1,000,000	\$5,000	\$250	\$255	\$5,505	
Auto	\$1,000,000 Liability and including physical damage - per vehicle premium	\$2,500	\$250	\$133	\$2,883	Purchase of vehicles and/or employee use of personal vehicles for business purposes (hired/non-owned auto coverage). Per vehicle premium estimate based on use of vehicle for delivery purposes. Drivers meet standard driver guidelines.
Workers' Compensation	Statutory Benefits	\$10,000	N/A	N/A	\$10,000	Timing: First dollar of payroll, first date of employment.

Executive Risk						
Directors & Officers including Employment Practices Liability	\$ 1,000,000	\$ 5,000	\$ 250	\$ 255	\$ 5,505	Timing: Formation of the board. Will require copy of by-laws, pro-form budget, list of board members, and carrier application. Limit recommended will depend upon LA governmental immunity application and/or final entity structure.
Crime	\$ 1,000,000	\$ 3,000	N/A	N/A	\$ 3,000	Timing: Establishment of bank account. Employee theft coverage, ERISA for retirement plans, social engineering coverage, funds transfer fraud. Limit recommended will depend upon exposures determined at start of operations and following review of completed application.
Fiduciary	\$ 1,000,000	\$ 1,000	N/A	N/A	\$ 1,000	Timing: Establishment of retirement or employee welfare plans
Network Security, Privacy Liability, Cyber risk including Cyber Extortion	\$ 1,000,000					Timing: Review need for coverage based on exposure to handling of personally identifiable information, web site, credit card transactions, if any. Always exposure to Network Security risk but may be minimal. Review at time operations begin.
Professional Liability	TBD					Minimal if any exposure as a grower, manufacturer. Dispensaries need this coverage. Manufacturers would need coverage if they are manufacturing products for others under a licensing agreement.
Intellectual property	TBD					Research and intellectual property exposures should be reviewed prior to start of operations.
GRAND TOTAL - FIRST YEAR					\$ 160,161	

h. APPENDIX H – IRS 280 E Information

26 U.S.C.

United States Code, 1998 Edition

Title 26 - INTERNAL REVENUE CODE

CHAPTER 1 - NORMAL TAXES AND SURTAXES

Subchapter B - Computation of Taxable Income

PART IX - ITEMS NOT DEDUCTIBLE

Sec. 280E - Expenditures in connection with the illegal sale of drugs

From the U.S. Government Printing Office, www.gpo.gov

§280E. Expenditures in connection with the illegal sale of drugs

No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.

(Added Pub. L. 97–248, title III, §351(a), Sept. 3, 1982, 96 Stat. 640.)

1. References in Text

The Controlled Substances Act, referred to in text, is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of Title 21, Food and Drugs. Schedules I and II are set out in section 812 of Title 21. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

2. Effective Date

Section 351(c) of Pub. L. 97–248 provided that: “The amendments made by this section [enacting this section] shall apply to amounts paid or incurred after the date of the enactment of this Act [Sept. 3, 1982] in taxable years ending after such date.”

i. APPENDIX I – Disclosures.

This Project Concept serves as a comprehensive reference point for each aspect of the AgCenter’s proposed medical marijuana production program under the Act. This Project Concept has been prepared by the AgCenter with assistance from business consultants and business operators, with national industry expertise in the cultivation and sale of medical marijuana. This Project Concept document does not contain legal or tax advice, and is prepared based upon estimated data, industry presumptions, and information that is subject to change.

Medical (therapeutic) marijuana is classified by the federal government as a Schedule I Controlled Substance, under the Controlled Substance Act (CSA). Although medical marijuana has been legalized within specific regulations and parameters under the laws of the State of Louisiana, as well as other states and the District of Columbia, it remains illegal at the federal level and in 25 other states.

This Project Concept is not prepared for purposes of aiding in or influencing legislation, or regulatory rules. The AgCenter does not take a position or express views concerning the Act, as signed into law. Rather, the Act authorized the AgCenter to participate in the implementation of a medical marijuana program for the State of Louisiana, as proscribed under the Act, including both the research and utilization of medical marijuana.

This Project Concept does not constitute an offer for services.

This Project Concept may contain forward-looking statements and forecasts concerning the plans, intentions, strategies, expectations, predictions, and financial forecasts related to future activities and results of business operations, as well as other future events or conditions. For this purpose, any statements contained herein that are not statements of historical fact are deemed forward-looking statements. Without limiting the generality of the foregoing sentence, words such as “believe,” “may,” “will,” “could,” “intends,” “estimate,” “might,” “continue,” “forecast,” and their negatives or comparable terminology, indicate forward-looking statements. This Project Concept, including any attachments, does not constitute representations or warranties of the AgCenter. Anyone interested in participating in the medical marijuana program under a contract with the AgCenter needs to conduct its own research and perform its own due diligence in analyzing the financial and other issues involved, including any legal and tax issues, and including full compliance with the Act and all regulations.

Circular 230 Disclosure: To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. federal tax information contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (1) avoiding penalties under the Internal Revenue Code, or (2) promoting, marketing, or recommending to another party any transaction or matter addressed herein.

j. Citation Listing.

- ¹Dr. Neustrom's obituary is contained in [Appendix A](#).
- ²Marijuana Business Daily™, *Marijuana Business Factbook*, Chart 1.01 (4th ed. 2016).
- ³Adapted from Marijuana Business Daily™, *Marijuana Business Factbook*, Chart 1.11 (4th ed. 2016).
- ⁴Adapted from data contained in [Appendix D](#).
- ⁵Bradford AC, Bradford WD, *Medical Marijuana Laws Reduce Prescription Medication Use in Medicare Part D*, Health Affairs, Vol. 35:7 1230-1336 (July 2016).
- ⁶Hulak, John, *The DEA's Decision Is More Important Than Rescheduling*, THE BROOKINGS INSTITUTION, <https://www.brookings.edu/blog/fixgov/2016/08/11/the-deas-marijuana-decision-is-more-important-than-rescheduling/> (August 11, 2016) (last visited September 2, 2016).
- ⁷La. R.S. 12:1803 (A)(10)(d).
- ⁸La. R.S. 12:1822; La. R.S. 12:1824.
- ⁹La. R.S. 12:1821 (A), (C); La. R.S. 12:1822 (A), (E); La. R.S. 12:1823 (A), (C); La. 12:1824 (C).
- ¹⁰La. R.S. 12:1-831; see, e.g., *Levy v. Billeaud*, 443 2d 539, 543 (La. 1983); *Noe v. Roussel*, 310 So. 2d 806, 817 (La. 1975).
- ¹¹Subject to IRC 280E as referenced at subsection c., next, and at [Appendix H](#).
- ¹²Health Canada, *Access to Cannabis for Medical Purposes Regulations – Daily Amount Fact Sheet (Dosage)* (July 2016), at n. 19, <http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/daily-quotidienne-eng.php#fnb20> (last updated August 19, 2016) (citing Abbott Products Inc. Marinol® Product Monograph 2010, concluding an average daily dose of medical marijuana is 20mg THC per day).
- ¹³Adapted from Marijuana Business Daily™, *Marijuana Business Factbook*, Chare 4.14 (4th ed. 2016).
- ¹⁴Marijuana Business Daily™, *Marijuana Business Factbook*, p. 167, chart 4.04 (4th ed 2016).
- ¹⁵HIV/AIDS, Cancer, Wasting Syndrome, Seizure Disorders/Epilepsy, Spasticity, Crohn's Disease, Muscular Dystrophy and Multiple Sclerosis.
- ¹⁶Louisiana State Health Profile-2015, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, available at: https://www.cdc.gov/nchhstp/stateprofiles/pdf/louisiana_profile.pdf (last visited August 31, 2016).
- ¹⁷Joy, JE, Watson, SJ, and Benson, JA Jr., *Marijuana and Medicine, Assessing the Science Base*, INSTITUTE OF MEDICINE, (ND), available at: http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf.
- ¹⁸Louisiana State Health Profile-2015, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, available at: https://www.cdc.gov/nchhstp/stateprofiles/pdf/louisiana_profile.pdf (last visited August 31, 2016).
- ¹⁹Cannabis and Cannabinoids (PDQ®) Patient Version, NATIONAL CANCER INSTITUTE AT THE NATIONAL INSTITUTES OF HEALTH, available at: <http://www.cancer.gov/about%20cancer/treatment/cam/patient/cannabis-pdf> (last visited August 31, 2016).
- ²⁰Cancer Treatment & Survivorship Facts and Figures, 2014-2015, AMERICAN CANCER SOCIETY, available at: <http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-042801.pdf> (last visited August 31, 2016).
- ²¹Cancer in LA, LOUISIANA CANCER RESEARCH CONSORTIUM, available at: <http://www.louisianacancercenter.org/cancer-in-louisiana> (last visited August 31, 2016).
- ²²Chronic Conditions Prevalence, State/County 2014, Heart Failure, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at: <https://ccw.maps.arcgis.com/apps/MapSeries/index.html?appid=c125954f1a1e4582916d8a666f2bf581> (last visited August 31, 2016).

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- ²⁵M Hickson, *Malnutrition and Aging*, Postgrad Med J., (January 2006) 82(963).
- ²⁶Louisiana Policy Academy State Profile, US ADMINISTRATION ON AGING, (April 2-3, 2012), http://www.aoa.gov/AoA_Programs/HPW/Behavioral/docs2/Louisiana.pdf (last visited August 31, 2016).
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